UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF OHIO
EASTERN DIVISION

IN RE: NATIONAL PRESCRIPTION, OPIATE LITIGATION

MDL NO. 2804

Case No. 17-MD-2804

THIS DOCUMENT RELATES TO:

Judge Dan Aaron Polster

Salmons v. Purdue Pharma L.P., et al.
MDL Case #1:18-OP-45268;

Flanagan v. Purdue Pharma L.P., et al.
MDL Case #1:18-OP-45405

Doyle v. Purdue Pharma L.P., et al.
MDL Case No. #1:18-op-46327

Artz v. Purdue Pharma, L.P., et al.
MDL Case No. #1:19-op-45459

THE NAS GUARDIANS' NOTICE OF MOTION AND CONSOLIDATED MOTION FOR CLASS CERTIFICATION AND APPOINTMENT OF CLASS COUNSEL

Now come Plaintiffs Jacqueline and Roman Ramirez, Melissa Barnwell, Michelle Frost, and Stephanie Howell, Guardians of NAS[1] Children (collectively "Class Representatives"), will and hereby do move for an order certifying classes defined as:

I. NATIONWIDE CLASSES

A. DEFINITION

CLASS 1. Legal Guardians[2] of United States residents born after March 16, 2000, who

[1] The children made the subject of these complaints were diagnosed at birth with Neonatal Abstinence Syndrome (NAS), also sometimes referred to as Neonatal Opioid Withdrawal Syndrome (NOWS), arising out of their birth mothers' use of opioids during pregnancy.

[2] The term "Legal Guardian" is further defined for purposes of this putative class action as "any natural person or entity who has the primary legal responsibility under law for an infant or child's physical, mental,

were medically diagnosed with opioid-related NAS[3] at or near birth and whose birth mother received a prescription for opioids or opiates prior to the birth and those opioids or opiates were manufactured, distributed, or filled by a Defendant or Purdue entity. Excluded from the class are any infants and children who were treated with opioids after birth, other than for pharmacological weaning. Also excluded from the class are legal guardianships where a political subdivision, such as a public children services agency, has affirmatively assumed the duties of "custodian" of the child.

CLASS 2. Legal Guardians[4] of United States residents born after March 16, 2000, who were medically diagnosed with opioid-related NAS at or near birth and whose birth mother received and/or filled a prescription for opioids or opiates in the 10 months prior to the birth of said infant or child and those opioids or opiates were manufactured, distributed, or filled by a Defendant or Purdue entity.

B. DEFENDANTS

(1) MANUFACTURER DEFENDANTS

- Actavis Entities: Allergan PLC f/k/a Actavis PLC f/k/a Allergan, Inc.; Allergan Finance, LLC f/k/a Actavis, Inc. f/k/a Watson Pharmaceuticals, Inc.; Allergan Sales, LLC; Allergan USA, Inc.; Watson Laboratories, Inc.; Warner Chilcott Company, LLC; Actavis Pharma, Inc. f/k/a Watson Pharma Inc.; Actavis South Atlantic LLC; Actavis Elizabeth LLC; Actavis Mid Atlantic LLC; Actavis Totowa LLC; Actavis LLC; Actavis Kadian LLC; Actavis Laboratories UT, Inc. f/k/a Watson Laboratories, Inc.-Salt Lake City; Actavis Laboratories FL, Inc. f/k/a Watson Laboratories, Inc.-Florida.

- Cephalon Entities: Teva Pharmaceutical Industries Ltd.; Teva Pharmaceuticals USA, Inc.; Cephalon, Inc.

- Janssen Entities: Janssen Pharmaceuticals, Inc.; Janssen Pharmaceutica, Inc. n/k/a Janssen Pharmaceuticals, Inc.; Noramco, Inc.; Ortho-McNeil-

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and emotional development." Expressly excluded from the class of "Legal Guardians" are any governmental entities.

"Legal Guardians" include natural and adoptive parents who have not otherwise lost legal custody of their children, legal custodians, legal caretakers, and court-appointed guardians (including guardians of the person), whether temporary or permanent.

[3] The term "NAS" (Neonatal Abstinence Syndrome) is defined to include additional, but medically symptomatic identical, terminology and diagnostic criteria, including Neonatal Opioid Withdrawal Syndrome (NOWS) and other historically and regionally used medical and/or hospital diagnostic criteria for infants born addicted to opioids from *in utero* exposure. Additional specifics on these readily identifiable and ascertainable terms are set forth in the accompanying Consolidated Memorandum of Law, ¶ II., p. 7.

[4] The term "Legal Guardian" is defined at fn. 2.

Janssen Pharmaceuticals, Inc. n/k/a Janssen Pharmaceuticals, Inc.; Johnson & Johnson.

- Endo Entities: Endo Health Solutions Inc.; Endo Pharmaceuticals, Inc.; Par Pharmaceutical, Inc.; Par Pharmaceutical Companies, Inc. f/k/a Par Pharmaceutical Holdings, Inc.
- Mallinckrodt Entities: Mallinckrodt plc; Mallinckrodt LLC; SpecGx LLC.
- Co-Conspirator Purdue Entities: Richard S. Sackler; Jonathan D. Sackler; Mortimer D.A. Sackler; Kathe A. Sackler; Ilene Sackler Lefcourt; Beverly Sackler; Theresa Sackler; David A. Sackler; Rhodes Technologies; Rhodes Technologies Inc.; Rhodes Pharmaceuticals L.P.; Rhodes Pharmaceuticals Inc.; Trust for the Benefit of Members of the Raymond Sackler Family; The P.F. Laboratories, Inc.
- Non-Defendant, Co-Conspirator Purdue Entities: Purdue Pharma L.P.; Purdue Pharma Inc.; The Purdue Frederick Company, Inc.

(2) DISTRIBUTOR DEFENDANTS

- Cardinal Health, Inc.
- AmerisourceBergen Drug Corp.
- Mckesson Corporation

(3) PHARMACY DEFENDANTS

- HBC Service Company
- CVS Health Corporation; CVS Indiana, LLC; CVS Rx Services, Inc.
- Rite Aid Corporation; Rite Aid of Maryland, Inc.; Rite Aid of Maryland, Inc. d/b/a Rite-Aid Mid-Atlantic Customer Support Center, Inc.
- Walgreen Co.; Walgreens Boots Alliance, Inc.; Walgreen Eastern Co.
- Wal-Mart Inc. f/k/a Wal-Mart Stores, Inc.
- Miami-Luken, Inc.
- Costco Wholesale Corporation

C. CLAIMS

1. First Cause of Action – Violation of RICO, 18 U.S.C. § 1961 *et seq.* – Opioid Marketing Enterprise (against only Defendants Cephalon Entities, Janssen Entities, Endo Entities,

and Mallinckrodt Entities (the "RICO Marketing Defendants").

2. Second Cause of Action – Violation of RICO, 18 U.S.C. § 1961 et seq. – Opioid Supply Chain Enterprise (against only Defendants Cephalon Entities, Endo Entities, Mallinckrodt Entities, Actavis Entities, McKesson, Cardinal, and AmerisourceBergen (the "RICO Supply Chain Defendants").

D. RELIEF REQUESTED

1. Order Defendants to provide for the benefit of the Plaintiff Legal Guardians and the Putative Class Members ongoing medical monitoring, testing, intervention, provision of caregiver training and information, and medical referral, all of which are medically necessary for the NAS Children in their care, and all future medical care reasonably necessary to treat these children. Any injunctive relief to which Plaintiffs may justly show themselves entitled, including injunctive relief designed to reduce the incidence of children born with NAS.

2. Order creation of a Science Panel.

3. Alternatively, all incidental compensatory damages and medical expenses incurred by Plaintiff Legal Guardians and the Putative Class Members in connection with their care of the NAS Children. It is expressly alleged that all compensatory damages sought in the alternative are incidental to the injunctive relief requested by Plaintiffs and the Class, and are for those caused by the *in utero* exposure to opioids and NAS diagnosis suffered by the NAS Children.

4. Punitive damages.

5. Attorneys' fees and costs incurred by Plaintiff Legal Guardians and the Putative Class Members.

II. CLASS 3 – OHIO STATEWIDE CLASS[5]

A. DEFINITION

1. Legal Guardians[6] of Ohio residents born after March 16, 2000, who were medically diagnosed with opioid-related NAS[7] at or near birth and whose birth mother received a prescription for opioids or opiates prior to the birth and those opioids or opiates were manufactured, distributed, or filled by a Defendant or Purdue entity. Excluded from the class are any infants and children who were treated with opioids after birth, other than for pharmacological weaning. Also excluded from the class are legal guardianships where the State of Ohio or one of its political subdivisions, such as a public children services agency, has affirmatively assumed the duties of "custodian" of the child.

2. Legal Guardians[8] of Ohio residents born after March 16, 2000, who were medically diagnosed with opioid-related NAS[9] at or near birth and whose birth mother received and/or filled a prescription for opioids or opiates in the 10 months prior to the birth of said infant or child and those opioids or opiates were manufactured, distributed, or filled by a Defendant or Purdue entity.

B. DEFENDANTS

(1) MANUFACTURER DEFENDANTS

- Actavis Entities: Allergan PLC f/k/a Actavis PLC f/k/a Allergan, Inc.; Allergan Finance, LLC f/k/a Actavis, Inc. f/k/a Watson Pharmaceuticals, Inc.; Allergan Sales, LLC; Allergan USA, Inc.; Watson Laboratories, Inc.; Warner Chilcott Company, LLC; Actavis Pharma, Inc. f/k/a Watson Pharma Inc.; Actavis South Atlantic LLC; Actavis Elizabeth LLC; Actavis

[5] The Ohio statewide class is sought by putative Class Representatives Michelle Frost and Stephanie Howell.

[6] The term "Legal Guardian" is defined at fn. 2.

[7] The term "NAS" is defined at fn. 3.

[8] The term "Legal Guardian" is defined at fn. 2.

[9] The term "NAS" is defined at fn. 3.

Mid Atlantic LLC; Actavis Totowa LLC; Actavis LLC; Actavis Kadian LLC; Actavis Laboratories UT, Inc. f/k/a Watson Laboratories, Inc.-Salt Lake City; Actavis Laboratories FL, Inc. f/k/a Watson Laboratories, Inc.-Florida.

- Cephalon Entities: Teva Pharmaceutical Industries Ltd.; Teva Pharmaceuticals USA, Inc.; Cephalon, Inc.
- Janssen Entities: Janssen Pharmaceuticals, Inc.; Janssen Pharmaceutica, Inc. n/k/a Janssen Pharmaceuticals, Inc.; Noramco, Inc.; Ortho-McNeil-Janssen Pharmaceuticals, Inc. n/k/a Janssen Pharmaceuticals, Inc.; Johnson & Johnson.
- Endo Entities: Endo Health Solutions Inc.; Endo Pharmaceuticals, Inc.; Par Pharmaceutical, Inc.; Par Pharmaceutical Companies, Inc. f/k/a Par Pharmaceutical Holdings, Inc.
- Mallinckrodt Entities: Mallinckrodt plc; Mallinckrodt LLC; SpecGx LLC.
- Insys Therapeutics, Inc.
- Depomed, Inc.
- Indivior, Inc.
- Co-Conspirator Purdue Entities: Richard S. Sackler; Jonathan D. Sackler; Mortimer D.A. Sackler; Kathe A. Sackler; Ilene Sackler Lefcourt; Beverly Sackler; Theresa Sackler; David A. Sackler; Rhodes Technologies; Rhodes Technologies Inc.; Rhodes Pharmaceuticals L.P.; Rhodes Pharmaceuticals Inc.; Trust for the Benefit of Members of the Raymond Sackler Family; The P.F. Laboratories, Inc.
- Non-Defendant, Co-Conspirator Purdue Entities: Purdue Pharma L.P.; Purdue Pharma Inc.; The Purdue Frederick Company, Inc.

(2) DISTRIBUTOR DEFENDANTS

- Cardinal Health, Inc.
- AmerisourceBergen Drug Corp.
- Mckesson Corporation
- Anda, Inc.
- H. D. Smith, LLC d/b/a HD Smith f/k/a H. D. Smith Wholesale Drug Co.; H. D. Smith Holdings, LLC; H. D. Smith Holding Company
- Discount Drug Mart, Inc.
- Prescription Supply, Inc.

(3) PHARMACY DEFENDANTS

- HBC Service Company
- CVS Health Corporation; CVS Indiana, LLC; CVS Rx Services, Inc.
- Rite Aid Corporation; Rite Aid of Maryland, Inc.; Rite Aid of Maryland, Inc. d/b/a Rite-Aid Mid-Atlantic Customer Support Center, Inc.
- Walgreen Co.; Walgreens Boots Alliance, Inc.; Walgreen Eastern Co.
- Wal-Mart Inc. f/k/a Wal-Mart Stores, Inc.
- Miami-Luken, Inc.
- Costco Wholesale Corporation

C. CLAIMS

1. First Cause of Action – Violation of RICO, 18 U.S.C. § 1961 *et seq.* – Opioid Marketing Enterprise (against only Defendants Cephalon Entities, Janssen Entities, Endo Entities, and Mallinckrodt Entities (the "RICO Marketing Defendants").

2. Second Cause of Action – Violation of RICO, 18 U.S.C. § 1961 *et seq.* – Opioid Supply Chain Enterprise (against only Defendants Cephalon Entities, Endo Entities, Mallinckrodt Entities, Actavis Entities, McKesson, Cardinal, and AmerisourceBergen (the "RICO Supply Chain Defendants").

3. Third Cause of Action — Negligence.

4. Fourth Cause of Action — Negligence *Per Se*.

5. Fifth Cause of Action — Civil Battery.

6. Sixth Cause of Action — Civil Conspiracy.

D. RELIEF REQUESTED – *See* ¶ I.D., *supra,* which is incorporated by reference.

III. CLASS 4 – CALIFORNIA STATEWIDE CLASS[10]

A. DEFINITION

1. Legal Guardians[11] of residents born after March 16, 2000, who were medically diagnosed with opioid-related NAS[12] at or near birth and whose birth mother received a prescription for opioids or opiates prior to the birth and those opioids or opiates were manufactured, distributed, or filled by a Defendant or Purdue entity. Excluded from the class are any infants and children who were treated with opioids after birth, other than for pharmacological weaning. Also excluded from the class are legal guardianships where a political subdivision, such as a public children services agency, has affirmatively assumed the duties of "custodian" of the child.

2. Legal Guardians[13] of California residents born after March 16, 2000, who were medically diagnosed with opioid-related NAS[14] at or near birth and whose birth mother received and/or filled a prescription for opioids or opiates in the 10 months prior to the birth of said infant or child and those opioids or opiates were manufactured, distributed, or filled by a Defendant or Purdue entity.

3. Legal Guardians[15] of California residents born after March 16, 2000, who were medically diagnosed with opioid-related NAS[16] at or near birth and whose birth mother received

[10] The California statewide class is sought by putative Class Representatives Jacqueline Ramirez, Roman Ramirez, and Melissa Barnwell.

[11] The term "Legal Guardian" is defined at fn. 2.

[12] The term "NAS" is defined at fn. 3.

[13] The term "Legal Guardian" is defined at fn. 2.

[14] The term "NAS" is defined at fn. 3.

[15] The term "Legal Guardian" is defined at fn. 2.

[16] The term "NAS" is defined at fn. 3.

a prescription for opioids or opiates prior to the birth and those opioids or opiates were manufactured, distributed, or filled by a Defendant or Purdue entity.

B. DEFENDANTS – *See* ¶ II.B., *supra,* which is incorporated by reference.

C. CLAIMS

1. First Cause of Action – Violation of RICO, 18 U.S.C. § 1961 *et seq.* – Opioid Marketing Enterprise (against only Defendants Cephalon Entities, Janssen Entities, Endo Entities, and Mallinckrodt Entities (the "RICO Marketing Defendants").

2. Second Cause of Action – Violation of RICO, 18 U.S.C. § 1961 *et seq.* – Opioid Supply Chain Enterprise (against only Defendants Cephalon Entities, Endo Entities, Mallinckrodt Entities, Actavis Entities, McKesson, Cardinal, and AmerisourceBergen (the "RICO Supply Chain Defendants").

3. Third Cause of Action — Negligence.

4. Fourth Cause of Action — Negligence *Per Se*.

5. Fifth Cause of Action — Violations of the Unfair Competition Law.

D. RELIEF REQUESTED

1. Order Defendants to provide for the benefit of the Plaintiff Legal Guardians and the Putative Class Members ongoing medical monitoring, testing, intervention, provision of caregiver training and information, and medical referral, all of which are medically necessary for the NAS Children in their care, and all future medical care reasonably necessary to treat these children. Any injunctive relief to which Plaintiffs may justly show themselves entitled, including injunctive relief designed to reduce the incidence of children born with NAS.

2. Order creation of a Science Panel.

3. Alternatively, all incidental compensatory damages and medical expenses incurred

by Plaintiff Legal Guardians and the Putative Class Members in connection with their care of the NAS Children. It is expressly alleged that all compensatory damages sought in the alternative are incidental to the injunctive relief requested by Plaintiffs and the Class, and are for those caused by the *in utero* exposure to opioids and NAS diagnosis suffered by the NAS Children.

4. Disgorgement and other relief pursuant to the Unfair Competition Law.

5. Punitive damages.

6. Attorneys' fees and costs incurred by Plaintiff Legal Guardians and the Putative Class Members.

IV. ALTERNATIVE SUBCLASSES

1. Legal Guardians[17] of United States, Ohio and California residents born after May 9, 2000, who were medically diagnosed with opioid-related "Neonatal Abstinence Syndrome" ("NAS")[18] at or near birth and whose birth mother received a prescription for opioids or opiates either (1) prior to the birth or (2) ten months prior to the birth and those opioids or opiates were manufactured or distributed by one or more of the "Cephalon Defendants";[19]

2. Legal Guardians[20] of United States, Ohio and California residents born after May 9, 2000, who were medically diagnosed with opioid-related "Neonatal Abstinence Syndrome" ("NAS")[21] at or near birth and whose birth mother received a prescription for opioids or opiates either (1) prior to the birth or (2) ten months prior to the birth and those opioids or opiates were

[17] The term "Legal Guardian" is defined at fn. 2.

[18] The term "NAS" is defined at fn. 3.

[19] Defined in the "Manufacturer Defendants" section for those respective political subdivisions.

[20] The term "Legal Guardian" is defined at fn. 2.

[21] The term "NAS" is defined at fn. 3.

manufactured or distributed by one or more of the "Endo Defendants";[22]

3. Legal Guardians[23] of United States, Ohio and California residents born after May 9, 2000, who were medically diagnosed with opioid-related "Neonatal Abstinence Syndrome" ("NAS")[24] at or near birth and whose birth mother received a prescription for opioids or opiates either (1) prior to the birth or (2) ten months prior to the birth and those opioids or opiates were manufactured or distributed by one or more of the "Mallinckrodt Defendants";[25]

4. Legal Guardians[26] of United States, Ohio and California residents born after May 9, 2000, who were medically diagnosed with opioid-related "Neonatal Abstinence Syndrome" ("NAS")[27] at or near birth and whose birth mother received a prescription for opioids or opiates either (1) prior to the birth or (2) ten months prior to the birth and those opioids or opiates were manufactured or distributed by one or more of the "Actavis Defendants";[28]

5. Legal Guardians[29] of United States, Ohio and California residents born after May 9, 2000, who were medically diagnosed with opioid-related "Neonatal Abstinence Syndrome" ("NAS")[30] at or near birth and whose birth mother received a prescription for opioids or opiates either (1) prior to the birth or (2) ten months prior to the birth and those opioids or opiates were manufactured or distributed by one or more of the "Janssen Defendants";[31]

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[22] Defined in the "Manufacturer Defendants" section for those respective political subdivisions.

[23] The term "Legal Guardian" is defined at fn. 2.

[24] The term "NAS" is defined at fn. 3.

[25] Defined in the "Manufacturer Defendants" section for those respective political subdivisions.

[26] The term "Legal Guardian" is defined at fn. 2.

[27] The term "NAS" is defined at fn. 3.

[28] Defined in the "Manufacturer Defendants" section for those respective political subdivisions.

[29] The term "Legal Guardian" is defined at fn. 2.

[30] The term "NAS" is defined at fn. 3.

[31] Defined in the "Manufacturer Defendants" section for those respective political subdivisions.

f. Legal Guardians[32] of United States, Ohio and California residents born after May 9, 2000, who were medically diagnosed with opioid-related "Neonatal Abstinence Syndrome" ("NAS")[33] at or near birth and whose birth mother received a prescription for opioids or opiates either (1) prior to the birth or (2) ten months prior to the birth and those opioids or opiates were manufactured or distributed by one or more Defendant or Purdue entity.

V. PLAINTIFFS HAVE SATISFIED ALL REQUIREMENTS OF RULE 23

As set forth more fully in the accompanying Consolidated Memorandum of Law, Plaintiffs have satisfied the requirements of Fed. R. Civ. P. 23(a):

- The members of the classes are so numerous that joinder is impracticable;
- Membership in the classes is ascertainable and based on readily identifiable and objective criteria;
- The claims of the class members involve common questions of law and fact;
- The claims of the named plaintiffs are typical of the claims of the other class members, and they will otherwise adequately represent the classes and have no conflicts of interest; and
- The putative class counsel will fairly and adequately represent the interests of the classes.

Furthermore, the proposed classes also satisfy Fed. R. Civ. P. 23(b)(2) and 23(b)(3):

- The parties opposing the classes have acted or refused to act on grounds generally applicable to the class;
- Common questions of law and fact predominate over individual issues; and
- Class certification is superior to other available means of adjudication.

Rule 23 was designed to facilitate the class-wide adjudication of similar claims and to achieve economies of time, effort, and expense while promoting uniformity of decision as to all

[32] The term "Legal Guardian" is defined at fn. 2.

[33] The term "NAS" is defined at fn. 3.

persons similarly situated. The class action mechanism is not only the superior method to adjudicate claims such as those alleged here, but it is the only viable method of doing so.

Accordingly, Plaintiffs respectfully request the certification of their proposed classes.

DATED: January 7, 2020

Respectfully submitted,

/s/ Marc E. Dann
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Putative Class Co-Lead Counsel for Guardians of NAS Children

CERTIFICATE OF SERVICE

I certify that on January 7, 2020 a true and correct copy of the foregoing was automatically served on the parties registered with the Court's CM/ECF system.

/s/ Marc E. Dann
Marc E. Dann (0039425)

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THE NAS GUARDIANS' CONSOLIDATED MEMORANDUM OF LAW IN SUPPORT OF THEIR MOTION FOR CLASS CERTIFICATION

I. THE NEED TO CERTIFY A CLASS OF GUARDIANS IS URGENT

The NAS[1] Children are the most vulnerable and blameless victims of the opioid crisis. Through no fault of their own, they were bathed in opioids while their nervous systems, organ systems, and bodies were forming *in utero*. At birth the symptoms of their opioid exposure were so great that they were diagnosed with NAS. Their sad plight does not end at diagnosis. Instead, they entered the world facing a host of additional and significant needs, challenges, and additional risks as a result of their NAS. Medical and scientific evidence makes clear that early monitoring and surveillance will benefit them. Yet, despite over two decades of an opioid crisis and hundreds of thousands of NAS births, there exists at no level, whether federal, state or local, a long-term (longitudinal), large scale medical surveillance of these children.

The Guardians of the NAS Children, are the only entities legally bound to provide the ongoing care the Children require, including the monitoring and surveillance necessary to address and understand the effects of their NAS. **These needs are urgent.** Plaintiffs' Expert Kanwaljeet "Sunny" Anand, Professor at Stanford Medical School,[2] writes:

> [The] long-term impact [of the Opioids Crisis] is inestimable because of the pervasive and persistent effects of prenatal opioids on all aspects of an individual's development. Their cumulative burden of suffering, and the total impact of their exposures on all facets of our society is so huge and unparalleled in human history

[1] The children made the subject of these complaints were diagnosed at birth with Neonatal Abstinence Syndrome (NAS), also sometimes referred to as Neonatal Opioid Withdrawal Syndrome (NOWS), arising out of their birth mothers use of opioids during pregnancy.

[2] Dr. Anand, M.B.B.S., D.Phil, FAACP, FCCM, FRCPCH, is a Professor of Pediatrics, Anesthesiology, Perioperative & Pain Management at Stanford University School of Medicine. Dr. Anand graduated from M.G.M. Medical College in India, where he was awarded an M.B.B.S. As a Rhodes Scholar at the University of Oxford, UK, he received a Doctor of Philosophy, followed by a post-doctoral fellowship at Harvard Medical School, a categorical Pediatrics residency training at Boston Children's Hospital, and a Critical Care Medicine fellowship at Massachusetts General Hospital. Attached as Exhibit 5 to the Declaration of Marc Dann ("Dann Decl.") is the curriculum vitae and report of Dr. Anand.

> that this is truly the real emergency. **Unless they are monitored/supported/ treated NOW, the problems of these children will become intractable and unmanageable as they grow into adulthood, wiping away generations of human endeavor because of our short-sightedness.**

Anand Report, Dann Decl., Exhibit 5, at ¶ 2 (emphasis added).

Only the Guardians, who include grandparents, widowed single parents, adoptive parents, and other family members, are obligated to advance the best interest of the NAS Children. Only they can assert a current, justiciable claim against Defendants arising out of the NAS Children's special and ongoing medical needs and risks. Only they can secure relief that will **necessarily** result in aid to the NAS Children.[3] Absent action by this Court on behalf of the Guardians and the NAS Children in their care, future courts will necessarily confront the "wreckage of the broken man" and know the sad futility of trying to value that wreckage in dollars. **This generation of children is not yet lost, but without intervention by this Court, they will be.**

It is our position that the critical needs of the NAS Children should not be subordinated to the less urgent desires of the cities and counties that have dominated this MDL. These cities and counties (1) do not have the legal ability to bring claims for the benefit of the NAS Children, (2) do not owe a duty of care to the NAS Children, and (3) will never guarantee that they will provide ongoing care for the benefit of the NAS Children. Contrast this with the Guardians who have a fiduciary obligation to advance the singular goal of immediate aid to the Children in their care. Dr. Anand warns against their failure:

> Such bleak outcomes portend a <u>future tsunami</u> of neurocognitive and neuro-psychiatric disorders among the children and youth with NAS. The Opioid Crisis has increased over the past 20 years; therefore, <u>multiple generations</u> of such

[3] Without a nationwide certified class of Guardians focused on these needs alone, the creation of a medical monitoring program by some governmental entity is, at best, certain to be delayed for years. At worst, a medical monitoring program will never exist because (1) there is no guarantee that the patchwork of state and local government will commit funds to long-term programs, (2) these disparate entities lack the geographic jurisdiction to collect data from an equally disparate cohort of NAS children, and (3) there is no system of intergovernmental coordination that would otherwise allow them to tackle a national problem.

> children and youth have been affected. While we continue to argue about priorities and preferences, these children are growing up – and every day that passes without the medical monitoring or supportive services being offered to these children, it makes their problems more and more intractable, imposing on them poorer outcomes and greater societal disadvantages.

Anand Report, Dann Decl., Exhibit 5, p. 8 (emphasis in original).

The window of opportunity to provide salutary relief to the NAS Children is rapidly closing. No future court will be able to undo their injuries or offer a chance at mitigation if monitoring and surveillance is delayed. For them, it is now or never. Certification of a nationwide class of Guardians of NAS Children must occur in 2020. Medical monitoring claims exist as injunctive relief to ensure that money needed to pay for testing and epidemiology is actually spent for that purpose. Monitoring, surveillance, and epidemiology on a population basis, not on an individual basis, benefits everyone within the affected population benefits from the data generated by testing and participating members, all of whom are subject to the same protocol.

The Guardians also wish to highlight one of the most appalling misdeeds to have occurred during the Opioid Crisis — the flow of prescription opioids to pregnant women, especially those enrolled in Medicaid. With nationwide numbers of over 20% of Medicaid-enrolled mothers being prescribed opioids, some states—including Ohio—have been hit even harder with upwards of 30% of pregnant mothers receiving opioids.[4] Thus, the numbers of NAS Children within the Medicaid system are startling.

[4] Attached as Dann Decl., Exhibit 8 is Desai, R.J., "Increase in Prescription Opioid Use during Pregnancy among Medicaid-enrolled Women," *Obstetrics and Gynecology,* 123(5), 997-1002 (2014).

II. THE CLASS CLAIMS AND CLASS DEFINITIONS

In hope of speeding relief to the NAS Children and mitigating the care burden for them, the Guardians ask the Court to certify two different nation-wide classes asserting RICO claims. One nationwide class will be composed of Guardians of NAS Children whose birth mothers were prescribed opioids at any time before the child's birth, and that other will be composed of NAS Children whose birth mothers were prescribed opioids during her pregnancy.

The Guardians also ask the Court to certify an Ohio state-wide class asserting those same RICO claims, plus state law claims for negligence, negligence per se, battery, and conspiracy and a California state-wide class asserting RICO claims and similar state law claims to those brought in Ohio.[5] Across all four class actions, the operative facts, class definitions, class-wide proof, and requested relief are uniform.

The Guardians seek certification of these nationwide[6] classes:

> The Expansive Nationwide Class
> Legal Guardians[7] of United States residents born after May 25, 2000, who were medically diagnosed with opioid-related NAS[8] at or near birth and whose birth

[5] Attached as Appendix A is a Master Summary of Plaintiffs' class and subclass definitions, as well as the causes of action asserted by those classes and subclasses and the Defendants against whom the claims are asserted.

[6] As stated, the Guardians have also pleaded statewide classes for Ohio and California, which are similarly defined. *See* Appendix A.

[7] The term "Legal Guardians" is defined as "any natural person or entity who has the primary legal responsibility under their respective laws of their state for an infant or child's physical, mental, and emotional development." Expressly excluded from the class of "Legal Guardians" are any governmental entities. "Legal Guardians" include natural and adoptive parents who have not otherwise lost legal custody of their children, legal custodians, legal caretakers, and court-appointed guardians (including guardians of the person), whether temporary or permanent.

[8] The term "NAS" is defined "to include additional, but medically symptomatic identical, terminology and diagnostic criteria, including Neonatal Opioid Withdrawal Syndrome (NOWS) and other historically and regionally used medical and/or hospital diagnostic criteria for infants born addicted to opioids."

Additional specifics on these readily identifiable and ascertainable terms are included in this Motion (and are based on the expert medical opinions of Dr. Anand), Dann Decl., Exhibit 5. "The Class Is Ascertainable and Based on Objective Criteria," *infra*, at VIII.A, which discusses the objective categories to be used for certification. The objective criteria will become part of both any order of certification and, eventually, class

mother received a prescription for opioids or opiates prior to the birth and those opioids or opiates were manufactured, distributed, or filled by a Defendant or Purdue entity.

The Narrower Nationwide Class[9]
Legal Guardians of United States residents born after May 25, 2000, who were medically diagnosed with opioid-related NAS at or near birth and whose birth mother received and/or filled a prescription for opioids or opiates in the 10 months prior to the birth of said infant or child and those opioids or opiates were manufactured, distributed, or filled by a Defendant or Purdue entity.

Exclusions from All Classes (Including Statewide Classes)
Excluded from the class are any infants and children who were treated with opioids after birth, other than for pharmacological weaning. Also excluded from the class are legal guardianships where a political subdivision, such as a public children services agency, has affirmatively assumed the duties of "custodian" of the child.

Alternative subclasses are:

a. Legal Guardians[10] of Ohio residents born after May 9, 2000, who were medically diagnosed with opioid-related "Neonatal Abstinence Syndrome" ("NAS") at or near birth and whose birth mother received a prescription for opioids or opiates either (1) prior to the birth or (2) ten months prior to the birth and those opioids or opiates were manufactured or distributed by one or more of the "Cephalon Defendants";[11]

b. Legal Guardians[12] of Ohio residents born after May 9, 2000, who were medically diagnosed with opioid-related "Neonatal Abstinence Syndrome" ("NAS") at or near birth and whose birth mother received a prescription for opioids or opiates either (1) prior to the birth or (2) ten months prior to the birth and those opioids or opiates were manufactured or distributed by one or more of the "Endo Defendants";[13]

c. Legal Guardians[14] of Ohio residents born after May 9, 2000, who were medically diagnosed with opioid-related "Neonatal Abstinence Syndrome" ("NAS") at or near birth and whose birth mother received a prescription for opioids or opiates either (1) prior to the birth or (2) ten months prior to the birth and those opioids or opiates

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notice and proof of claim.

[9] The defined terms of "Legal Guardians" and "NAS" are the same for each class definition and are not repeated in this Memorandum again.

[10] The term "Legal Guardian" is defined at fn. 1.

[11] Defined in the "Manufacturer Defendants" section, *supra*.

[12] The term "Legal Guardian" is defined at fn. 1.

[13] Defined in the "Manufacturer Defendants" section, *supra.*

[14] The term "Legal Guardian" is defined at fn. 1.

were manufactured or distributed by one or more of the "Mallinckrodt Defendants";[15]

d. Legal Guardians[16] of Ohio residents born after May 9, 2000, who were medically diagnosed with opioid-related "Neonatal Abstinence Syndrome" ("NAS") at or near birth and whose birth mother received a prescription for opioids or opiates either (1) prior to the birth or (2) ten months prior to the birth and those opioids or opiates were manufactured or distributed by one or more of the "Actavis Defendants";[17]

e. Legal Guardians[18] of Ohio residents born after May 9, 2000, who were medically diagnosed with opioid-related "Neonatal Abstinence Syndrome" ("NAS") at or near birth and whose birth mother received a prescription for opioids or opiates either (1) prior to the birth or (2) ten months prior to the birth and those opioids or opiates were manufactured or distributed by one or more of the "Janssen Defendants";[19]

f. Legal Guardians[20] of Ohio residents born after May 9, 2000, who were medically diagnosed with opioid-related "Neonatal Abstinence Syndrome" ("NAS") at or near birth and whose birth mother received a prescription for opioids or opiates either (1) prior to the birth or (2) ten months prior to the birth and those opioids or opiates were manufactured or distributed by one or more Defendant or Purdue entity.[21]

In each class and subclass definition, the two primary objective and readily ascertainable criteria are obvious: (1) the birth mother of every NAS Child received a prescription for opioids prior to the birth of her child and (2) that child was medically diagnosed with NAS. By crafting the definitions in this manner, Guardians have excluded exposure-only victims who did not present with NAS symptoms at birth and receive a diagnosis of NAS. The weight of medical opinion is that when a child has been diagnosed with NAS, he or she absolutely requires medically-necessary

[15] Defined in the "Manufacturer Defendants" section, *supra.*

[16] The term "Legal Guardian" is defined at fn. 1.

[17] Defined in the "Manufacturer Defendants" section, *supra.*

[18] The term "Legal Guardian" is defined at fn. 1.

[19] Defined in the "Manufacturer Defendants" section, *supra.*

[20] The term "Legal Guardian" is defined at fn. 1.

[21] Defined in the "Non-Defendant, Co-Conspirator Purdue Entities" and "Defendant Co-Conspirator Purdue Entities"" sections, *supra.*

surveillance and monitoring for both the existing effects of NAS, as well as the heightened risk of additional disease and disorders that may manifest in the future as a result of NAS.

It is also notable under these definitions and because of the nature of Defendants' alleged underlying conspiracy, that the birth mother's history of drug usage (other than the prescribed opioid required by the definition) is irrelevant. Whether the birth mother continued to draw down on a supply of opioids medically prescribed to her (including opioids-replacement therapy during pregnancy), whether she pivoted to the oversupplied diversionary market, or whether she even began her usage on that diversionary market before receiving a prescription for opioids does not matter. **But for the conspiracy to create the diversionary market and oversupply opioids to targeted, at-risk Americans who should not have access to addictive quantities or *not have access to opioids at all* (such as pregnant women, women of childbearing years, women co-using other addictive drugs, or women at risk for addiction), there would not exist two generations and hundreds of thousands of NAS Children in the United States.** And, yet, that is exactly what Defendants conspired to do, knowing full well the consequences of targeting at-risk Americans and at-risk communities. They cannot create the criminal conspiracy that resulted in this foreseeable and intended epidemic of addiction by birth mothers while also claiming that the individual mechanics of a birth mother's addiction protect them from the Guardians' claims arising out of their duty of care for the NAS Children.

III. THE GUARDIANS BEFORE THIS COURT

The following Guardians seek to be appointed as Class Representatives for the nationwide classes, and also as Class Representatives for the statewide classes of their respective states:

A. California and the Nation

1. Jacqueline and Roman Ramirez

Jacqueline and Roman Ramirez, California residents, are the birth parents and Guardians of Minor R.R., aged 14, the youngest of their three children and the only one born with NAS. R.R.'s parents have been married for over 30 years. Jacqueline was injured in 2001, while attending her older daughter's softball tournament. As a result of her injury, she was diagnosed with pain disorder and prescribed opioids. Jacqueline became dependent on opioids prior to becoming pregnant with R.R. She also continued to be prescribed opioids throughout her pregnancy. Minor R.R. was diagnosed at birth with NAS and discharged to the care of Jacqueline and Roman.

2. Melissa Barnwell

In 2004, Melissa Barnwell was severely injured when she was struck by a car. She had multiple broken bones and was prescribed opioids for chronic pain. During her pregnancy with minor C.G., Melissa's physicians continued to prescribe her opioids. Melissa is the birth mother of C.G., a 13-year-old minor child who resides in California with Melissa. C.G. was diagnosed at birth with NAS.

B. Ohio and the Nation

1. Michelle Frost

D.F. is a minor child residing in Ohio. He is two years old and lives with Michelle Frost, his legal guardian and biological grandmother. Ms. Frost became D.F.'s guardian in 2018. D.F.'s birth mother was prescribed opioids for pain treatment associated with a melanoma in her right eye which ultimately caused her eye to be removed. She subsequently became addicted, and, as a result, she was on Medication Assisted Therapy while pregnant with D.F. At birth D.F. was diagnosed with NAS. Not long after D.F.'s birth, his grandmother took over his care and later became his guardian.

2. Stephanie Howell

C.L. is a minor child who resides in Ohio with his biological mother and legal guardian Stephanie Howell. C.L. is currently five years old. He is the youngest of three children born to Stephanie, and her only child with NAS. In 2010, Stephanie was prescribed opioids for back pain, and she subsequently became addicted. She continued to be prescribed and take prescription opioids while she was pregnant with C.L.

IV. CLASS COUNSEL

The Putative Class Representatives have retained and employed for over the past two years a cohesive and well-functioning group of 20+ law firms to represent the interests of all Guardians and the NAS Children in this MDL and in other related actions. Of those firms, four have been selected by the Class Representatives to seek appointment as Class Counsel for the Guardian Classes. Attached and incorporated at Dann Decl., Exhibits 1, 2, 3, and 4, are the Declarations and Firm Resumes of these firms. These firms have a thorough understanding of the facts, relevant documents and claims asserted in this litigation. They also are highly experienced in class actions of this nature and have been appointed as Lead and Co-Lead Counsel in a number of complex class actions. They will fairly and adequately represent the interests of the Class.

A. Dann Law (Class Counsel and Liaison Counsel)

Marc Dann has practiced law for 33 years and has represented thousands of consumers individual and class action cases. Dann has served as Lead and Liaison counsel in the Sonic MDL and has been appointed class counsel in Miller v. Intellos and Lieber v. Wells Fargo in the Northern District of Ohio. Dann was elected Ohio Attorney General in 2006 and oversaw several MDL and class action matters where the State of Ohio served as lead counsel. Dann also served on the National Association of Attorneys General Committee overseeing the National Tobacco

Settlement. Dann and his firm have the financial resources to represent the interests of the Guardians of NAS Children before this court.

B. Martzell, Bickford & Centola (Class Counsel)

Scott R. Bickford of Martzell, Bickford & Centola of New Orleans, Louisiana, has practiced law for 36 years and has represented thousands of personal injury victims in class action, MDL and mass tort litigation. Bickford has been lead counsel in multiple civil and criminal trials including lead counsel in an MDL bellwether proceeding. Bickford is also an associate professor of law at Tulane Law School. Bickford and his firm have the financial resources to represent the interests of the Guardians of the NAS Children before this Court.

C. The Bilek Law Firm

Thomas E. Bilek of The Bilek Law Firm, L.L.P. of Houston, Texas ("Bilek Law"), has been appointed by courts as lead, co-lead, or liaison class counsel in over 20 certified class actions in state and federal courts. Bilek has practiced law for 33 years and specializes in mass and class actions arising from toxic exposures, environmental contamination, and securities fraud. Bilek is also one of the only attorneys in the United States to have tried two class actions to verdict as lead attorney. Bilek was co-liaison counsel in the class action *In re Enron Corp. Securities* that ultimately settled for $7.2B. Bilek Law also was a committee chair in the class action *In re Deepwater Horizon,* which settled for in excess of $10B. Bilek and his firm have the financial resources to represent the interests of the Guardians of the NAS Children before this Court.

D. The Cooper Law Firm

The Cooper Law Firm is a New Orleans based mass tort/class action firm specializing in representing plaintiffs. Cooper's cases are large matters involving radiation exposure, toxic chemical exposure, and injuries arising from defective medical devices and pharmaceuticals. The firm has the resources to equip our class action team as it has done since this litigation was

originally instituted. Of counsel to the Cooper Law Firm is Stuart H. Smith a pioneer in the NORM litigation leading Smith to represent over 100 cancer victims harmed by radiation exposure. Smith was lead counsel in the landmark case of Grefer v. Alpha where he obtained a judgment of over one billion dollars against Exxon Mobil. Smith represented 1000s of plaintiffs- both individuals and businesses- in the BP oil spill. Celeste Brustowicz is the managing partner of the Cooper Law Firm. Celeste has practiced law for 34 years, primarily in Louisiana, but also in California (2007) and Mississippi (2011) where she is also licensed. Brustowicz obtained a B.A. in Political Science from Louisiana State University and a J.D. in 1985 from the Paul M. Hebert Law School at LSU. For over a decade, Brustowicz graded the torts portion of the Louisiana Bar examination. Brustowicz has been involved with many class actions over the years, representing states, counties, police agencies, and even judges in a variety of case types including civil rights, pharmaceutical, and torts matters.

V. BY CERTIFYING A CLASS OF GUARDIANS, THE COURT WILL ADVANCE THE GOALS OF THIS MDL

Certification of a class of Guardians will advance the MDL process in two important ways. First, it will put the Guardians and Class Counsel in the best position to negotiate a comprehensive resolution of the Guardians' and NAS Children's claims. Class Counsel already represents hundreds of NAS Children and Guardians individually and is in the process of building a larger group by working with lawyers who represent others individually. Certification of a class of Guardians will therefore facilitate negotiations with the potential to resolve all pending lawsuits in which NAS Children or their Guardians seek damages or injunctive relief.

Negotiations led by the PSC cannot resolve these cases. Although the cities and counties can release their own claims, they cannot release claims held individually by the Guardians or their wards. The *parens patriae* power does not extend that far. *See* X.E.1, "The Entities Neither

Represent the NAS Children *Parens Patriae*, Nor Can Release Their Claims". Because, as the Court observed when certifying the Negotiation Class, "Defendants have insisted throughout on the need for a 'global settlement' … that resolves most, if not all, lawsuits against them arising out of the opioid epidemic," *In re: National Prescription Opiate Litigation*, Case No. 1:17-MD-2804, (N.D. Ohio), 2019 WL 4307851, the PSC's inability to release claims held by the Guardians and the NAS Children may be a serious obstacle to any eventual global settlement.

Second, certification of these classes will allow a significant number of identical claims to proceed expeditiously and efficiently within the MDL process, create desirable incentives for negotiation or settlement with Defendants, and allow for ultimate trial of the Guardians' claims for injunctive relief. Lawsuits by individual Guardians pit people with limited resources against Big Pharma, whose wealth and political power are infinitely greater. Aggregation will level the playing field by outfitting all Guardians with representation by lawyers whose financial incentives are tied to the recovery for the entire group. Individual lawsuits would also be duplicative and wasteful. Finally, class certification will promote accuracy at the remedies stage by facilitating the use of statistics that are far more reliable when applied to all Guardians collectively than when applied to Guardians one by one.

In January 2018, the Court expressed the desire "to do something meaningful to abate this crisis…." (Dkt. 58, p. 5). The Court then observed that meaningful action would address the need for "new systems" and "treatment." *Id.* at 9. ***This Motion offers the best opportunity the Court will have to provide meaningful relief***. The States are actively working to sideline, and even shut down, the cities and counties' efforts to assert their own public nuisance claims and settle with Defendants. It is fair to say that, regardless of how that intragovernmental squabble works out, this Court will never receive a guarantee of how settlement funds secured by the governmental

entities will be spent. All that can be known is that both sides want Defendants' money for themselves, that they cannot be required to use any of the money to help victims of the crisis, and that they have historically demonstrated an unwillingness to use received funds to benefit individual victims. Unless the Court certifies a class of Guardians, there is a real danger that, despite years of effort, this MDL will end without helping any victims at all.

VI. THE GUARDIANS ARE NOT ASSERTING PERSONAL INJURY CLAIMS

Because litigation classes containing personal injury claims are disfavored, it is important to understand at the outset that **the Guardians are not asserting personal injury claims in their amended complaints**. The Guardians are suing only in their capacity as caregivers for symptomatic NAS Children who require urgent and specialized medical monitoring as a result of both their NAS status at birth and the host of additional needs and risks that arise for an NAS Child after birth. Medical monitoring classes ***are*** certifiable, as shown further below. The Guardians are asking the Court to follow an existing path, not to blaze a new one, in helping them to carry their heavy burden to care for the NAS Children and expeditiously secure this much-need injunctive and declaratory relief.

VII. SPECIALIZED MEDICAL MONITORING AND ASSESSMENT MUST BEGIN IMMEDIATELY

"Unless they are monitored/supported/treated NOW, the problems of these children will become intractable and unmanageable as they grow into adulthood, wiping away generations of human endeavor because of our short-sightedness." Anand Report, Dann Decl., Exhibit 5.

The exigent and medically-necessary monitoring and surveillance needs of the NAS Children are fully briefed in Plaintiffs' expert reports that are relied on in this Memorandum, and which are attached and incorporated at Dann Decl., Exhibits 5, 6, and 7. The host of problems

after birth[22] that these children and their caregivers face are overwhelming and include delayed and impaired cognitive development and long-term behavioral problems. The resultant increased care burden faced by the NAS Guardians is nondelegable, immense, and cannot be met without the intervention of this Court and an order of declaratory and injunctive relief that requires financing by the Defendant responsible parties. Regarding the timing of these efforts, "the best possible outcomes can only be achieved with proper management of NAS before hospital discharge, couple with increased monitoring and surveillance, as well as active multi-disciplinary interventions that are initiated just after birth and continued for the child's entire childhood and adolescence (up to 18 years of age)." Anand Report, Dann Decl., Exhibit 5, at ¶ 4.

Plaintiffs are not, of course, required to prove the merits of their claims or requested relief at this stage, nor even establish a probability that they will be successful. *Eisen v. Carlisle & Jacquelin*, 417 U.S. 156, 177-78 (1974). Plaintiffs do, however, meet their obligation to provide "some" evidence favoring the underlying class claims for relief. *Wal-Mart Stores v. Dukes*, 564 U.S. 338, 350-51 (2011).

A. The Mechanism of Injury and Disease in Cases of NAS

Dr. Anand details extensively the mechanism of opioid exposure on brain development and brain growth.

> Brain Development: Opioids have drastic and sustained effects on brain development in the fetal and postnatal periods, affecting the brain's size, architecture, networks and connections between brain cells, neurochemical and other functions of each cell, as well as the brain DNA's structure, its expression and regulation. Thus, prenatal opioid exposures have robust and long-term effects on the cognitive and behavioral outcomes of the individuals diagnosed with NAS. Opioids affect brain development by disrupting oligodendrocyte development,

[22] At birth some of the NAS Children are also diagnosed with birth defects, including facial/oral defects, limb deformities, congenital neurological defects, and congenital heart defects. Anand Report, Dann Decl., Exhibit 5, *passim*. Other NAS Children, however, had such defects at birth, but they have not yet been diagnosed. The Surveillance Protocol provides for testing to identify such yet-undiagnosed defects. *Id*. at 9-11.

> altering the temporal sequencing and quality of nerve fiber myelination, decreasing the growth of nerve cell dendrites, and their branching pattern complexity of pyramidal neurons in the cerebral cortex, and by suppressing cell proliferation and neuronal migration to the cortical plate. These effects may reduce regional brain volumes in the basal ganglia and other brain areas with lower developmental potential.
>
> Brain Growth: A large number of studies have reported lower birth weights and smaller head circumferences in opioid-exposed babies with relatively increased risks in those exposed. A controlled comparison showed that reduced fetal head and body growth in infants of opioid-dependent mothers were not explained by gestational age, cigarette smoking, area deprivation, infant gender, maternal age or parity. Given the limited maternal/environmental effects on head circumference, it is likely that the robust effects of opioid exposure on head circumference occur by reducing brain growth. This was confirmed in a pilot study of 16 infants, where volumetric MRI scans showed smaller whole brain volumes and basal ganglia volumes compared to age-matched population means. In another follow-up MRI study that included 38 youths in the opioid-exposed group and 44 youths in the non-exposed group (aged 17 to 22 years), the drug-exposed group displayed smaller brain volumes, smaller surface areas of the cerebral cortex, and thinner cortical mantles than unexposed youth.

Anand Report, Dann Decl., Exhibit 5, at 5 (footnotes omitted).

As a result of the mechanisms of disease and injury discussed above, the increased care burden faced by the NAS Guardians is nondelegable, immense, and cannot be met without the intervention of this Court and an order of declaratory and injunctive relief that requires financing by the Defendant responsible parties. Regarding the timing of these efforts, "the best possible outcomes can only be achieved with proper management of NAS before hospital discharge, coupled with increased monitoring and surveillance, **as well as active multi-disciplinary interventions that are initiated just after birth and will continue for the child's entire childhood and adolescence** (up to 18 years of age)." Anand Report, Dann Decl., Exhibit 5, at ¶ 4 (emphasis added).

B. The Increased Risk of Additional and Future Disease and Disorder as a Result of NAS at Birth

That the care needs of diagnosed NAS child are both exigent and significant is addressed by Anand in his discussion of the long-term risks and consequences of this exposure.

> Neurodevelopmental Consequences: Differences in neurodevelopment between children with and without exposure to prenatal opioids are related to the age at which they were assessed, with milder differences occurring at birth, greater differences during infancy and early childhood but widening gaps noted during school age and adolescence. Individuals with NAS at birth had impaired behavioral regulation, greater excitability and arousal, and poorer quality of their movements. Among infants and toddlers, NAS was associated with impaired mental and language development as well as poorer neuromotor and psychomotor development before 24 months of age. Because of the very limited roles for cognitive or executive functions in early childhood, studies performed in the younger age groups showed minimal differences in cognitive or executive functions with and without NAS (e.g., every infant is likely to fail an algebra test). In contrast, the Bayley Scales of Infant Development revealed more prominent neurodevelopment deficits, with greater vulnerability among boys than in girls. Assessment in later childhood revealed differences in IQ, motor performance, language performance, lower IQ scores, behavior and attention problems compared with unexposed children at 8.5 years of age. Children exposed to methadone prenatally also had elevated levels of aggression, fear, and anxiety. Even after controlling for their sociodemographic factors and birth mother's medical history, elevated symptoms of ADHD occurred in children who were exposed to prenatal opioids compared with children not exposed to opioids *in utero*.
>
> Executive Functions: Executive functions are thinking skills that help us with the information processing, reasoning, planning, problem-solving, for coping with stress, regulating our emotions and managing our lives. As a child progresses through school, the executive functions assume greater importance in their academic success, goal setting, and employability. Children exposed to prenatal opioids have difficulties with information processing, poorer performance on a vigilance task, lower overall executive functioning[105], significantly lower visual acuity, impaired visual-motor and perceptual performances, and fewer goal-directed eye movements. Children with NAS were far more likely to have developmental delays and lower IQ, 2.3 times more likely to be hospitalized for neuropsychiatric disorders, 4.5 times more likely to be hospitalized for child abuse[144] and die during hospitalization, perform poorly on educational testing, and show cognitive disabilities requiring extra classroom therapies and services. CDC compared 1815 children with NAS and 5441 children without NAS (age 3-8 years). Children with NAS were more likely referred for disability evaluation (19.3% vs. 13.7%), have a learning disability (15.6% vs. 11.7%) and require classroom therapies (15.3% vs. 11.4%). These differences remained significant even after controlling for maternal smoking, maternal education, birth weight, gestational age, and/or NICU admission[146]. Children with NAS had lower scores on standardized testing in grade 3; by grade 7, children with NAS were scoring lower than other children in grade 5 and showing progressively greater deficits[145]. The increasingly

> complex cognitive processing and executive functioning required within a competitive high school environment place these children with NAS at progressively greater disadvantage and much higher likelihood of adverse outcomes, thus widening the gap between those with and without NAS.
>
> Neuropsychiatric outcomes: Although Uebel et al. (2015) had found that more children with NAS were hospitalized with neuropsychiatric disorders (adjustment, conduct, anxiety, emotional, or speech disorders), three recent studies have highlighted the very high prevalence and distribution of mental health conditions among individuals with prenatal opioids. Using a Medicaid database, Sherman et al. (2019) found that half of all children with NAS were diagnosed with mental disorder before age 5, compared with 30% of all other births. Children with NAS were more likely to have conduct disturbances (2.7-fold), hyperkinetic syndromes (2.6-fold), adjustment difficulties (2.5-fold), stress/anxiety disorders (1.5-fold), emotional problems (1.9-fold), childhood-onset psychoses (1.7-fold), intellectual disabilities (2.3-fold), specific developmental delays (1.7-fold. Mental health conditions were 1.6-fold more prevalent in children with a history of NAS than the opioid-exposed children without a history of NAS, and 1.4-fold higher among children with Medicaid vs. commercial health insurance (Table 2 from Conner et al., 2019). From a longitudinally followed youth cohort (17-22 years) with prenatal opioid exposures (± other drugs) who were adopted/fostered before 1 year of age, Nygaard et al. (2019) found **2- to 8-fold higher lifetime risk of mental disorders** compared to matched controls. These risks mainly included **major depression, alcohol abuse, ADHD**, and **aggressive behaviors** even after controlling for age, gender, and caregivers' education. These children not only engaged in sex at younger ages and had **more sexual partners** compared to controls, but also experienced **suicidality** (28.8%), **psychoses** (17.7%), or **antisocial personality disorder** (15.6%) more often than their peers.

Anand Report, Dann Decl, Exhibit 5, pp. 6-7 (internal footnotes omitted) (emphasis in original).

The enormity of the risks and challenges that the NAS Children face cannot be overstated. The Guardians need intervention from this Court to carry this immense care burden and that help must come swiftly.

C. The Medical Monitoring and Surveillance Program that Is Required

At the heart of the Guardians' claims is the imposition through injunctive and declaratory relief of a medical monitoring and assessment plan for the symptomatic NAS Children in their care. Attached at Anand Report, Dann Decl., Exhibit 5, pp. 9-12, is the "Protocol for Routine[23]

[23] The term "routine" is used by Dr. Anand to refer to the necessary monitoring and surveillance for all

Monitoring/Surveillance of Children Diagnosed with NAS at Birth" developed by Dr. Anand. For each critical developmental period in a child's life,[24] Dr. Anand lays out the specific "Physical Health," "Behavior/motor development," "Cognition/learning," "Mental Health," and "Quality of Life" monitoring and surveillance care requirements for an NAS Child at each of those stages. A substantially similar protocol is set out by Dr. Carl Werntz[25] in his report, Dann Decl., Exhibit 6, "Proposed Medical Monitoring and Intervention Program," at pp. 10-14, with categories of "Educational Component for Caretakers," "Annual Assessment- Pediatrician," "Educational Readiness Assessment," "Additional (Specialist) Assessments," "Additional/Social Risk Assessment," and "Vocational Assessment and Recommendations."

For example, at Years 03-05 under the Anand Protocol, a Guardian will need to discharge their unique and elevated care for an NAS Child in the area of "Cognition/Learning" by securing four different yearly tests—the Kaufman Assessment Battery for Children, Preschool Language Scale (PLS4), Behavior Rating of Executive Function- Preschool Version (BRIEF-P), and Conner's Test—3rd edition (ADHD screen). *Id.* These are in addition to the yearly care requirement of twenty other tests and assessments for an NAS Child, and do not even include the general "Quality of Life" care burdens on a Guardian. *Id.*

Though there are minor variations across the case law of the fifty states regarding the availability of medical monitoring relief for **a**symptomatic claimants, these variations are irrelevant to the instant case which involves **symptomatic, NAS-diagnosed** children. Traditional

children diagnosed with NAS. To be clear, this protocol goes above, beyond, and is quite different from routine pediatric care of children not diagnosed with NAS or otherwise born addicted to opioids.

[24] Those periods are Year 01 (subdivided into 0-1 months, 1-6 months, 6-12 months), Year 02, Years 03-05, Years 06-09, Years 10-14, and Years 15-18. Anand Report, Dann Decl., Exhibit 5, at pp. 9-12.

[25] Dr. Werntz is a physician Board Certified in Preventative Medicine, specializing in Occupational and Environmental Medicine, with experience in developing and implementing medical monitoring and surveillance in both industrial and litigation contexts. Werntz Report, Dann Decl., Exhibit 6, *passim*.

legal debates about medical monitoring hinge on an exposed, but asymptomatic population, and have no applicability here.

The NAS Children for whom the Guardians have an absolute care duty are all symptomatic, having been diagnosed at birth with NAS. (To be clear, children who were exposed *in utero* to opioids but whose exposure did not result in a diagnosable case of NAS are excluded from the class definition.) Instead, these putative classes before the Court are defined to address the immediate needs of Guardians who do not have expert knowledge about the specific medical and developmental needs of the children they care for, nor the financial resources to carry such a heightened care burden.

Dr. Werntz writes:

> The development of the human brain before and after birth is complex, and multifactorial. There are general themes about the timing of organ development, but the development of the pathways and mechanisms necessary for learning, understanding, decision making and behavior control are not completely understood. … The long-term consequences of NAS for each child is multifactorial, depending on individual differences between humans that are difficult to determine with specificity but a medical monitoring program is necessary for all of NAS victims [because] they all face common risks of latent disease that can be mitigated and abated through medical monitoring.

Werntz Report, Dann Decl, Exhibit 6, at p. 5.

Plaintiff Guardians seek to transfer (or at least alleviate) their current heightened care burden for the symptomatic NAS Children (who are also at risk for additional latent diseases) onto the responsible parties. These underlying facts are not what is traditionally referred to in jurisprudence as "medical monitoring" which almost exclusively arise out of exposure-only underlying facts Because these are not personal injury claims, but guardianship claims arising solely out of the care burden, the relief sought by the Guardians is roughly analogous to the judicially created construct of "medical monitoring," but the causation leading to the necessity

relief in the instant case is entirely different. A review of the traditional legal framework for exposure-only, **a**symptomatic medical monitoring makes this distinction immediately obvious:

(1) Was there significant exposure? In this matter all exposures have, by definition, already reached the threshold of medical "significance" because they resulted in symptomatic NAS. To be clear, the class is defined to include only significant, symptomatic, and diagnosed disease and disorder.

(2) Was the substance to which the NAS Children were exposed toxic, hazardous, or otherwise has the potential risk for serious harm? Again, the class is defined to include only exposure to highly dangerous controlled substances that by definition have already resulted in significant, symptomatic, and diagnosed disease and disorder. Regardless, Plaintiffs' experts address both the "toxicity" and the "seriousness of harm" in their reports.

(3) What is the relative increase in risk in those exposed? Once again, by definition the NAS Children already have significant, symptomatic, and diagnosed disease and disorder. Having already been diagnosed, they are also expected to have progression of symptoms as well as additional disease and symptoms that will manifest over childhood and adolescence that must be monitored for. There is no risk of developing NAS absent an exposure to opioids and there is no background level of opioids in the environment, nor other exposure routes for a fetus. Further, absent exposure to an opioid, there is no chance for the public at large to develop both addiction to that opioid, nor, when the exposure occurs *in utero*, to result in the significant additional risks of health and developmental problems beyond the initial NAS diagnosis. Plaintiffs' expert reports detail the increased risk for all such known manifest and latent health problems of the NAS Children above and beyond that of an unexposed population that was not diagnosed at birth with NAS.

(4) Is monitoring for the effects of the disease medically reasonable and necessary? Once opioid exposure reaches the level of significance such that a child has numerous manifest symptoms at birth and is diagnosed with NAS, the weight of medical opinion is that monitoring is medically reasonable and necessary. Again, by defining the class as only diagnosed cases, the medical reasonability and necessity is self-evident.

(5) Is the monitoring different from that normally recommended in the absence of exposure? Plaintiffs' experts have offered the Court a monitoring plan that is specifically tailored for both the needs and risks of symptomatic, diagnosed NAS Children that is different and beyond routine pediatric care.

(6) Is there clinical value in early detection and diagnosis? Because the care burden of all Guardians is to maximize health and developmental outcomes of the children in their care and protect them against negative outcomes, the value of early detection and diagnosis of health and developmental problems in children is also self-evident.

D. Convocation and Administration of a Science Panel

The Guardians have also requested the relief of the convocation of court-supervised[26] Science Panel(s), which shall collect and analyze medical monitoring results so that other heretofore unrecognized latent, dread diseases and symptoms that are associated with *in utero* exposure to opioids may be identified so that the Guardians may properly care for the NAS Children. The Science Panel will also allow medical professionals engaged in research and development of treatments and interventions for NAS Children to have access to a broader universe of data. The Guardians have requested a fund for expenses for maintenance and

[26] If a nationwide class is certified, then only one Science Panel need be convened. If, however, only statewide classes are certified then the originating courts have the discretion to coordinate with each other to on Science Panels.

administration of this Science Panel which shall be created by and costs borne by Defendants. The costs, nature, and extent of epidemiological studies and actions of the Science Panel(s) will be subject to approval and supervision of the courts pursuant to the Guardians and Counsel's recommendations and input. The Science Panel(s) will be composed of academic and medical institutions appointed by the courts in consultation with the Guardians and their Counsel.

Regarding the need for the Panel(s), the Guardians' experts write:

> As mentioned several times, there is limited information on the long-term effects of NAS, and effectiveness of specific interventions. The final aspect of this [monitoring and surveillance] program would be a funded arrangement with an academic or public health organization to collect, curate, analyze and publish the results of the assessments, interventions, and outcomes of NAS survivors. This epidemiological component confers a medical benefit to the population.

Werntz Report, Dann Decl., Exhibit 6, "Data Collection, Analysis, and Publication," at p. 13.

> It is certain that in the future new technology or better understandings of the long-term effects of NAS may require updating of this program. This could be based upon changes in medical knowledge, improvements in technology to detect diseases associated with these exposures, or additional conditions of concern that are identified by the epidemiologist. This protocol should be reviewed periodically by the supervising physician or a committee appointed for that purpose to ensure that the screenings and follow-up described herein remain consistent with best medical practice.

Id. at 14.

> The establishment of Scientific Panels to participate in a medical monitoring program would, in my opinion, be beneficial for the following reasons. Monitoring for the post-natal consequences [of] NAS is reasonable and necessary, according to contemporary scientific principles. The monitoring program should include periodic diagnostic medical examinations, as there is clinical value in early detection and diagnosis.
>
> Such Scientific Panels should be composed of experts from the multiple medical and scientific disciplines that are required to fully understand the complex condion, including (but not necessarily restricted to): paediatricians, epidemiologists, physicians specializing in opioid addiction, psychiatrists, behavioural psychologists, toxico-pathologists, [and] neurobiologists.

Howard Report[27], Dann Decl., Exhibit 7, at § 11, "Summary and Opinion."

VIII. THE REQUIREMENTS FOR CLASS CERTIFICATION ARE MET

Certification of a class is proper when the requirements set out in Fed. R. Civ. P. 23(a) are met and the matter fits into at least one subpart of Rule 23(b). *See, e.g., Clemons v. Norton Healthcare Inc. Ret. Plan*, 890 F.3d 254, 278 (6th Cir. 2018). The requested NAS Guardianship Class satisfies all elements of Rule 23(a), as well as those in Rule 23(b)(2) and 23(b)(3).

A. The Class Is Ascertainable and Based on Objective Criteria

For a class action to be certified, the "class definition must be sufficiently definite so that it is administratively feasible for the court to determine whether a particular individual is a member of the proposed class." *Young v. Nationwide Mut. Ins. Co.,* 693 F.3d 532, 537-38 (6th Cir. 2012). *See also Cole v City of Memphis*, 839 F.3d 530, 541 (6th Cir. 2016). Administrative feasibility exists when membership can be determined on the basis of "objective criteria." *Id.* at 538-39. *See also Rikos v. Procter & Gamble Co.*, 799 F.3d 497, 525 (6th Cir. 2015). "[P]erfection" is not the standard. *Young*, 693 F.3d at 537-38. As the Court noted when certifying the negotiation class, "minor technical issues can be worked out going forward." 2019 WL 4307851.

Whether a class member meets the three objective criteria of the class definitions can be determined on the basis of documentary evidence, as explained in the subsections that follow. Class Counsel are ready, willing, and able to gather the documents that are required.

1. "Legal Guardian"

[27] Dr. Charles Vyvyan Howard is a toxico-pathologist specializing in the problems associated with the action of toxic substances on health, particularly during the period of development in the womb. He is an Emeritus Professor of Bioimaging at the University of Ulster and has authored/co-authored over 130 peer reviewed scientific papers, predominantly in the field of quantitative developmental toxicology. He is a Fellow of the Royal College of Pathologists, Fellow of the Collegium Ramazzini, Past President of the Royal Microscopical Society, Member of the British Society of Toxico-Pathologists, Past President of the International Society of Doctors for the Environment. Dann Decl, Exhibit 7.

The phrase "Legal Guardian" is further defined as "any natural person or entity who has the primary legal responsibility under their respective laws of their state for an infant or child's physical, mental, and emotional development." *See, e.g., Second Amended Class Action Complaint*, ("California Nationwide NAS Complaint"), (Dkt. 2747, n.155). (All class definitions are set out at Apx. A). It includes "natural and adoptive parents who have not otherwise lost legal custody of their children, legal custodians, legal caretakers, and court-appointed guardians (including guardians of the person), whether temporary or permanent." *Id.*

Guardianship can be established simply and by reference to objective criteria. A person may document parenthood (natural or by adoption) by filing an affidavit along with a copy of a child's birth certificate or adoption papers. A person may also establish all other forms of guardianship by filing a birth certificate and a copy of a judicial order of appointment.

Legal guardianship responsibility "under state law" does not, however, require a fifty-states analysis of the underlying guardianship laws, however. Whether someone has or has not been appointed as a guardian requires no legal analysis. It is a fact question: is there an order of appointment? Similarly, whether someone is an adoptive parent involves a question of legal status, not legal analysis. Is there an order of adoption?

2. "Medically Diagnosed with NAS"

In addition to Neonatal Abstinence Syndrome, the term NAS has been defined to encompasses "additional, but medically symptomatic identical, terminology and diagnostic criteria, including Neonatal Opioid Withdrawal Syndrome (NOWS) and other historically and regionally used medical and/or hospital diagnostic criteria for infants born addicted to opioids." Appendix A, *passim*. In addition to some states that have birth registries for children born with NAS, the objective medical criteria for such medical diagnosis can also be found in the child's

medical records at birth.[28]

Dr. Anand identifies those criteria as: (1) diagnosis of NAS or NOWS as documented in the child's medical record; (2) monitoring of NAS/NOWS score(s) after birth, meeting the diagnostic criteria he sets out; (3) postnatal weaning of the child with opioid replacement drugs (morphine, methadone, buprenorphine, or other opioids); and (4) opioid-positive toxicology screening of either umbilical cord blood or the baby's meconium.[29] Anand Report, Dann Decl., Exhibit 5, at "Definitions," ¶ 2 at p. 2.

3. The Birth Mother Received a Prescription for Opioids

Finally, in order to establish class membership after a settlement has been reached or a verdict secured, a Guardian must show that the NAS Child's mother received a prescription for opioids or opiates before the child was born. (Some Guardians will be able to provide prescriptions

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[28] The Putative Class Representatives and Class Counsel are well-versed in the significant privacy and confidentiality issues relating both to minor children and to their medical records and how this will affect contemplated Notice in the Class.

Once the Court makes a decision about the type of classes, claims, and requested relief it wishes to certify, Class Counsel will craft Class Notice for its review (until such guidance is received, a nearly infinite number of Notices could result). Notice will include the following: (1) a description of the certified claims, parties, and requested relief; (2) a clear statement about what claims, i.e. personal injury, are not made the subject of the lawsuit and are not being certified and which must be brought, if at all, on an individual basis and within any applicable limitations periods; (3) a description of all confidentiality efforts that will be exercised by Class Counsel and the Claims Administrator to insure that minor identities and medical records will be protected and de-identified, as necessary; (4) a description of the three subjective criteria needed to establish membership in the class and how that criteria will be provided in a confidential and secure manner; (5) assuming membership in the class is established, an overview of how the child could be enrolled in the monitoring and surveillance program and an overview of the type of relief that will be sought at trial; and (6) all other standard requirements for class notice.

[29] Dr. Anand is of the professional opinion that medical monitoring and surveillance should be afforded to an even greater cohort of children than those for whom the Guardians bring this case—children whose birth mothers were diagnosed with OUD, but who do not otherwise meet the other objective diagnostic criteria, due mainly to the aversion of OB/GYNs to diagnose a child with NAS at birth due to the concern that the child will be taken away from the birth mother. The Guardians and putative class counsel recognize and feel deeply for this group of children but have not posited how that criteria soundly meets the Rule 23(a) requirement of objectivity and ready identification as do the others. To that end, the Class definitions advanced by the Guardians require diagnostic criteria for the child, not the birth mother.

issued during the birth mother's pregnancy, for which a separate class is sought.) All classes and subclasses can be proven with pharmacy records. Because membership in the class can be determined on the basis of documentary evidence, the administrative feasibility of fixing a class member's status is clear. It is also contemplated that Court Order regarding production of documents by the Pharmacy Defendants will assist Class Members in establishing this criteria.

B. The Subclasses

The Guardians ask *strictly in the alternative* for certification of a series of subclasses to be employed by this Court in the event that it finds that further refinement of the proposed class definitions are necessary. The alternative subclasses require that the birth mother's prescription be for an opioid produced by a specific manufacturing defendant, regardless of when the prescription was written or filled. The Guardians believe that because of the nature of the alleged conspiracy amongst the Defendants that their more expansive class definitions satisfy all requirements of Rule 23(a) and 23(b), but offer these subclass definitions for use by the Court if it does not agree with Plaintiffs' interpretation of the legal requirements. To be clear, however, the Guardians contend that joint and several liability for the conspiracy renders these subclasses moot.

C. The Requirements of Rule 23(a) Are Met

Having previously certified a nationwide class of cities and counties for the purpose of attempting to negotiate a global resolution of their claims, the Court is thoroughly familiar with the requirements set out in Rule 23. Movants therefore discuss the legal requirements as briefly as possible here.

Movants also abbreviate this discussion by adopting all findings made in the Court's *Memorandum Opinion Certifying Negotiation Class* that apply to the requested class of Guardians. *See* 2019 WL 4307851. This is appropriate because the Guardians adopted the counties' RICO pleadings by reference. *See, e.g., Second Amended California Nationwide Complaint*, (Dkt. 2747)

(adopting the Summit County complaint). The Court's prior analysis of RICO claims and issues raised by the negotiation class of counties applies with full force to this motion. *See* 2019 WL 4307851.

1. The Class Is Sufficiently Numerous

Fed. R. Civ. P. 23(a)(1) permits a class to be certified when claimants are so numerous as to render the joinder as parties impracticable. *In re Whirlpool Corp. Front-Loading Washer Prod. Liab. Litig*., 722 F.3d 838, 852 (6th Cir. 2013). Courts typically find that this requirement is met when the number of claimants is greater than 40 and the claimants are unknown or widely dispersed.

Since 2000, the start date for the class, tens of thousands of infants have been born with NAS. As Dr. Anand writes: "Based on trend analyses for birth mothers suffering from OUD [first usage, so spell this out] in pregnancy, approximately 36,000 babies [were] likely to [have been] born with prenatal opioid exposures in 2018" alone. Anand Report, Dann Decl., Exhibit 5, "The Numbers of Babies Exposed to Prenatal Opioids Annually," at p. 2. Dr. Anand also includes for the Court the well-known "National Inpatient Sample" derived from the Healthcare Cost and Utilization Project for 1999-2014, and further projects up-to-date numbers which have grown to "10.1 per 1,000 delivery hospitalizations." *Id.* at pp. 3-4.

The guardians for these children must be approximately equal in number and must also be widely dispersed. The numerosity requirement is plainly met.

2. Common Issues Exist

In *Wal-Mart Stores, Inc. v. Dukes*, 564 U.S. 338, 349-50, 131 S. Ct. 2541, 2550-51, 180 L.Ed.2d 374, 389-90 (2011), the Supreme Court clarified the commonality requirement, stating the plaintiffs' claims "must depend upon a common contention … that it is capable of classwide

resolution—which means that determination of its truth or falsity will resolve an issue that is central to the validity of each one of the claims in one stroke."

When certifying the PEC's negotiation class, the Court found that the commonality requirement is met, for two reasons. First, when the JPML transferred the pending cases to this forum, it determined that "[a]ll of the actions can be expected to implicate common fact questions as to the allegedly improper marketing and widespread diversion of prescription opiates into states, counties and cities across the nation...." 2019 WL 4307851. Second, "there is direct evidence of the commonality of the claims and issues in this matter given that the short-form complaint process enabled MDL plaintiffs to adopt these specific claims and issues, and many did so." *Id.*

Movants' cases were transferred to this MDL by the JPML. Movants have also used the short-form complaint process to adopt Summit County's claims. Both justifications for finding commonality therefore apply equally well to Movants' request to certify a class of Guardians.

Because the Guardians request injunctive relief, the remedy stage raises additional issues that are common to the class. At trial, common evidence will establish (1) the necessary medical monitoring and assessment protocol to be followed for the NAS Children due to the known risks associated with their medically diagnosed conditions; and (2) the convocation of and establishment of parameters of inquiry for a Science Panel which will gather and analyze the data arising from the monitoring and assessment of the NAS Children.

3. The Named Plaintiffs' Claims Are Typical

Rule 23(a)(3) requires that "the claims or defenses of the representative parties [be] typical of the claims or defenses of the class." Fed. R. Civ. P. 23(a)(3). "Typicality is met if the class members' claims are 'fairly encompassed by the named plaintiffs' claims'" such that "by pursuing their own interests, the class representatives also advocate the interests of the class members." *In re Whirlpool Corp.*, 722 F.3d at 852-53 (6th Cir. 2013) (quoting *Sprague v. Gen. Motors Corp.*,

133 F.3d 388, 399 (6th Cir. 1998)). "[T]he plaintiffs' claims need not be identical to those of the class; typicality will be satisfied so long as the named representatives' claims share the same essential characteristics as the claims of the class at large." 1 Newberg on Class Actions § 3:29 (internal quotation marks and footnotes omitted).

The putative Class Representatives are all (1) legal guardians of (2) children diagnosed at or near birth with NAS. Based on these two factors alone, the NAS Guardians' claims are typical of all NAS Guardian class members who owe care duties to the NAS Children. Those care duties must be put before the NAS Guardians' own needs and interests and are different from and beyond those they would owe to an ordinary child who does not have the risks arising from an NAS diagnosis.

When certifying a negotiation class at the request of the PEC, the Court observed that the cities and counties serving as named plaintiffs were typical because all such governmental entities are:

> generally interested in the same end: recouping money they have been forced to pay to address the opioid epidemic and ameliorating that epidemic. If the Class Representatives pursue their own interests identified in these complaints, they will necessarily be pursuing the interests of the absent class members. There is nothing unique about any of the proposed Class Representatives that would set them apart in meaningful ways from the absent class members

2019 WL 4307851. *Mutatis mutandis*, the relationship between Plaintiffs and other guardians is the same.

It does not matter that some guardians will benefit from injunctive relief more than others because their wards' injuries and their own care responsibilities are more severe. As the Court noted when granting the PEC's motion:

> [The] typicality requirement met where class representative's and "other class members' claims arise from the same practice...[and] the same defect...and are based on the same legal theory. Typicality is satisfied despite the different factual circumstances regarding the manifestation of the [defect]...."

2019 WL 4307851 (quoting *Daffin v. Ford Motor Co*., 458 F.3d 549, 553 (6th Cir. 2006)).

The typicality of the putative class representatives and their claims is also borne out by the testimony of their well-qualified and experienced experts who opine that a medically necessary and class-wide medical monitoring and assessment plan which is uniform for all children diagnosed with NAS must be provided through injunctive relief so that the NAS Guardians may carry out their specific care duties. And, of course, the Science Panel which arises out of this monitoring and assessment will function in a uniform (and typical) manner, provide a uniform (and typical) benefit and further facilitate (in a typical manner) the execution of the NAS Guardians' care duties.

While it goes beyond the scope of this Motion, the NAS Guardians are well-aware of the governmental entities' representations that these care duties have already been/are being addressed by Medicaid or private insurance. The NAS Guardians are not suing to implement injunctive relief for routine pediatric care. Instead, the NAS Guardians are suing in order to obtain something very different and absolutely necessary for the at-risk NAS Children — implementation of a medical monitoring and assessment protocol developed by experts in NAS and the unique care needs it presents. *See* Anand Report, Dann Decl., Exhibit 5, at pp. 9-12, and Werntz Report, Dann Decl., Exhibit 6, at pp. 10-14.

In suing to implement this relief, the Class Representatives "also advocate the interests of Class members," who will receive the identical relief. *See In re Whirlpool*, 722 F.3d at 852-53. Indeed, the relief will function only if all NAS Guardians are able to ensure the enrollment of a significant number of NAS Children in the monitoring and assessment protocols. A Science Panel convened to analyze the monitoring and surveillance data of the random smattering of NAS Guardians who might be able to prosecute to verdict and preserve on appeal individual relief in 5-

7 years would do absolutely nothing to advance the medical and scientific knowledge in this field, nor would it allow a Science Panel to address the needs of the NAS Guardian caregivers and the NAS Children as they arise during the work of the Panel. *See* Anand Report, Dann Decl., Exhibit 5 and Werntz Report, Dann Decl., Exhibit 6, *passim*. At best, a series of individual case studies written by Medicaid-reimbursed doctors and physicians assistants might be the sole result absent the requested relief, but more likely, little will occur to advance medical knowledge about the plight of the NAS Children.

4. The Class Representatives Will Adequately Represent the Class

Rule 23(a)(4) requires that "the representative parties will fairly and adequately protect the interests of the class." Fed. R. Civ. P. 23(a)(4). The Court looks to two criteria in determining adequacy of representation: "1) the representative must have common interests with unnamed members of the class, and 2) it must appear that the representatives will vigorously prosecute the interests of the class through qualified counsel." *Young v. Nationwide Mut. Ins. Co.*, 693 F.3d 532, 543 (6th Cir. 2012) (quoting *In re Am. Med. Sys., Inc.,* 75 F.3d 1069, 1083 (6th Cir. 1996)). In addition, the proposed class representatives should not have any conflicts of interest with the class that they seek to represent. *Amchem Prods. Inc. v. Windsor,* 521 U.S. 591, 625 (1997).

As borne out by the fact sheet and discovery responses of the putative class representatives which are a matter of record in this proceeding, the Guardians have established that (1) they are members of the class, i.e., they are the Guardians of NAS Children; (2) they have the same interests as the class members and no conflict otherwise, i.e., they are legally obligated to carry out the heightened care duties owed to NAS Children and carrying out those care duties does not conflict with, nor adversely affect the ability of any other class member to do the same; and (3) the injuries they suffered are the same as those of the class members, i.e., they have an increased duty of care because the child in their care was diagnosed with NAS and has specific increased medical risks

and needs. Record, *passim.* The class representatives have no conflicts with the class and otherwise satisfy all requirements of Rule 23(a)(4). Additionally, the Court should consider their efforts in advancing these claims and supervising the litigation.

All while bearing the significant burdens of caring for NAS Children, Roman and Jacqueline Ramirez, Melissa Barnwell, Michelle Frost, and Stephanie Howell have been active participants in the prosecution of these claims and have established through the discovery process that they meet all criteria set forth in the class definitions. Record, *passim. See also* Declaration of Marc E. Dann on Confidential Medical Information of Plaintiffs' Wards, Plaintiffs' Discovery Responses [under seal]. Specifically, they have conducted numerous interviews to inform Plaintiff's Counsel about their claims; provided comprehensive information about the birth mother's history of opioid exposure; assisted counsel in coordinating discovery, including answering and reviewing questions for fact sheets and interrogatories; and submitted documentation and signed HIPAA forms to help confirm custody and validate their claims. *Id.* Also, during the pendency of this Motion, it is expected that they will be presented for deposition.

5. Class Counsel Are Adequate

The adequacy requirement in Rule 23(a) extends to Class Counsel. Rule 23(g), which requires the appointment of class counsel, directs the Court to consider: "(i) the work counsel has done in identifying or investigating potential claims in the action; (ii) counsel's experience in handling class actions, other complex litigation, and the types of claims asserted in the action; (iii) counsel's knowledge of the applicable law; and (iv) the resources that counsel will commit to representing the class." Fed. R. Civ. P. 23(g).

Attached and incorporated by reference is the Declaration of Marc Dann which addresses the various efforts of Class Counsel since inception of these cases, competency issues relating to class counsel, and also includes the CVs for the law firms applying to be appointed as Lead

Counsel for the class. *See* Dann Decl., Exhibits 1, 2, 3, and 4. All have been actively engaged for years now in efforts to investigate and advance the interests of the Guardians and the NAS Children they care for in this MDL, as well as other multiple fronts, including bankruptcy and state court proceedings. *Id.* These firms also have substantial prior class action experience and have been appointed Lead and/or Liaison Class Counsel by state and federal courts throughout the United States. *Id.* The firms have the committed legal resources and ability to serve fully the needs of the putative classes and have no conflicts with class members. *Id.* Finally, the firms have engaged Professor Charles Silver, an authority on procedural and ethical issues in aggregate litigation, to help with questions that arise in the course of litigation and settlement negotiations.

6. The Elements of Rule 23(b)(2) Are Met Because the Class Chiefly Seeks a Declaratory Judgment and Uniform Injunctive Relief

The Guardians ask the Court to certify nationwide classes for injunctive and declaratory relief under Rule 23(b)(2), and additionally for damages under Rule 23(b)(3). The *Manual for Complex Litigation* observes that "Rule 23(b)(2) generally applies when the relief sought is a court-supervised program for periodic medical examination and research to detect diseases attributable to the product in question." That is the relief the Guardians seek. *Accord Wilson v. Brush Wellman*, 817 N.E.2d 59, 65 (Ohio 2004) ("Court supervision and participation in medical-monitoring cases is a logical and sound basis on which to determine whether the action is injunctive. It has the added advantage of being a bright-line test, which can be readily and consistently applied.").

The requirements of predominance and superiority do not apply to Rule 23(b)(2). Instead:

> The key to the (b)(2) class is "the indivisible nature of the injunctive or declaratory remedy warranted—the notion that the conduct is such that it can be enjoined or declared unlawful only as to all of the class members or as to none of them." In other words, Rule 23(b)(2) applies only when a single injunction or declaratory judgment would provide relief to each member of the class.

Wal-Mart Stores, Inc. v. Dukes, 564 U.S. 338, 360, 131 S. Ct. 2541, 2557, 180 L. Ed. 2d 374 (2011); *see* Richard A. Nagareda, *Class Certification in the Age of Aggregate Proof*, 84 N.Y.U. L. Rev. 97, 132 (2009). In *Dukes*, the Supreme Court found that certification under Rule 23(b)(2) was improper because the class members' claims for monetary relief belonged, if anywhere, under Rule 23(b)(3).

Here, Plaintiffs seek injunctive relief in the form of a medical monitoring program funded by Defendants. In *Dukes*, the Supreme Court did not discuss this form of relief, but in the article upon which it heavily relied, Professor Nagareda did—and his observations weigh heavily in favor of certifying Rule 23(b)(2) classes in cases that seek this form of relief. He first addressed medical monitoring classes in the following passage:

> In toxic tort and product liability litigation, a frequent battleground for class certification concerns class actions that seek the establishment of a court-supervised program to provide medical monitoring for all persons in the exposed group so as to facilitate early detection of disease and, in turn, to mitigate its ultimate severity. Battles over the certification of medical monitoring classes remain high pitched, but their nature is such as to reinforce the content of governing law as the centerpiece of the certification dispute. The crux of the dispute concerns not the use of epidemiological evidence as part of the class certification determination but, instead, *whether governing law authorizes medical monitoring as an injunction-like remedy for exposed persons*. Only when governing law does so will the fact of exposure, in itself, operate to make all exposed persons the victims of the same wrong.

Nagareda, 84 N.Y.U. L. Rev. at 119–20. The point is straightforward: By establishing that the governing law entitles the Guardians to a medical monitoring remedy, the Guardians will satisfy the requirement contained in Rule 23(b)(2).

Nagareda later confirmed that medical monitoring is an indivisible remedy, that is, a remedy of the type that is suitable for certification under Rule 23(b)(2).

> The gap in time between exposure and disease manifestation creates a window during which the defendant may be enjoined to take action to mitigate the effects of the tortious exposure. The analogy here is to the familiar notion that a motorist who negligently runs over a pedestrian is under an affirmative obligation to mitigate

> the resulting harm—say, to take the injured person to the hospital for proper treatment. [] The medical monitoring remedy operates injunctively to enforce this affirmative obligation on the defendant's part. When properly crafted, the remedy also operates injunctively vis-à-vis exposed persons, covering their medical expenses only as incurred via the court-supervised monitoring program rather than simply paying them damages to spend as they wish.

Id. at 173 n.77.

In support of the propriety of certifying medical monitoring classes under (b)(2), Nagareda cited the American Law Institutes' Principles of the Law of Aggregate Litigation, § 2.04 of which discusses medical monitoring. The final version of that document states that (b)(2) certification is proper when the following conditions are met.

(1) The evidence to be offered in support of liability "consists of epidemiological or other aggregate proof applicable to all those exposed to the disputed toxic substance";

(2) "[T]he connection between the elevated risk of future disease and exposure to the substance for which Defendant is legally responsible does not involve individualized inquiry into the circumstances of particular persons";

(3) "[A]ll persons allege that, in light of such exposure, a reasonable physician would prescribe a medical-monitoring regime above and beyond the medical services that such a physician otherwise would recommend"; and

(4) "[S]uch monitoring will be instrumental in guiding medical intervention to mitigate the effects of disease manifestation, should disease ultimately occur."

Principles of the Law of Aggregate Litigation § 2.04, Illus. 3 (2010). When the identified conditions are met and the substantive law makes medical monitoring available as a remedy:

> [T]hen the court should find that the requested relief demands a form of performance other than the distribution of money. Medical monitoring with the capacity to guide medical intervention to mitigate the effects of disease differs from the distribution of money to compensate for past harm, because the basis for the

> claimed program stems from a shared risk among similarly situated persons. [T]he court has discretion to characterize such a remedy as indivisible and, hence, capable of treatment on an aggregate basis. Such a characterization would operate irrespective of whether applicable substantive law treats medical monitoring as a legal or equitable remedy.

Id.

The four conditions listed in the principles read like a roadmap of the trial of this case. First, the evidence to be offered in support of liability and causation will be the same evidence used to establish that the Defendants committed the alleged RICO violations. The Court has already found that "[a]s applied to Plaintiffs' allegations concerning the existence of two national enterprises that disseminated a set of standard falsehoods in marketing and distributing opioids, all of the elements except injuries are common, not individual." 2019 WL 4307851. And with respect to causation, the Court wrote, "Whether there was [] third-party reliance is a question susceptible to class-wide proof" as well. *Id*. The Court found that questions relating to the Controlled Substances Act, namely, the nature of Defendants' responsibilities under the Act and their alleged failure to carry out those responsibilities, "are 'capable of resolution with generalized, class-wide proof' and 'need only be answered once because the answers apply in the same way' across the Class." *Id.* at *3 (quoting *Martin v. Behr, Dayton Thermal Prod. LLC*, 896 F.3d 405, 414 (6th Cir. 2018)).

Second, injury will be proven by "epidemiological [and] other aggregate proof" that exposure to opioids *in utero* causes NAS and results in additional and substantial risk of other diseases and disorders. Because all members of the class are guardians whose wards were diagnosed with NAS at or near the time of birth, no individualized proof of exposure or injury will be required. Aggregate proof will also establish the link between exposure to opioids and an elevated risk of additional complications and future health impairments.

Third, all class members allege that, because of the children's exposure to opioids, "a reasonable physician would prescribe a medical-monitoring regime above and beyond the medical services that such a physician otherwise would recommend," and this too will be established by expert testimony at the aggregate level. *See* Anand Report, Dann Decl., Exhibit 5, at pp. 9-11; Werntz Report, Dann Decl., Exhibit 6, at pp. 10-14. Finally, expert testimony will also show at the aggregate level that monitoring will be instrumental in guiding medical intervention to mitigate the effects of NAS.

7. The Single-State Class Actions Are Also Certifiable under Rule 23(b)(2)

The reasons set forth above also establish that the Ohio and California statewide class actions meet the requirements for certification under Rule 23(b)(2). Although the Guardians prefer the certification of a single nationwide RICO class, they urge the Court to certify the single-state classes too so that the 6th Circuit will have all options before it.

8. All Actions Are Also Certifiable under Rule 23(b)(3)

Because of the unique nature of the relief requested, certification is most appropriate under Rule 23(b)(2). However, the Guardians are aware that most courts consider analyze a motion under both Rules 23(b)(2) and (b)(3) standards in event that a reviewing court finds that one or the other is more appropriate. Additionally, requests for punitive damages are also certifiable under Rule 23(b)(3).

Certification under Rule 23(b)(3) is appropriate where (1) "the questions of law or fact common to class members predominate over any questions affecting only individual members," and (2) class resolution is "superior to other available methods for fairly and efficiently adjudicating the controversy." Fed. R. Civ. P. 23(b)(3).

The Court certified the PEC's negotiation class under subparagraph (b)(3) of Rule 23. When doing so, it found that common questions of law and fact predominate and that a class action

would be a superior method of adjudication. 2019 WL 4307851. Because the Guardians have adopted the counties' pleadings, including the portion relating to the RICO conspiracy, these findings apply to the Guardian's request to certify a Rule 23(b)(3) class with equal force.

To be clear, if the cities and counties are able to assert classwide claims arising out of the opioid crisis in their communities, then the Guardians are able to assert classwide claims for the opioid crisis in their own homes. Because the Guaridans seek to require Defendants to fund a medical monitoring program that satisfies their clear and aboslute duty to care for the NAS Children, their claims are actually more suitable for classwide treatment under Rule 23(b)(3) than the claims of the cities and counties for unrestricted lump sums of cash that can be spent however they want.

9. Common Issues Predominate

The Court set out the law governing the predominance requirement in its opinion certifying the City and County Negotiation Class, writing that "[t]he predominance inquiry consists of two steps: "[a] court must first characterize the issues in the case as common or individual and then weigh which predominate." Common questions are those where "the same evidence will suffice for each member to make a prima facie showing." 2019 WL 4307851. Notably, Rule 23(b)(3) does not require a complete absence of individual issues. A case may be certified under Rule 23(b)(3) even if there are some individual causation or damage issues. *See Martin*, 896 F.3d at 405; *Sterling v. Velsicol Chem. Corp.,* 855 F.2d 1188 (6th Cir. 1988). When a uniform and pervasive pattern of conduct is alleged, there is predominance even if the common conduct caused varying harm to individual class members. *Martin*, 896 F.3d at 408. *Accord Tyson Foods, Inc. v. Bouaphakeo*, 136 S.Ct. 1036, 1045 (2016).

When the Court certified the Negotiation Class under Rule 23(b)(3), it found that common issues predominate over individual ones. The overarching prevalence of the RICO marketing and

CSA abrogation claims throughout the pleadings supported this conclusion. As the Court wrote, "the Opioids Litigation raises questions of law and fact with common answers, and it is the answers to these common questions that predominate in importance—that matter most—to the advancement and disposition of the Opioids litigation. These are the questions that have consumed most of the Courts', the Special Masters', and the parties' attention[.]" *Memorandum of Law*, (Dkt. 1820-1, at pp. 74-75). The Court added later that, "here, the entire class makes the same core factual allegations and the same core legal claims against the defendants who operated nationwide. And most of the evidence to prove those claims is exactly the same for every plaintiff." *Id*. at 80. These findings are even truer for the Guardians, all of whose claims are stated in a single nationwide pleading, as contrasted with the 1300+ pleadings that were surveyed for common questions raised by the members of the Negotiation Class.

10. Anticipated Claims of Individual Issues Will Not Disrupt the Predominance Balance

While it is possible that Defendants will not launch a "blame the mother" campaign to dispute predominance, that is unlikely. It is not inappropriate for this Court to consider now that the very "individual" issues that Defendants are expected to rely upon in their predominance opposition are all themselves foreclosed to Defendants. These issues actually "turn on the [defendants'] common course of conduct," which satisfies the predominance requirement. *In re Hyundai and Kia Fuel Economy Litigation*, 926 F.3d 539, 563 (9th Cir. 2019). The Guardians' pleadings are unique because through their carefully crafted class definition and liability theory they have: (1) established how Defendants' vast conspiracy to create the secondary, diversionary market for opioids obviates the need for any individual Guardian to establish product identification (or the route of any opioid through the pharmaceutical supply chain) specific to an NAS Child; (2) obviated the need for any dose calculation, because the NAS diagnosis at birth itself is proof of

the sufficiency of dosage; (3) excluded other potential sources of exposure, intervening causes, or the relevancy of unique medical histories as the exposure occurred *in utero*; (4) plead a completely uniform actual injury and common medical concern which is based on a credible, non-conjectural risk to the NAS Children which in turn gives rise to immediate and necessary care duties of the NAS Guardians for the benefit of the NAS Children; and (5) established the traceablity of Defendants' bad acts to the Plaintiffs' harm through the class definition requirement of an opioid prescription for the birth mother. Defendants' traditional bases for opposing class certification cannot stand and this Court should exercise its discretion to come to the aid of the NAS Guardians and the Children for whom they owe the ultimate duty of care.

A thorough discussion of any alleged individual issues that Defendants actually claim will be found in the Guardians' reply brief. The limited discussion herein is meant only to apprise the Court that the Guardians have contemplated these challenges and are well-ready to establish that they are meritless in these proceedings. The examples below anticipate these arguments, but show that each is truly a common issue arising out Defendants' vast conspiracy and ultimate liability:

Example 1
Alleged individual issue: the birth mother of an NAS Child bought additional, non-prescription opioids in the diversionary market
True common issues: (1) Defendants created the scourge of addiction by hiding the significant risk from their products; (2) Defendants created both a source of and demand for additional opioids in that diversionary market; and (3) the diversionary market could never have existed but for Defendant's conspiracy to violate the Controlled Substances Act

Example 2
Alleged individual issue: the birth mother of an NAS Child used other prescription or illegal drugs during her pregnancy
True common issues: (1) Defendants conspired to market drugs to women of child-bearing age and pregnant women regardless of the birth mother's previous or current drug usage and (2) Defendants conspired to mislead medical providers and the public about the highly addictive quality of those drugs as compared to their limited benefit, especially where the birth mother was already using other prescription or illegal drugs and/or had access to the illegal/diversionary market

Example 3
Alleged individual issue: the birth mother of an NAS Child had a drug addiction before she was prescribed opiates
True common issue: Defendants conspired to market drugs to women of child-bearing age and pregnant women without a determination of whether that woman already had a drug addiction or otherwise fit the profile for being at-risk of addiction

Thus, as this Court undertakes its predominance inquiry, it should be mindful that the anticipated "individual issues" that Defendants will likely raise are themselves part of the alleged bad acts and conspiracy that were intended by Defendants. Simply put, when Defendants conspire to addict and then illegally supply the addiction of an entire populace, they cannot avoid legal responsibility by claiming that their products were consumed by addicts who, shockingly, might have additionally supplied their addiction from that illegal, diversionary market. That would be a neat trick, but tortfeasors cannot use their greatest intentional misdeeds to shift blame onto the victims.

The predominance requirement is met in the requested nationwide and single-state class actions for the same reason. The evidence relating to the conspiracy, including documents and fact and expert testimony, will be the same for all Guardians on both the federal and state law claims. Because the remedy sought is a medical monitoring program, proof at the remedy stage will be common to all Guardians too.[30]

11. A Class Action Is Superior to Other Ways of Proceeding

When certifying the Negotiation Class, the Court found that the superiority requirement was met because the four factors listed in Rule 23(b)(3)(A)–(D) "all cut in favor of certification of both the two RICO claims and two CSA issues as against all Defendants." 2019 WL 4307851.

[30] Additional discussions of the certifiable quality of the statewide Ohio and California complaints and the state law claims alleged therein follow at the end of this consolidated memorandum.

The same holds true for the nationwide and single-state classes for which certification is requested by the Guardians.

a) The class members' interests in individually controlling the prosecution or defense of separate actions

As was true for the cities and counties, the Guardian class consists of thousands of persons, few of whom have been able to prosecute individual actions. Although the exact percentage of the Guardians who are actively litigating is not known, "[t]he vast bulk of class members are not actively involved in opioid litigation" and "[t]his factor cuts in favor of certifying a nationwide class." *Id.*

As was also true for the negotiation class, any guardian who may be "interested in individually controlling its action can opt out and the proposed procedure will in no way interfere with that individual litigation." Moreover, by communicating with class members via notice and the internet post-certification, Class Counsel can "engage[] absent class members" in the litigation and in any settlement negotiations that may occur. *Id.* By this means, absent Guardians can decide whether their interests and those of their wards are best served by remaining in or opting out of the class.

b) The extent and nature of any litigation concerning the controversy already begun by or against class members

There are more than a dozen individual and putative class action cases within this federal MDL and many more filed in state courts that relate to the NAS Children and their Guardians. Per order by this Court, only four putative classes may apply for class certification. Discovery relating these putative class representatives as well as their class experts has proceeded under the Court's scheduling order. Other than these claims, all others are at earlier litigation phases. The proposed Guardians' class will not displace nor interfere with any of this other litigation. At the same time, this other litigation will resolve only a small quantity of the putative class's claims, and, indeed,

cannot result in the same valuable relief (especially as respects the convocation of a Science Panel) to all Guardian's and NAS Children than if individual relief was pursued. All of these factors weigh in favor of certifying a nationwide class which can deliver monitoring and surveillance relief to a large cohort of NAS Children (thereby alleviating their Guardians' care burden), and drive that data into a much-needed Science Panel.

c) The desirability or undesirability of concentrating the litigation of the claims in the particular forum

The JPML has already coordinated the many pending cases in this forum and the issue need not be revisited. This factor therefore supports certification of the class, as it is an efficient means of resolving the many cases pending now and the multitude of individual actions that will follow if certification is not granted.

d) The likely difficulties in managing a class action

Management of a nationwide class of Guardians who chiefly seek declaratory and injunctive relief which will allow the NAS Children in their care to receive necessary medical monitoring and surveillance will not be especially difficult. Trial of the common issues will resolve all matters that establish the necessity of the relief, the nature of the relief, and liability for providing the relief as a result of the conspiracy by Defendants. Notice to the Class will provide members with a thorough explanation of how to prove membership, and how to enroll the monitoring protocol once membership has been established.

IX. INJUNCTIVE RELIEF IS AVAILABLE UNDER RICO

As discussed *supra*, certification of an injunctive class is proper under Rule 23(b)(2) when the governing law entitles the claimants to this form of relief. Whether injunctive relief is an available remedy under RICO has been addressed by some federal circuits, but not by the Sixth Circuit. A review of the cases shows that the better view is that RICO makes available equitable

relief. In the event that this Court or a reviewing court does not agree, then the requested relief can be also be categorized (and has been alternatively plead) as monetary relief to be awarded in the form of a trust for the use and benefit of the Guardians to discharge their care duties to the NAS Children.

The Second Circuit has held that "RICO authorizes private rights of action for injunctive relief." *Gingras v. Think Fin., Inc.,* 922 F.3d 112, 124 (2d Cir. 2019). *Compare Religious Tech. Ctr. v. Wollersheim,* 796 F.2d 1076 (9th Cir. 1986) (injunctive relief not available to private parties under RICO). The decisive case in the Second Circuit is *Chevron Corp. v. Donziger,* 833 F.3d 74, 137 (2d Cir. 2016), in which the Second Circuit read subsection (a) of § 1964 as expansively authorizing federal courts to exercise their traditional equity powers:

> When Congress entrusts to an equity court the enforcement of prohibitions contained in a regulatory enactment, it must be taken to have acted cognizant of the historic power of equity to provide complete relief in light of the statutory purposes. As ... long ago recognized, "there is inherent in the Courts of Equity a jurisdiction to ... give effect to the policy of the legislature."

Id. at 137 (quoting *United States v. Sasso,* 215 F.3d 283, 289 (2d Cir. 2000)). The Second Circuit then stated specifically that "§ 1964, subsection (a) gives the federal courts jurisdiction to hear RICO claims and sets out general remedies, including injunctive relief," *id.* at 138, and added that its

> interpretation of § 1964 as authorizing the grant of equitable relief to private plaintiffs is consistent with Congress's intent "to 'encourag[e] civil litigation to supplement Government efforts to deter and penalize the ... prohibited practices. The object of civil RICO is thus not merely to compensate victims but to turn them into prosecutors, "private attorneys general," dedicated to eliminating racketeering activity.' " [*National Organization for Women, Inc. v. Scheidler*, 267 F.3d 687, 698 (7th Cir. 2001)] (quoting *Rotella v. Wood*, 528 U.S. 549, 557, 120 S.Ct. 1075, 145 L.Ed.2d 1047 (2000)); *cf. Sedima, S.P.R.L. v. Imrex Co.*, 473 U.S. 479, 492 n.10, 105 S.Ct. 3275, 87 L.Ed.2d 346 (1985) ("Indeed, if Congress' liberal-construction mandate is to be applied anywhere, it is in § 1964, where RICO's remedial purposes are most evident.").

Id. at 139.

In the passage just quoted, the Second Circuit relied upon *National Organization for Women, Inc. v. Scheidler,* 267 F.3d 687 (7th Cir. 2001), in which the Seventh Circuit also ruled in favor of the availability of injunctive relief. Although *Scheidler* was reversed on other grounds, *see Scheidler v. NOW, Inc.*, 537 U.S. 393, 397, 123 S. Ct. 1057, 1061, 154 L.Ed.2d 991, 999 (2003), its discussion of the availability of equitable relief remains good law, and has been relied upon in other circuits. *See CGC Holding Co., LLC v. Hutchens,* No. 11-CV-01012-RBJ-KLM, 2017 WL 4621094, at *4 (D. Colo. Sept. 26, 2017) (unpublished) (holding that a "constructive trust in appropriate circumstances could promote the objectives of subsection [1964](a) because it limits the [RICO] violator's ability to retain or conceal property traceable to monies extracted from the victim by fraud"); *Absolute Activist Value Master Fund Ltd. v. Devine,* No. 215CV328FTM29MRM, 2016 WL 1572388, at *4 (M.D. Fla. Apr. 19, 2016) (finding "the reasoning in *Scheidler* to be persuasive" and noting that "[o]ther courts have found that injunctive relief is available to private litigants in a civil federal RICO action"). *See also Bennett v. Berg,* 685 F.2d 1053, 1064-65 (8th Cir. 1982) (injunctive relief possibly available), *aff'd on reh'g,* 710 F.2d 1361 (8th Cir. 1983); *In re Managed Care Litig.,* 298 F. Supp. 2d 1259, 1282-83 (S.D. Fla. 2003) (finding that the civil remedies portion of the federal RICO act authorized injunctive and declaratory relief to private plaintiffs); and *Motorola Credit Corp. v. Uzan,* 202 F. Supp. 2d 239, 243-44 (S.D.N.Y 2002) (finding that courts have inherent equitable powers to grant injunctive relief in civil cases, including civil RICO actions), remanded on other grounds, 322 F.3d 130 (2d Cir. 2003).

In the district court proceeding in *Donziger*, Judge Jed Rakoff explained why the Second Circuit decision in *Scheidler* got the law right.

> The Supreme Court repeatedly has rejected efforts to curtail the scope of civil RICO actions where courts ignore Congress's insistence that the statute be "liberally

> construed to effectuate its remedial purposes." Indeed, if Congress' liberal-construction mandate is to be applied anywhere, it is in § 1964, where RICO's remedial purposes are most evident."
>
> This reading is supported also by the context in which RICO was enacted, a context of which Congress is deemed to have been aware. Article III of the Constitution provides that the judicial power of the United States extends "to all Cases, in Law and Equity." Congress implemented Article III in 1789 by conferring "jurisdiction over 'all suits ... in equity.' The Supreme Court has rejected efforts to curtail the equitable powers of district courts in cases in which they otherwise have subject matter jurisdiction unless "a statute in so many words, or by a necessary and inescapable inference, restricts the court's jurisdiction in equity.
>
> RICO does not "in so many words, or by a necessary and inescapable inference," foreclose equitable relief in actions brought by private plaintiffs. Accordingly, this Court agrees with *Motorola Credit Corp. v. Uzan*, that "[i]t would be extraordinary indeed if Congress, in enacting a statute that Congress expressly specified was to be 'liberally construed to effectuate its remedial purposes,' intended, without expressly so stating, to deprive the district courts of utilizing this classic remedial power in private civil actions brought under the act. Absent just such an express Congressional deprivation, the Court declines to divest itself of equitable powers that the Framers intended district courts to have and that they have possessed since 1789.

Donziger, 974 F. Supp. 2d at 568–70.

X. ADDITIONAL LEGAL ANALYSIS OF THE STATEWIDE CLAIMS

A. The Ohio State Law Claims

In their Second Amended Complaint, Plaintiffs assert claims on behalf of the Ohio Guardians for Negligence (Third Cause of Action), Negligence Per Se (Fourth Cause of Action), Battery (Fifth Cause of Action), and Civil Conspiracy (Sixth Cause of Action). In addition, Plaintiffs seek equitable relief including ongoing medical monitoring, the creation of a Science Panel for epidemiological studies, and alternatively, recovery of compensatory damages. Plaintiffs also seek punitive damages. As shown below, these state law claims are appropriate for class certification.

As an initial matter, Ohio law clearly authorizes Legal Guardian plaintiffs, such as the Putative Class Representatives, to file suit on behalf of themselves solely in their capacity as legal

guardians for the NAS children. Ohio law imposes upon Legal Guardians the legal duty to protect the welfare of the NAS Children in their care. Ohio Admin. Code. § 3109.401 ("State Policy on Parent and Child Relationship) ("parents have the responsibility to make decisions and perform other parenting functions necessary for the care and growth of their children."); Ohio Admin. Code § 5101-2-1 (171) and (206) (legal custodians have a duty to "provide" children with "medical care[.]") Ohio law further imposes a duty upon parents and guardians to support minor children, including furnishing and paying for necessaries including medical care. R.C. § 3103.03(A), (D); *see also Univ. of Cincinnati Hosp. v. Cohen,* First App. Dist., 57 Ohio App. 3d 30, 31 ("Since medical services constitute necessaries, a parent having custody of a child is likewise liable for the debt under an implied contract for the minor child's medical care because of the duty to support required by R.C. 3103.03."). An injury to the child is necessarily an injury to the Legal Guardian as a result of the Legal Guardian's unlimited, and non-delegable duty of care owed to the child, as well as the duty of care, custody, and control of the Legal Guardian over children in their custody.

Additionally, as each of the Defendants acted in concert (*see* Second Amended Complaint, ¶ 13), resulting in damage to the Plaintiffs and Putative Legal Guardian Class, each Defendant, as a participant in the wrongful acts is equally liable. *Williams v. Aetna Fin. Co.*, 83 Ohio St. 3d 464, 476 (1998) ("In a conspiracy, the acts of co-conspirators are attributable to each other."); *Matthews v. New Century Mortgage Corp.*, 185 F. Supp. 2d 874, 889 (S.D. Ohio 2002) (holding that each conspirator in a civil conspiracy is equally liable for each other's acts).

1. Negligence Claim (Third Cause of Action)

Under Ohio law, the elements of negligence are the existence of a duty of care, breach of that duty and proximate cause resulting in injury. *Menifee v. Ohio Welding Products*, 15 Ohio St. 3d 75, 77 (1984). Plaintiffs have alleged, *inter alia*, that each Defendant owed a duty to the Legal Guardians, and that duty fell below the reasonable standard of care and was negligent in numerous

ways. (*See, e.g.*, Amended Complaint at ¶ 419.) Both of these elements present significant common issues of fact that can be determined on a class wide basis. *See, e.g., Barrow v. New Miami*, Ohio 12th Dist., 58 N.E. 3d 532, 542 (2016) (holding that common issues of fact exist where a claim has the potential to generate common answers that drive the resolution of the litigation, and class members share a common prayer for relief). The remaining element, proximate cause resulting in injury, is also a common issue of fact to Plaintiffs and all Class Members.

2. The Negligence Per Se Claim (Fourth Cause of Action)

Under Ohio law, "where a legislative enactment imposes a specific duty for the safety of others, failure to perform that duty is negligence *per se*." *Chambers v. St. Mary's School*, 82 Ohio St. 3d 563, 565 (1998). In their Fifth Cause of Action, Plaintiffs assert that Defendants have violated 21 U.S.C. § 823(a) and implementing regulations, the purpose of which is to, among other things, maintain effective controls against diversion of controlled substances such as opioids, and protect the health and general welfare of the American people. NAS children are within the class of persons for whose protection the statute and regulations were adopted. Defendants' violations of these provisions have led to the injuries suffered by Legal Guardians and Putative Class Members. As with the elements of negligence, each element required for the negligence per se action presents a common issue of fact.

3. Battery (Fifth Cause of Action)

In their Fifth Cause of Action, Plaintiffs assert state tort claims for battery. Courts have long recognized an individual's interest in the physical security of their person and the integrity of their body, and violation of this interest is actionable through the tort claim of battery. Unwanted or unconsented to touching of the body, including through the administration of drugs or treatment

by a physician in a non-emergency situation without first obtaining the individual's informed consent constitutes battery. *Davis v. Hubbard*, 506 F. Supp. 915, 930-33 (N.D. Ohio 1980).

Here, Plaintiffs have alleged injury to the Legal Guardians by Defendants' intentional and unconsented-to touching of the NAS Children by opiates manufactured and/or distributed by Defendants. The touching was both direct and entirely foreseeable because of the known health risks to birth mothers, the known risks of NAS to the infants they carried, and the known adverse impact and increased burden on the ability of the Legal Guardians to care for the NAS Children after birth. These claims are appropriate for class treatment because Plaintiffs' battery claim presents a common issue of fact.

4. Civil Conspiracy (Sixth Cause of Action)

Ohio law recognizes a cause of action for civil conspiracy, which is "a malicious combination of two or more persons to injure another in person or property, in a way not competent for one alone, resulting in actual damages." *Kenty v. Transamerica Premium Ins*., 72 Ohio St. 3d 415, 419 (1995); *LeFort v. Century 21-Maitland Realty Co.*, 32 Ohio St. 3d 121, 126 (1987). A civil conspiracy requires an underlying unlawful act. *Gosden v. Louis*, 116 Ohio App.3d 195, 219 (1996). A "malicious combination" exists between defendants where there is a common understanding or design to commit an unlawful act, and there is no requirement of an express agreement or meeting among defendants. *Gosden v. Louis*, 9th Dist., 116 Ohio App.3d 195, 219 (1996).

> When the mischief is accomplished, the conspiracy becomes important, as it affects that means and measure of redress; for the party wronged may look beyond the actual participants in committing the injury, and join with them as defendants all who conspired to accomplish it. The significance of the conspiracy consists, therefore, in this: That it gives the person injured a remedy against parties not otherwise connected with the wrong. It is also significant as constituting matter of aggravation, and as such tending to increase the plaintiff's recovery.

Minarik v. Nagy, Cuyahoga Court of Appeals, 8 Ohio App.2d 194, 195 (1963). These claims are appropriate for class treatment because Plaintiffs' civil conspiracy claim presents a common issue of fact.

5. Medical Monitoring

Court-supervised medical monitoring is recognized as an equitable remedy available under Ohio law when liability is established under traditional tort theories. *See, e.g.*, *Hirsch v. CSX Transp. Inc.*, 656 F.3d 359, 363 (6th Cir. 2011); *Baker v. Chevron U.S.A. Inc.*, 533 Fed. App'x 509, 517 (6th Cir. 2013); *see also Wilson v. Brush Wellman*, 103 Ohio St.3d 538, 2004-Ohio-5847, 817 N.E.2d 59 (2004); *Hardwick v. 3M Co.*, Case No. 18-CV-1185, 2019 U.S. Dist. Lexis 169322, *6-9 (S.D. Ohio Sept. 30, 2019) (also discussing the relief of a court-supervised Science Panel). In order to be entitled to medical monitoring, a plaintiff must show exposure to an increased risk of disease that warrants medical monitoring by demonstrating that the expenses are reasonable and that a reasonable physician would order medical monitoring under the circumstances. *Hirsch*, 656 F.3d at 363. As to a Science Panel, the *Hardwick* court writes: "[R]equesting oversight of further scientific study in some fashion in an Ohio tort claim with medical monitoring as the remedy is not exceptional." 2019 U.S. Dist. Lexis 169322, at 18. As shown by the Guardians' experts, in order to safeguard the NAS children, Plaintiffs and each of the Putative Class Members must demand, among other things, ongoing medical testing and monitoring of NAS children, and the effect of those efforts must be amplified to further benefit the NAS Children by convening a Science Panel to study those results.

B. The California State Law Claims[31]

[31] The California Guardians also assert federal RICO claims. The previous discussion of certification of these claims on a nationwide basis apply equally to a request for a certification of a California-only class and are incorporated by reference.

In their Second Amended Complaint, Plaintiffs assert state claims on behalf of the California Subclass for Negligence (Third Cause of Action), Negligence Per Se (Fourth Cause of Action) and Violations of the Unfair Competition Law ("UCL") (Fifth Cause of Action). In addition to remedies outlined under the UCL, Plaintiffs seek, *inter alia*, equitable relief including ongoing medical monitoring, the creation of a Science Panel for epidemiological studies, and alternatively, recovery of compensatory damages. Plaintiffs also seek punitive damages. As shown below, these state claims are appropriate for class certification under Rule 23(b)(2).

As an initial matter, legal guardians in California, not only have the right, but have the responsibility to take care of the child's medical needs, making sure he or she gets proper care.[32] Indeed, Guardians have a fiduciary relationship to the wards. *See, e.g., Persson v. Smart Inventions, Inc*., 125 Call App 4th 1141, 1160 (2005); *Patriot Scientific Corp. v. Korodi*, 504 F. Supp. 2d 952, 966 (S.D. Cal. 2007). *See also* Cal. Fam. Code § 3900 (parents have duty to support child).

California courts have long allowed parents to sue for medical expenses that they incurred as a result of defendants' wrongful actions. *See Laughner v. Byrne*, 18 Cal.App.4th 904, 909 (1993) ("When a parent brings the action, loss of services, medical attention, expenses of nursing, and the like are compensable to parents. (*McManus v. Arnold Taxi Corp*. (1927) 82 Cal.App. 215, 255 P. 755.)"; *Valenzuela v. Millard*, 2002 WL 31658571 (Cal.App. 3d, November 26, 2002) (authorizing parents to pursue independent action for incurred expenses for medical care, services and supplies for the treatment of their minor child). The Legal Guardians clearly have authority to seek relief in this action which seeks the exact same effect of meeting their legal care burden for the NAS Children.

[32] Attached as Dann Decl., Exhibit 10 is California Courts, Duties of a Guardian (https://www.courts.ca.gov/1211.htm).

Additionally, as each Defendant acted in concert (*see, e.g.,* Second Amended Complaint, ¶ 13), which conduct resulted in damage to the Plaintiffs and Putative Legal Guardian Class, each Defendant, as a participant in the wrongful acts is "responsible as a joint tortfeasor for all damages ensuing from the wrong, irrespective of whether or not he was a direct actor and regardless of the degree of the activity." *Applied Equipment Corp. v. Litton Saudi Arabia, Ltd.*, 7 Cal.4th 503, 511 (Cal.1994).

1. The Negligence Claim (Third Cause of Action)

Under California law, the elements of negligence are the existence of a duty of care, breach of that duty and proximate cause resulting in injury. *Merrill v. Navegar, Inc*., 26 Cal. 4th 465, 477 (2001). Plaintiffs have alleged, *inter alia*, that each of the Defendants owed a duty to the Legal Guardians, and that duty fell below the reasonable standard of care and was negligent in numerous ways. Both of these elements present significant common issues of fact that can be determined on a class-wide basis. *See Lockheed Martin v. Carillo*, 29 Cal. 4th 1096, 1107 (2003) (duty of polluters to class members and determination of whether defendant's conduct was negligent are common issues of fact). The remaining element, proximate cause resulting in injury, is also a common issue of fact to Plaintiffs and all Class Members.

2. The Negligence Per Se Claim (Fourth Cause of Action)

Under California law, the elements of negligence per se are: "(1) the defendant violated a statute, ordinance, or regulation of a public entity; (2) the violation proximately caused death or injury to person or property; (3) the death or injury resulted from an occurrence the nature of which the statute, ordinance, or regulation was designed to prevent; and (4) the person suffering the death or the injury to his person or property was one of the class of persons for whose protection the statute, ordinance, or regulation was adopted." *Quiroz v. Seventh Ave, Ctr*, 140 Cal.App. 4th 1256, 1285 (2006). In their Fourth Cause of Action, Plaintiffs assert that Defendants have violated 21

U.S.C. § 823(a) and implementing regulations, the purpose of which is to, among other things, maintain effective controls against diversion of controlled substances such as opioids, and protect the health and general welfare of the American people. NAS children are within the class of persons for whose protection the statute and regulations were adopted. Defendants' violations of these provisions have led to the injuries suffered by Legal Guardians and Putative Class Members. As with the elements of negligence, each element required for the negligence per se action presents a common issue of fact. *See, e.g., Lockheed Martin v. Carillo*, 29 Cal. 4th 1096, 1107 (2003).

3. The Violations of the Unfair Competition Law (Fifth Cause of Action)

In their Fifth Cause of Action, Plaintiffs assert violations of the California Unfair Competition Law (UCL), citing violations of the Consumer Legal Remedies Act (CLRA), which specifically provides for a class action. Cal.Civ.Code § 1781. In accordance with the UCL and CLRA, Plaintiffs are seeking injunctive relief, including restitution of all costs incurred as a result of caring for an NAS child, disgorgement of profits realized by Defendants and civil penalties. Federal courts in California have consistently certified class actions in matters under the UCL and CLRA. *See Krueger v. Wyeth*, 310 FRD 468 (S.D. Cal. 2015); 2011 WL 8971449, No. 03V2496 (S.D. Cal. March 30, 2011) (hormone replacement therapy); *Zakaria v. Gerber Products Co*., 2016 WL 6662723 (C.D. Cal., March 23, 2016) (infant formula): *Johns v. Bayer Corp.,* 280 FRD 551 (S.D. Cal. 2012) (vitamins). In fact, the California legislature specifically endorses class actions for violations of the UCL. As the California Supreme Court wrote in *in re Tobacco II Cases*, 46 Cal. 4th 298, 313 (2009), class actions serve an important role in the enforcement of consumers' rights:

> As we commented in *Kraus v. Trinity Management Services, Inc*. (2000) 23 Cal.4th 116, [126, additional citations omitted] 'consumer class actions and representative UCL actions serve important roles in the enforcement of consumers' rights. [They] make it economically feasible to sue when individual claims are too small to justify the expense of litigation, and thereby encourage attorneys to undertake private

> enforcement actions. Through the UCL a plaintiff may obtain restitution and/or injunctive relief against unfair or unlawful practices in order to protect the public and restore to the parties in interest money or property taken by means of unfair competition. These actions supplement the efforts of law enforcement and regulatory agencies. This court has repeatedly recognized the importance of these private enforcement efforts."

As with the decades-long campaign by the tobacco industry of deceptive advertising and misleading statements, Defendants' deceptive advertising and misleading statements relating to opioids is appropriate for class treatment under the UCL.

4. Medical Monitoring

The California Supreme Court has made clear that medical monitoring costs "are a compensable item of damage in a negligence action where the proofs demonstrate, through reliable medical expert testimony that the need for future monitoring is a reasonably certain consequence of the plaintiffs' toxic exposure and that the recommended monitoring is reasonable." *Potter v. Firestone*, 863 P. 2d 965 (1993). As shown by the Guardians' experts and discussed above, in order to safeguard the NAS children, Plaintiffs and each of the Putative Class Members must demand ongoing medical monitoring and surveillance of NAS children. In *Lockheed v. Martin*, 29 Cal. 4th 1096, 1105-06 (2003), the California Supreme Court acknowledged that "no per se or categorical bar exists to a court's finding medical monitoring claims for class treatment, as long as any individual issues the claims present are manageable."[33] Indeed, in 1998, a federal court certified a class seeking medical monitoring based on exposure to radiation. *O'Connor v. Boeing*, 184 FRD 311, 338-39 (C.D. Cal 1998). The court in *Boeing* found, as here, that the medical monitoring plan was certifiable as a class and membership therein could be established by

[33] The Court in *Lockheed* found that actual dosages and variations in individual responses would have to be litigated individually, precluding class certification. By contrast, all NAS children require the same medical monitoring protocol.

objective standards.[34] Indeed, the members of the class are readily identifiable from medical records and pharmacy records. The use of uniform billing codes and other objective diagnostic criteria that will be found in medical records for NAS-diagnosed children will render this determination a simple mechanical one. As such, any individual issues that the claims present here are manageable. As discussed**,** Plaintiffs meet all the criteria for class certification, and the Court should certify the class for the purposes of seeking medical monitoring.

XI. OTHER PARTIES ARE IGNORING THE INTERESTS OF THE GUARDIANS AND THE NAS CHILDREN

A. The PSC

The lawyers appointed to the PSC individually represent significant numbers of cities and counties. Consequently, and as the fiduciary duty requires, they have devoted themselves solely to the pursuit of the cities' and counties' interests and have ignored the conflicting interests of non-clients, including the Guardians and the NAS Children. These lawyers have done the same in the Purdue bankruptcy proceeding, where all claimants are competing for shares of a limited fund. They know that any funds given to the Guardians or the NAS Children will leave less money for the cities and counties, so they are fighting to secure for their clients the largest possible share.

When moving to certify a class of cities and counties, the PEC observed that "[s]ome method must be found to conserve finite funds otherwise exhausted in replicative litigation, ***and to allocate them fairly among all who need them***."[35] Memorandum of Law, (Dkt. 1820-1) (emphasis added). It is abundantly clear that the Guardians and the NAS Children will be treated

[34] The Court in *Boeing* later decertified the class on grounds that the limitations defense made treatment inappropriate. *See O'Connor v. Boeing*, 197 FRD 404 (C.D. Cal. 2000). Here, by contrast, there is no issue relating to limitations due to both minor status and the ongoing care duty of the Guardians.

[35] Somehow, though, the PEC has come to believe that it is some extra-judicial arbiter of claims and fairness who can choose which of the claimants to help and which to abandon.

fairly only if they are represented by lawyers who are devoted solely to them. The need to allocate funds fairly makes the certification of a class of Guardians practically and ethically imperative.

B. Litigation, Settlement Negotiations, and Damage Awards Are Moving Forward Without Consideration for the NAS Children

The necessity of allowing the Guardians' class-wide claims to move forward without further delay is also especially critical where multiple claimants are competing for and even winning relief from Defendants in early bellwether proceedings, as well as working to establish the *gravitas* of their claims for the limited shares of bankrupt estate and within the MDL structure. Additionally, the Court "has repeatedly expressed a desire to settle the [opioid] litigation before it proceeds to trial." 2019 WL 4307851. The Guardians cannot allow the NAS Children to be left behind in this process. In order that the NAS Children's needs are properly weighed by Defendants and the varying claimants, the Guardians must insist that this Court recognize the class-wide merit of their claims so that they too have an opportunity to have their voices heard in current negotiations. And, of course, if the NAS Children's care needs are not properly addressed, Class Representatives and their counsel will proceed to trial. By certifying the Guardians' classes, the Court will enable them to negotiate with Defendants, prepare for trial, and protect the NAS Children's care needs against the encroachment of other claimants.

C. The Governmental Entities that Neither Represent the NAS Children *Parens Patriae* Nor Can Release Their Claims

Governmental entities, paradigmatically states, acting as parens patriae can "represent the interests of their citizens in enjoining public nuisances." *Alfred L. Snapp & Son, Inc. v. Puerto Rico, ex rel., Barez*, 458 U.S. 592, 603, 102 S. Ct. 3260, 3266, 73 L. Ed. 2d 995 (1982). To sue in parens patriae, however, a state "must articulate an interest apart from the interests of particular private parties," that is, a sovereign or quasi-sovereign interest. *Id.* at 607. Because the "[i]nterests of private parties are obviously not in themselves sovereign interests" of any type, *id.* at 602, the

governmental entities that belong to the existing negotiation class lack standing to assert them. Consequently, they can neither sue on behalf of the Guardians or the NAS Children nor release their private claims.

The Tenth Circuit reached exactly this conclusion in *Satsky v. Paramount Commc'ns, Inc*., 7 F.3d 1464 (10th Cir. 1993). There, the question was whether a consent decree entered into by the State of Colorado prevented private individuals who subsequently asserted claims for personal injuries, property damage, and economic losses from suing. Even though the consent decree contained a broad release, the Tenth Circuit allowed the individuals to sue. The consent decree did not release the individuals' claims because "a state may not sue to assert the rights of private individuals." *Id*. at 1469 (citing *Snapp & Son,* 458 U.S. at 600; *Pennsylvania v. New Jersey,* 426 U.S. 660, 665 (1976); *New York by Abrams v. Seneci,* 817 F.2d 1015, 1017 (2nd Cir. 1987); *Illinois v. Life of Mid–America Ins. Co.,*805 F.2d 763, 766 (7th Cir. 1986), and 13A Charles A. Wright, Arthur R. Miller & Edward H. Cooper, Federal Practice & Procedure: Jurisdiction 2d § 3531.11 at 19 (1984). Lacking power to assert private claims, Colorado could not release them either.

The Sixth Circuit has also recognized that a governmental entity lacks standing to assert a claim held by a private individual. In *Chapman v. Tristar Prod., Inc*., 940 F.3d 299, 306 (6th Cir. 2019), it held that Arizona lacked standing to appeal the fairness of a class action settlement because "the only objections that Arizona can make are indistinguishable from the objections which individual Arizonans might raise." Having failed to assert an independent sovereign interest, Arizona could not sue. Similarly, the governmental entities herein do not have sovereign or semi-sovereign interests that are concomitant with those of the Guardians or the NAS Children and cannot assert or release claims the latter hold individually.[36]

[36] The governmental entities *are* in a *parens patriae* relationship with NAS children who are wards of the

The clarity of the law notwithstanding, lawyers for some governmental entities have asserted that their clients and other members of the Negotiation Class are entitled to sue *parens patriae* because they are obligated "to keep them [the NAS Children] safe and healthy as they grow." *Plaintiffs Statement of Interest in Response to Proposed Class Counsels' Amended Joint Proposed Scheduling Order and Positions on Scheduling*, (Dkt. 27120). The lawyers identified no legal basis for this purported duty, however, and the Guardians know of none. Moreover, if such a duty does exist, the entities have been ignoring it since the start of the opioid crisis.

Addressing the legal limits of these governmental claims, this Court rightly recognized (though in a different context), that they are based upon a "clearly faulty premise." *In re: State of Ohio Originating Case*, Case No. 19-3827 (6th Cir. 2019), Letter of this Court, dated October 1, 2019 (Dkt. 23). This Court explained the "faulty premise," writing:

> While it may be true that "**a political subdivision may not sue to enforce it residents' rights**," the bellwether Plaintiffs have consistently stated, and I have likewise repeatedly concluded, that **the city and county Plaintiffs do not seek to recover based on injuries to individual residents**; rather the Plaintiffs seek recovery for direct injuries suffered by the Plaintiffs themselves.

Id. (internal citations omitted and emphasis added).

Regardless, this Court went on to speculate that relief recovered by these governmental entities "will also tend to collaterally benefit their residents," but that "this does not mean that Plaintiffs seek to litigate on behalf of those residents." *Id.* While the NAS Guardians offer a cautious prayer that largesse from settlement-rich governmental entities might somehow trickle down to "collaterally" benefit the NAS Children (as this Court is hopeful), **the Guardians are the only entities who have a clear fiduciary duty to care for the NAS Children and a legal right**

States and can sue to recover the cost of caring for them. Those children are excluded from the class.

to sue on their behalf. This is why only the Guardians have sought relief that is tailored to the NAS Children's specific needs.

The Representatives of the Negotiation Class have already admitted to this Court that they cannot bind the class members to use prospective funds for any specific purpose, much less to pay for long-term and expensive medical monitoring and surveillance. Nothing in their Motion, Memorandum, FAQs, or other associated filings would require the governmental entities in the class to use any amount of funds to alleviate the financial burden that caring for the NAS Children imposes on the Guardians. Record, *passim*. Even if they are successful, city and county elected officials will receive unrestricted monies they can use however they please. They can balance their budgets, meet unfunded pension obligations, pave roads, promote tourism, or spend the money in other ways that local officials prefer.

It is time to put to rest the fiction that the cities and counties have the same legal duty to care for the NAS Children that the Guardians do.[37] The Court can do this by asking the government entities to swear on the record that they owe fiduciary duties to the NAS Children and by ordering them to make a fully-funded medical monitoring and treatment program for the Children part of their settlement negotiations.[38] Movants expect that few cities or counties, if any, will agree to these requirements. Only the Guardians stand willing, ready, and able to protect the NAS Children and to seek a settlement or judgment that advances their interests.

D. The Allocation Model for the Proposed Negotiation Class Ignores the Needs of the NAS Children and the Guardians

[37] The matter is, of course, on appeal in the Sixth Circuit.

[38] In the alternative, the Putative NAS Guardian Class Representatives should be granted leave to depose and propound written discovery on the Putative City and County Negotiation Class Representatives on these matters.

In the event that the PSC somehow might negotiate a global settlement for the cities and counties, the putative class representatives have set out a proposed settlement Allocation Model that assigns weight to (1) the volume of opioids distributed in a county, (2) the number of opioid deaths in a county, and (3) the number of persons suffering from "opioid use disorder" in the county. *Cities/Counties Negotiation Class Frequently Asked Questions ("FAQs")*, (Dkt. 1820-2).

The factors contained in the Allocation Model are not proxies for the number of NAS Children and Guardians because (1) the volume of opioids "distributed" in a county is in no way a proxy for the number of NAS Children and Guardians living in that county; (2) unlike the tragic victims of fatal overdoses, the NAS Children and their Guardians are very much alive, and (3) "opioid use disorder" (OUD) is a clinical, diagnostic term which necessarily excludes the NAS Children. OUD is defined as the "signs and symptoms that reflect compulsive, prolonged self-administration of opioid substances that are used for no legitimate medical purpose." Diagnostic and Statistical Manual of Mental Disorders, 5th ed., American Psychiatric Assoc. (2013).

The fundamental problem with all of these self-selected factors is that opioid consumption and its consequences vary across demographic groups. For example, in 2017, more than twice as many men as women died from opioid abuse.[39] The "deaths per county" factor in the allocation formula will therefore strongly favor counties that skew male, to the disadvantage of NAS Children, all of whom were born to women. Historically, younger people, i.e., those whose ages range from 15 to 24 or from 25 to 34, have also died at lower rates than other opioid users.[40]

[39] Attached as Dann Decl., Exhibit 9 is National Center for Health Statistics, Drug Overdose Deaths in the United States, 1999–2017, NCHS Data Brief No. 329 (2018), https://www.cdc.gov/nchs/data/databriefs/db329-h.pdf.

[40] *Id.*

Though OUD necessarily excludes children by its very definition (OUD is limited to adults who intentionally use opioids), the prevalence of OUD in adults also correlates poorly with the number of NAS Children. One reason is that OUD is more likely to be diagnosed in users who have health insurance than in uninsured users because the latter are less likely to visit physicians.[41] Unless insurance coverage affects the birth rate for NAS Children similarly, the OUD factor will allocate funds without regard to the number of NAS Children, counties with large numbers of them will again be shortchanged, and NAS Children who live in these counties will again be neglected. And, because young men are far more likely to be diagnosed with OUD than young women, the gender skew will make matters even worse. *Id.*

Second, in addition to ignoring the NAS Children, the proposed allocation model is a public policy disaster which promotes ill-considered and inadequate governing, policing, and public health efforts. Perversely, the counties that did the least to combat the Defendants, to limit the flow of opiates, to prevent fatal overdoses, and help addicted adults are the most richly rewarded. Counties that have historically behaved responsibly in these areas by funding proactive anti-addiction measures and dedicating policing and social services resources will be severely under-compensated.[42] Those governmental entities least capable of managing their affairs will be favored over the actual victims, such as the NAS Children and their Guardians, but also over other governmental entities that worked most effectively to combat the effects of Defendants' bad acts.

[41] Attached as Dann Decl., Exhibit 11 is Stoddard Davenport and Katie Matthews, Opioid use disorder in the United States: Diagnosed prevalence by payer, age, sex, and state (2018), http://www.milliman.com/insight/2018/Opioid-use-disorder-in-the-United-States-Diagnosed-prevalence-by-payer--age--sex--and-state.

[42] Obviously, these are laudable governmental functions. There are not, however, anywhere similar to the fiduciary care duties the NAS Guardians owe to the NAS Children.

E. The Proposed Cuyahoga County, Ohio Settlement Disposition Ignores the NAS Children

The plan that Cuyahoga County, Ohio announced in October of 2019 to distribute settlement funds garnered on the eve of its bellwether trial illustrates the reality that the needs of the Guardians and the NAS Children will be neglected by governmental entities. It proposes to use its funds as follows:

- 47% ($10.9 M) for treatment and programming for current adult addicts suffering from Opioid Use Disorder (OUD);
- 32% ($7.35 M) for Policing and Detention services;
- 20% ($4.5M) for Foster Care services;[43] and
- 0.17% ($400k) for "K-12 educational services."[44]

Not one penny of Cuyahoga County's proposed settlement allocation will benefit the NAS Children aged 0-5 who are the focus of Plaintiffs' proposed Ohio statewide Class. And, using current U.S. Census Bureau estimates,[45] we can further determine that Cuyahoga County's *only* proposed "collateral benefit" to that county's NAS Guardians and Children is a one-time and paltry *$2.15 per child aged 5-18* for undefined "educational training" for public school teachers. (It is unknown if this training is for addiction prevention, much less whether it is targeted for the educational needs of NAS Children.) Amortizing this over the life of a recently-born NAS Child, the "collateral benefit" Cuyahoga County it proposes to confer upon one of the neediest casualties

[43] $1M is for boarding and care of foster care children who are already in state care and is in no way specifically targeted towards NAS children or even children who are in placement due to the opioid crisis. This line item appears to be a simple budget-balancing technique for pre-existing obligations. The other $3.5M is to hire new staff members for the department that manages foster care. *Id.*

[44] Attached as Dann Decl., Exhibit 12 is "Cuyahoga County Announces How It'll Use $23 Million in Opioid Settlement Money on Treatment and Prevention Services," Vince Grzegorek, October 11, 2019, clevescene.com.

[45] Fifteen percent of Cuyahoga County's population is aged 5-18. https://www.census.gov/quickfacts/fact/table/cuyahogacountyohio,US/PST045218.

of the opioid crisis plummets to *less than 12 cents a year.* **If there is something less than *de minimis* or smaller than a peppercorn, this is it.**

F. The State of Oklahoma Made No Claims Relating to an Ongoing Duty of Care for the NAS Children

As the Court is aware, a lengthy bench trial occurred in Oklahoma State Court in 2019, resulting in a judgment against many of the Opiate Defendants and in favor of the State of Oklahoma's public nuisance claims. Based on the State's proof, the trial court made certain findings regarding NAS Children in Oklahoma. However, it must be appreciated that Oklahoma made absolutely no claims, nor put on any proof regarding care for the NAS Children **after their birth**. *State of Oklahoma v. Purdue Pharma L.P., Case No. CJ-2017*-816 (Cleveland County Dist. Ct., Okla.) (August 29, 2019), Judgment at p. 35-37, ¶¶ 25-35) ("Abatement of the Nuisance"). While the objectives of Oklahoma's efforts are laudable and welcomed, they have no applicability to the ongoing care duties of the Guardians, nor do they benefit the NAS Children after their hospital discharge. *Id., passim.*

G. The Known Risk of Governmental "Slush Funds"

As this Court is aware, the risk of enabling vast governmental "slush funds" that never result in trickle-down benefits for victims is very real. Attempts to create "lock boxes" to protect opioid litigation recoveries from state legislatures (such as that proposed by the Ohio Attorney General[46]) are laudable, but highlight the inherent flaws in these settlements and judgments, as well as the fact that "lock boxes" are often quite unpopular with elected officials. A state government cannot be told by this MDL Court how to spend its money, nor is any state, county,

[46] Ohio Attorney General Dave Yost's proposal is opposed by Ohio Gov. Mike DeWine and has not been championed, nor, apparently, even discussed by the Ohio State Legislature. Attached as Dann Decl., Exhibit 13 is Darrel Rowland and Randy Ludow, "Ohio voters could decide constitutional amendment to split up opioid lawsuit cash," *The Columbus Dispatch*, December 5, 2019.

or city pledging to restrict funds nor otherwise bind itself ahead of litigation or settlement negotiations with the Opioid Defendants to dispose of a potential recovery in any specific manner.[47]

As this Court is aware, governmental entities are not strongly inclined to help vulnerable persons and cannot be obligated by courts to do so. A study of the uses six states made of funds paid out by the tobacco settlement summarized its findings as follows:

> State allocation decisions were diverse; substantial shares were allocated to areas other than tobacco control and health, including capital projects and budget shortfalls. The allocations did not reflect the stated goals of the lawsuits leading to the settlements. This outcome reflects a lack of strong advocacy from public health interest groups, an unreliable public constituency for tobacco control, and inconsistent support from state executive and legislative branches, all combined with sizable budget deficits that provided competing uses for settlement funds.

Frank A. Sloan, Jennifer S. Allsbrook, Leanne K. Madre, Leah E. Masselink, and Carrie A. Mathews, "States' Allocations Of Funds From The Tobacco Master Settlement Agreement," *Health Affairs*, Vol. 24 (2005). The cities and counties that are involved in this MDL are no more trustworthy than the states. They cannot be relied upon to use the funds they receive to provide the NAS Children the help they need, especially where they have no duty to do so. It is also self-evident that children are not voters, and programs that benefit those who do not vote are the most vulnerable to legislative vicissitudes.

XII. CONCLUSION

For the reasons stated herein, Movants ask the Court to certify two nationwide RICO classes of Guardians of NAS Children (one where the birth mother's opioids prescription came at

[47] The only mention of the "use" of settlement proceeds is a non-binding recommendation from the PEC that it would "prefer" that "each State … reach agreement with the cities and counties with the State on the allocation and use of the [settlement] money within the State." (Dkt. 1820-2).

any point prior to the birth of and NAS Child and one where the prescription came during pregnancy), as well as statewide class actions for California and Ohio.

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Respectfully submitted,

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APPENDIX A

MASTER SUMMARY

1. NATIONWIDE CLASS

A. DEFINITION

CLASS 1. Legal Guardians[1] of United States residents born after March 16, 2000, who were medically diagnosed with opioid-related NAS[2] at or near birth and whose birth mother received a prescription for opioids or opiates prior to the birth and those opioids or opiates were manufactured, distributed, or filled by a Defendant or Purdue entity. Excluded from the class are any infants and children who were treated with opioids after birth, other than for pharmacological weaning. Also excluded from the class are legal guardianships where a political subdivision, such as a public children services agency, has affirmatively assumed the duties of "custodian" of the child.[3]

CLASS 2. Legal Guardians[4] of United States residents born after March 16, 2000, who were medically diagnosed with opioid-related NAS at or near birth and whose birth mother received and/or filled a prescription for opioids or opiates in the 10 months prior to the birth of said infant or child and those opioids or opiates were manufactured, distributed, or filled by a Defendant or Purdue entity.[5]

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[1] The term "Legal Guardian" is further defined for purposes of this putative class action as "any natural person or entity who has the primary legal responsibility under law for an infant or child's physical, mental, and emotional development." Expressly excluded from the class of "Legal Guardians" are any governmental entities.

"Legal Guardians" include natural and adoptive parents who have not otherwise lost legal custody of their children, legal custodians, legal caretakers, and court-appointed guardians (including guardians of the person), whether temporary or permanent.

[2] The term "NAS" (Neonatal Abstinence Syndrome) is defined to include additional, but medically symptomatic identical, terminology and diagnostic criteria, including Neonatal Opioid Withdrawal Syndrome (NOWS) and other historically and regionally used medical and/or hospital diagnostic criteria for infants born addicted to opioids from *in utero* exposure. Additional specifics on these readily identifiable and ascertainable terms will be provided in Plaintiffs' Motion for Class Certification.

[3] There are only two causes of NAS: (1) *in utero* exposure to opioids via the birth mother, and (2) post-birth treatment of the infant with opioids for pain. The latter category does not include pharmacological weaning for dependency, as those infants are necessarily part of the former category, i.e., infants who were exposed *in utero* and then treated with opioids pursuant to a weaning protocol of gradually tapering doses. Whether a newborn or an infant was treated with opioids for pain can be determined from medical records. Any such children are necessarily excluded from the class definition.

[4] The term "Legal Guardian" is defined at fn. 1, *supra*.

[5] Defined in the "Non-Defendant Co-Conspirator Purdue Entities" and "Defendant Co-Conspirator Purdue Entities" sections, *infra*.

B. DEFENDANTS

(1) MANUFACTURER DEFENDANTS

- Actavis Entities: Allergan PLC f/k/a Actavis PLC f/k/a Allergan, Inc.; Allergan Finance, LLC f/k/a Actavis, Inc. f/k/a Watson Pharmaceuticals, Inc.; Allergan Sales, LLC; Allergan USA, Inc.; Watson Laboratories, Inc.; Warner Chilcott Company, LLC; Actavis Pharma, Inc. f/k/a Watson Pharma Inc.; Actavis South Atlantic LLC; Actavis Elizabeth LLC; Actavis Mid Atlantic LLC; Actavis Totowa LLC; Actavis LLC; Actavis Kadian LLC; Actavis Laboratories UT, Inc. f/k/a Watson Laboratories, Inc.-Salt Lake City; Actavis Laboratories FL, Inc. f/k/a Watson Laboratories, Inc.-Florida.

- Cephalon Entities: Teva Pharmaceutical Industries Ltd.; Teva Pharmaceuticals USA, Inc.; Cephalon, Inc.

- Janssen Entities: Janssen Pharmaceuticals, Inc.; Janssen Pharmaceutica, Inc. n/k/a Janssen Pharmaceuticals, Inc.; Noramco, Inc.; Ortho-McNeil-Janssen Pharmaceuticals, Inc. n/k/a Janssen Pharmaceuticals, Inc.; Johnson & Johnson.

- Endo Entities: Endo Health Solutions Inc.; Endo Pharmaceuticals, Inc.; Par Pharmaceutical, Inc.; Par Pharmaceutical Companies, Inc. f/k/a Par Pharmaceutical Holdings, Inc.

- Mallinckrodt Entities: Mallinckrodt plc; Mallinckrodt LLC; SpecGx LLC.

- Co-Conspirator Purdue Entities: Richard S. Sackler; Jonathan D. Sackler; Mortimer D.A. Sackler; Kathe A. Sackler; Ilene Sackler Lefcourt; Beverly Sackler; Theresa Sackler; David A. Sackler; Rhodes Technologies; Rhodes Technologies Inc.; Rhodes Pharmaceuticals L.P.; Rhodes Pharmaceuticals Inc.; Trust for the Benefit of Members of the Raymond Sackler Family; The P.F. Laboratories, Inc.

- Non-Defendant, Co-Conspirator Purdue Entities: Purdue Pharma L.P.; Purdue Pharma Inc.; The Purdue Frederick Company, Inc.

(2) DISTRIBUTOR DEFENDANTS

- Cardinal Health, Inc.

- AmerisourceBergen Drug Corp.

- Mckesson Corporation

(3) PHARMACY DEFENDANTS

- HBC Service Company

- CVS Health Corporation; CVS Indiana, LLC; CVS Rx Services, Inc.
- Rite Aid Corporation; Rite Aid of Maryland, Inc.; Rite Aid of Maryland, Inc. d/b/a Rite-Aid Mid-Atlantic Customer Support Center, Inc.
- Walgreen Co.; Walgreens Boots Alliance, Inc.; Walgreen Eastern Co.
- Wal-Mart Inc. f/k/a Wal-Mart Stores, Inc.
- Miami-Luken, Inc.
- Costco Wholesale Corporation

C. CLAIMS

1. First Cause of Action – Violation of RICO, 18 U.S.C. § 1961 *et seq.* – Opioid Marketing Enterprise (against only Defendants Cephalon Entities, Janssen Entities, Endo Entities, and Mallinckrodt Entities (the "RICO Marketing Defendants").

2. Second Cause of Action – Violation of RICO, 18 U.S.C. § 1961 *et seq.* – Opioid Supply Chain Enterprise (against only Defendants Cephalon Entities, Endo Entities, Mallinckrodt Entities, Actavis Entities, McKesson, Cardinal, and AmerisourceBergen (the "RICO Supply Chain Defendants").

D. RELIEF REQUESTED

1. Order Defendants to provide for the benefit of the Plaintiff Legal Guardians and the Putative Class Members ongoing medical monitoring, testing, intervention, provision of caregiver training and information, and medical referral, all of which are medically necessary for the NAS Children in their care, and all future medical care reasonably necessary to treat these children. Any injunctive relief to which Plaintiffs may justly show themselves entitled, including injunctive relief designed to reduce the incidence of children born with NAS.

2. Order creation of a Science Panel.

3. Alternatively, all incidental compensatory damages and medical expenses incurred by Plaintiff Legal Guardians and the Putative Class Members in connection with their care of the NAS Children. It is expressly alleged that all compensatory damages sought in the alternative are incidental to the injunctive relief requested by Plaintiffs and the Class, and are for those caused by the *in utero* exposure to opioids and NAS diagnosis suffered by the NAS Children.

4. Punitive damages.

5. Attorneys' fees and costs incurred by Plaintiff Legal Guardians and the Putative Class Members.

2. CLASS 3 – Ohio Statewide Class

A. DEFINITION

(1) Legal Guardians[6] of Ohio residents born after March 16, 2000, who were medically diagnosed with opioid-related NAS[7] at or near birth and whose birth mother received a prescription for opioids or opiates prior to the birth and those opioids or opiates were manufactured, distributed, or filled by a Defendant or Purdue entity. Excluded from the class are any infants and children who were treated with opioids after birth, other than for pharmacological weaning. Also excluded from the class are legal guardianships where the State of Ohio or one of its political subdivisions, such as a public children services agency, has affirmatively assumed the duties of "custodian" of the child under Ohio Rev. Code § 2151.011.[8]

(2) Legal Guardians[9] of Ohio residents born after March 16, 2000, who were medically diagnosed with opioid-related NAS at or near birth and whose birth mother received and/or filled a prescription for opioids or opiates in the 10 months prior to the birth of said infant or child and those opioids or opiates were manufactured, distributed, or filled by a Defendant or Purdue entity.[10]

B. DEFENDANTS

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[6] The term "Legal Guardian" is further defined for purposes of this putative class action as "any natural person or entity who has the primary legal responsibility under Ohio state law for an infant or child's physical, mental, and emotional development." Expressly excluded from the class of "Legal Guardians" are any governmental entities.

Under Ohio law, "Legal Guardians" include natural and adoptive parents who have not otherwise lost legal custody of their children, "custodians" and "caretakers" of children (but excluding public children's services agencies), and court-appointed "guardians," whether temporary or permanent. *See* OHIO ADMIN. CODE § 5102-2-1(36), (84), (130), (171), and (206) (respective definitions of "Caretaker," "Custodian," "Guardian," "Legal Custody," and "Parental Rights").

[7] The term "NAS" (Neonatal Abstinence Syndrome) is defined to include additional, but medically symptomatic identical, terminology and diagnostic criteria, including Neonatal Opioid Withdrawal Syndrome (NOWS) and other historically and regionally used medical and/or hospital diagnostic criteria for infants born addicted to opioids from *in utero* exposure. Additional specifics on these readily identifiable and ascertainable terms are set forth in the accompanying Consolidated Memorandum of Law.

[8] There are only two causes of NAS: (1) *in utero* exposure to opioids via the birth mother, and (2) post-birth treatment of the infant with opioids for pain. The latter category does not include pharmacological weaning for dependency, as those infants are necessarily part of the former category, i.e., infants who were exposed *in utero* and then treated with opioids pursuant to a weaning protocol of gradually tapering doses. Whether a newborn or an infant was treated with opioids for pain can be determined from medical records. Any such children are necessarily excluded from the class definition.

[9] The term "Legal Guardian" is defined at fn. 6.

[10] Defined in the "Non-Defendant Co-Conspirator Purdue Entities" and "Defendant Co-Conspirator Purdue Entities" sections, *infra*.

(1) MANUFACTURER DEFENDANTS

- Actavis Entities: Allergan PLC f/k/a Actavis PLC f/k/a Allergan, Inc.; Allergan Finance, LLC f/k/a Actavis, Inc. f/k/a Watson Pharmaceuticals, Inc.; Allergan Sales, LLC; Allergan USA, Inc.; Watson Laboratories, Inc.; Warner Chilcott Company, LLC; Actavis Pharma, Inc. f/k/a Watson Pharma Inc.; Actavis South Atlantic LLC; Actavis Elizabeth LLC; Actavis Mid Atlantic LLC; Actavis Totowa LLC; Actavis LLC; Actavis Kadian LLC; Actavis Laboratories UT, Inc. f/k/a Watson Laboratories, Inc.-Salt Lake City; Actavis Laboratories FL, Inc. f/k/a Watson Laboratories, Inc.-Florida.

- Cephalon Entities: Teva Pharmaceutical Industries Ltd.; Teva Pharmaceuticals USA, Inc.; Cephalon, Inc.

- Janssen Entities: Janssen Pharmaceuticals, Inc.; Janssen Pharmaceutica, Inc. n/k/a Janssen Pharmaceuticals, Inc.; Noramco, Inc.; Ortho-McNeil-Janssen Pharmaceuticals, Inc. n/k/a Janssen Pharmaceuticals, Inc.; Johnson & Johnson.

- Endo Entities: Endo Health Solutions Inc.; Endo Pharmaceuticals, Inc.; Par Pharmaceutical, Inc.; Par Pharmaceutical Companies, Inc. f/k/a Par Pharmaceutical Holdings, Inc.

- Mallinckrodt Entities: Mallinckrodt plc; Mallinckrodt LLC; SpecGx LLC.

- Insys Therapeutics, Inc.

- Depomed, Inc.

- Indivior, Inc.

- Co-Conspirator Purdue Entities: Richard S. Sackler; Jonathan D. Sackler; Mortimer D.A. Sackler; Kathe A. Sackler; Ilene Sackler Lefcourt; Beverly Sackler; Theresa Sackler; David A. Sackler; Rhodes Technologies; Rhodes Technologies Inc.; Rhodes Pharmaceuticals L.P.; Rhodes Pharmaceuticals Inc.; Trust for the Benefit of Members of the Raymond Sackler Family; The P.F. Laboratories, Inc.

- Non-Defendant, Co-Conspirator Purdue Entities: Purdue Pharma L.P.; Purdue Pharma Inc.; The Purdue Frederick Company, Inc.

(2) DISTRIBUTOR DEFENDANTS

- Cardinal Health, Inc.

- AmerisourceBergen Drug Corp.

- Mckesson Corporation

- Anda, Inc.
- H. D. Smith, LLC d/b/a HD Smith f/k/a H. D. Smith Wholesale Drug Co.; H. D. Smith Holdings, LLC; H. D. Smith Holding Company
- Discount Drug Mart, Inc.
- Prescription Supply, Inc.

(3) PHARMACY DEFENDANTS

- HBC Service Company
- CVS Health Corporation; CVS Indiana, LLC; CVS Rx Services, Inc.
- Rite Aid Corporation; Rite Aid of Maryland, Inc.; Rite Aid of Maryland, Inc. d/b/a Rite-Aid Mid-Atlantic Customer Support Center, Inc.
- Walgreen Co.; Walgreens Boots Alliance, Inc.; Walgreen Eastern Co.
- Wal-Mart Inc. f/k/a Wal-Mart Stores, Inc.
- Miami-Luken, Inc.
- Costco Wholesale Corporation

C. CLAIMS

1. First Cause of Action – Violation of RICO, 18 U.S.C. § 1961 *et seq.* – Opioid Marketing Enterprise (against only Defendants Cephalon Entities, Janssen Entities, Endo Entities, and Mallinckrodt Entities (the "RICO Marketing Defendants").

2. Second Cause of Action – Violation of RICO, 18 U.S.C. § 1961 *et seq.* – Opioid Supply Chain Enterprise (against only Defendants Cephalon Entities, Endo Entities, Mallinckrodt Entities, Actavis Entities, McKesson, Cardinal, and AmerisourceBergen (the "RICO Supply Chain Defendants").

3. Third Cause of Action — Negligence.

4. Fourth Cause of Action — Negligence *Per Se*.

5. Fifth Cause of Action — Civil Battery.

6. Sixth Cause of Action — Civil Conspiracy.

1. RELIEF REQUESTED – *See* ¶ 1.D. above.

3. CLASS 4 – California Statewide Class

A. DEFINITION

(1) Legal Guardians[11] of residents born after March 16, 2000, who were medically diagnosed with opioid-related NAS[12] at or near birth and whose birth mother received a prescription for opioids or opiates prior to the birth and those opioids or opiates were manufactured, distributed, or filled by a Defendant or Purdue entity. Excluded from the class are any infants and children who were treated with opioids after birth, other than for pharmacological weaning. Also excluded from the class are legal guardianships where a political subdivision, such as a public children services agency, has affirmatively assumed the duties of "custodian" of the child.[13]

(2) Legal Guardians[14] of California residents born after March 16, 2000, who were medically diagnosed with opioid-related NAS at or near birth and whose birth mother received and/or filled a prescription for opioids or opiates in the 10 months prior to the birth of said infant or child and those opioids or opiates were manufactured, distributed, or filled by a Defendant or Purdue entity.[15]

(3) Legal Guardians[16] of California residents born after March 16, 2000, who were medically diagnosed with opioid-related NAS at or near birth and whose birth mother

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[11] The term "Legal Guardian" is further defined for purposes of this putative class action as "any natural person or entity who has the primary legal responsibility under law for an infant or child's physical, mental, and emotional development." Expressly excluded from the class of "Legal Guardians" are any governmental entities.

"Legal Guardians" include natural and adoptive parents who have not otherwise lost legal custody of their children, legal custodians, legal caretakers, and court-appointed guardians (including guardians of the person), whether temporary or permanent.

[12] The term "NAS" (Neonatal Abstinence Syndrome) is defined to include additional, but medically symptomatic identical, terminology and diagnostic criteria, including Neonatal Opioid Withdrawal Syndrome (NOWS) and other historically and regionally used medical and/or hospital diagnostic criteria for infants born addicted to opioids from *in utero* exposure. Additional specifics on these readily identifiable and ascertainable terms are set forth in the accompanying Consolidated Memorandum of Law.

[13] There are only two causes of NAS: (1) *in utero* exposure to opioids via the birth mother, and (2) post-birth treatment of the infant with opioids for pain. The latter category does not include pharmacological weaning for dependency, as those infants are *[footnote continued next page]* necessarily part of the former category, i.e., infants who were exposed *in utero* and then treated with opioids pursuant to a weaning protocol of gradually tapering doses. Whether a newborn or an infant was treated with opioids for pain can be determined from medical records. Any such children are necessarily excluded from the class definition.

[14] The term "Legal Guardian" is defined at fn. 11.

[15] Defined in the "Non-Defendant Co-Conspirator Purdue Entities" and "Defendant Co-Conspirator Purdue Entities" sections, *infra*.

[16] The term "Legal Guardian" is defined at fn. 11.

received a prescription for opioids or opiates prior to the birth and those opioids or opiates were manufactured, distributed, or filled by a Defendant or Purdue entity.[17]

B. DEFENDANTS – *See* ¶ 2.B. above.

C. CLAIMS

1. First Cause of Action – Violation of RICO, 18 U.S.C. § 1961 *et seq.* – Opioid Marketing Enterprise (against only Defendants Cephalon Entities, Janssen Entities, Endo Entities, and Mallinckrodt Entities (the "RICO Marketing Defendants").

2. Second Cause of Action – Violation of RICO, 18 U.S.C. § 1961 *et seq.* – Opioid Supply Chain Enterprise (against only Defendants Cephalon Entities, Endo Entities, Mallinckrodt Entities, Actavis Entities, McKesson, Cardinal, and AmerisourceBergen (the "RICO Supply Chain Defendants").

3. Third Cause of Action — Negligence.

4. Fourth Cause of Action — Negligence *Per Se*.

5. Fifth Cause of Action — Violations of the Unfair Competition Law.

D. RELIEF REQUESTED

1. Order Defendants to provide for the benefit of the Plaintiff Legal Guardians and the Putative Class Members ongoing medical monitoring, testing, intervention, provision of caregiver training and information, and medical referral, all of which are medically necessary for the NAS Children in their care, and all future medical care reasonably necessary to treat these children. Any injunctive relief to which Plaintiffs may justly show themselves entitled, including injunctive relief designed to reduce the incidence of children born with NAS.

2. Order creation of a Science Panel.

3. Alternatively, all incidental compensatory damages and medical expenses incurred by Plaintiff Legal Guardians and the Putative Class Members in connection with their care of the NAS Children. It is expressly alleged that all compensatory damages sought in the alternative are incidental to the injunctive relief requested by Plaintiffs and the Class, and are for those caused by the *in utero* exposure to opioids and NAS diagnosis suffered by the NAS Children.

4. Disgorgement and other relief pursuant to the Unfair Competition Law.

5. Punitive damages.

[17] Defined in the "Non-Defendant Co-Conspirator Purdue Entities" and "Defendant Co-Conspirator Purdue Entities" sections, *infra*.

6. Attorneys' fees and costs incurred by Plaintiff Legal Guardians and the Putative Class Members.

4. ALTERNATIVE CLASSES

a. Legal Guardians[18] of Ohio residents born after May 9, 2000, who were medically diagnosed with opioid-related "Neonatal Abstinence Syndrome" ("NAS") at or near birth and whose birth mother received a prescription for opioids or opiates either (1) prior to the birth or (2) ten months prior to the birth and those opioids or opiates were manufactured or distributed by one or more of the "Cephalon Defendants";[19]

b. Legal Guardians[20] of Ohio residents born after May 9, 2000, who were medically diagnosed with opioid-related "Neonatal Abstinence Syndrome" ("NAS") at or near birth and whose birth mother received a prescription for opioids or opiates either (1) prior to the birth or (2) ten months prior to the birth and those opioids or opiates were manufactured or distributed by one or more of the "Endo Defendants";[21]

c. Legal Guardians[22] of Ohio residents born after May 9, 2000, who were medically diagnosed with opioid-related "Neonatal Abstinence Syndrome" ("NAS") at or near birth and whose birth mother received a prescription for opioids or opiates either (1) prior to the birth or (2) ten months prior to the birth and those opioids or opiates were manufactured or distributed by one or more of the "Mallinckrodt Defendants";[23]

d. Legal Guardians[24] of Ohio residents born after May 9, 2000, who were medically diagnosed with opioid-related "Neonatal Abstinence Syndrome" ("NAS") at or near birth and whose birth mother received a prescription for opioids or opiates either (1) prior to the birth or (2) ten months prior to the birth and those opioids or opiates were manufactured or distributed by one or more of the "Actavis Defendants";[25]

e. Legal Guardians[26] of Ohio residents born after May 9, 2000, who were medically diagnosed with opioid-related "Neonatal Abstinence Syndrome" ("NAS") at or near birth and whose birth mother received a prescription for opioids or opiates either (1) prior to the birth or (2) ten months prior to the birth and those opioids or opiates

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[18] The term "Legal Guardian" is defined at fn. 1.

[19] Defined in the "Manufacturer Defendants" section, *supra*.

[20] The term "Legal Guardian" is defined at fn. 1.

[21] Defined in the "Manufacturer Defendants" section, *supra.*

[22] The term "Legal Guardian" is defined at fn. 1.

[23] Defined in the "Manufacturer Defendants" section, *supra.*

[24] The term "Legal Guardian" is defined at fn. 1.

[25] Defined in the "Manufacturer Defendants" section, *supra.*

[26] The term "Legal Guardian" is defined at fn. 1.

were manufactured or distributed by one or more of the "Janssen Defendants";[27]

f. Legal Guardians[28] of Ohio residents born after May 9, 2000, who were medically diagnosed with opioid-related "Neonatal Abstinence Syndrome" ("NAS") at or near birth and whose birth mother received a prescription for opioids or opiates either (1) prior to the birth or (2) ten months prior to the birth and those opioids or opiates were manufactured or distributed by one or more Defendant or Purdue entity.[29]

[27] Defined in the "Manufacturer Defendants" section, *supra*.

[28] The term "Legal Guardian" is defined at fn. 1.

[29] Defined in the "Non-Defendant, Co-Conspirator Purdue Entities" and "Defendant Co-Conspirator Purdue Entities" sections, *supra*.

UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF OHIO
EASTERN DIVISION

IN RE: NATIONAL PRESCRIPTION, OPIATE LITIGATION

MDL NO. 2804

Case No. 17-MD-2804

THIS DOCUMENT RELATES TO:

Judge Dan Aaron Polster

Salmons v. Purdue Pharma L.P., et al.
MDL Case #1:18-OP-45268;

Flanagan v. Purdue Pharma L.P., et al.
MDL Case #1:18-OP-45405

Doyle v. Purdue Pharma L.P., et al.
MDL Case No. #1:18-op-46327

Artz v. Purdue Pharma, L.P., et al.
MDL Case No. #1:19-op-45459

ORDER CERTIFYING THE NAS GUARDIAN CLASSES

The Court held a hearing on ____, 2020, to consider and determine the NAS Guardians' Consolidated Motion for Class Certification. Dkt. ___. Upon review and consideration of all papers and presentations submitted in connection with the proposed classes, this Court finds and **ORDERS** the following:

The following classes are certified:

I. NATIONWIDE CLASSES

A. DEFINITION

CLASS 1. Legal Guardians[1] of United States residents born after March 16, 2000, who were medically diagnosed with opioid-related NAS[2] at or near birth and whose birth mother received a prescription for opioids or opiates prior to the birth and those opioids or opiates were manufactured, distributed, or filled by a Defendant or Purdue entity. Excluded from the class are any infants and children who were treated with opioids after birth, other than for pharmacological weaning. Also excluded from the class are legal guardianships where a political subdivision, such as a public children services agency, has affirmatively assumed the duties of "custodian" of the child.

CLASS 2. Legal Guardians[3] of United States residents born after March 16, 2000, who were medically diagnosed with opioid-related NAS at or near birth and whose birth mother received and/or filled a prescription for opioids or opiates in the 10 months prior to the birth of said infant or child and those opioids or opiates were manufactured, distributed, or filled by a Defendant or Purdue entity.

B. DEFENDANTS

(1) MANUFACTURER DEFENDANTS

- Actavis Entities: Allergan PLC f/k/a Actavis PLC f/k/a Allergan, Inc.; Allergan Finance, LLC f/k/a Actavis, Inc. f/k/a Watson Pharmaceuticals, Inc.; Allergan Sales, LLC; Allergan USA, Inc.; Watson Laboratories, Inc.; Warner Chilcott Company, LLC; Actavis Pharma, Inc. f/k/a Watson Pharma Inc.; Actavis South Atlantic LLC; Actavis Elizabeth LLC; Actavis Mid Atlantic LLC; Actavis Totowa LLC; Actavis LLC; Actavis Kadian LLC; Actavis Laboratories UT, Inc. f/k/a Watson Laboratories, Inc.-Salt Lake City; Actavis Laboratories FL, Inc. f/k/a Watson Laboratories, Inc.-

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[1] The term "Legal Guardian" is further defined for purposes of this putative class action as "any natural person or entity who has the primary legal responsibility under law for an infant or child's physical, mental, and emotional development." Expressly excluded from the class of "Legal Guardians" are any governmental entities.

"Legal Guardians" include natural and adoptive parents who have not otherwise lost legal custody of their children, legal custodians, legal caretakers, and court-appointed guardians (including guardians of the person), whether temporary or permanent.

[2] The term "NAS" (Neonatal Abstinence Syndrome) is defined to include additional, but medically symptomatic identical, terminology and diagnostic criteria, including Neonatal Opioid Withdrawal Syndrome (NOWS) and other historically and regionally used medical and/or hospital diagnostic criteria for infants born addicted to opioids from *in utero* exposure. Additional specifics on these readily identifiable and ascertainable terms are set forth in the accompanying Consolidated Memorandum of Law, ¶ II., p.7.

[3] The term "Legal Guardian" is defined at fn. 2.

Florida.

- Cephalon Entities: Teva Pharmaceutical Industries Ltd.; Teva Pharmaceuticals USA, Inc.; Cephalon, Inc.
- Janssen Entities: Janssen Pharmaceuticals, Inc.; Janssen Pharmaceutica, Inc. n/k/a Janssen Pharmaceuticals, Inc.; Noramco, Inc.; Ortho-McNeil-Janssen Pharmaceuticals, Inc. n/k/a Janssen Pharmaceuticals, Inc.; Johnson & Johnson.
- Endo Entities: Endo Health Solutions Inc.; Endo Pharmaceuticals, Inc.; Par Pharmaceutical, Inc.; Par Pharmaceutical Companies, Inc. f/k/a Par Pharmaceutical Holdings, Inc.
- Mallinckrodt Entities: Mallinckrodt plc; Mallinckrodt LLC; SpecGx LLC.
- Co-Conspirator Purdue Entities: Richard S. Sackler; Jonathan D. Sackler; Mortimer D.A. Sackler; Kathe A. Sackler; Ilene Sackler Lefcourt; Beverly Sackler; Theresa Sackler; David A. Sackler; Rhodes Technologies; Rhodes Technologies Inc.; Rhodes Pharmaceuticals L.P.; Rhodes Pharmaceuticals Inc.; Trust for the Benefit of Members of the Raymond Sackler Family; The P.F. Laboratories, Inc.
- Non-Defendant, Co-Conspirator Purdue Entities: Purdue Pharma L.P.; Purdue Pharma Inc.; The Purdue Frederick Company, Inc.

(2) DISTRIBUTOR DEFENDANTS

- Cardinal Health, Inc.
- AmerisourceBergen Drug Corp.
- Mckesson Corporation

(3) PHARMACY DEFENDANTS

- HBC Service Company
- CVS Health Corporation; CVS Indiana, LLC; CVS Rx Services, Inc.
- Rite Aid Corporation; Rite Aid of Maryland, Inc.; Rite Aid of Maryland, Inc. d/b/a Rite-Aid Mid-Atlantic Customer Support Center, Inc.
- Walgreen Co.; Walgreens Boots Alliance, Inc.; Walgreen Eastern Co.
- Wal-Mart Inc. f/k/a Wal-Mart Stores, Inc.
- Miami-Luken, Inc.
- Costco Wholesale Corporation

C. CLAIMS

1. First Cause of Action – Violation of RICO, 18 U.S.C. § 1961 *et seq.* – Opioid Marketing Enterprise (against only Defendants Cephalon Entities, Janssen Entities, Endo Entities, and Mallinckrodt Entities (the "RICO Marketing Defendants").

2. Second Cause of Action – Violation of RICO, 18 U.S.C. § 1961 *et seq.* – Opioid Supply Chain Enterprise (against only Defendants Cephalon Entities, Endo Entities, Mallinckrodt Entities, Actavis Entities, McKesson, Cardinal, and AmerisourceBergen (the "RICO Supply Chain Defendants").

D. RELIEF REQUESTED

1. Order Defendants to provide for the benefit of the Plaintiff Legal Guardians and the Putative Class Members ongoing medical monitoring, testing, intervention, provision of caregiver training and information, and medical referral, all of which are medically necessary for the NAS Children in their care, and all future medical care reasonably necessary to treat these children. Any injunctive relief to which Plaintiffs may justly show themselves entitled, including injunctive relief designed to reduce the incidence of children born with NAS.

2. Order creation of a Science Panel.

3. Alternatively, all incidental compensatory damages and medical expenses incurred by Plaintiff Legal Guardians and the Putative Class Members in connection with their care of the NAS Children. It is expressly alleged that all compensatory damages sought in the alternative are incidental to the injunctive relief requested by Plaintiffs and the Class, and are for those caused by the *in utero* exposure to opioids and NAS diagnosis suffered by the NAS Children.

4. Punitive damages.

5. Attorneys' fees and costs incurred by Plaintiff Legal Guardians and the Putative

Class Members.

II. CLASS 3 – OHIO STATEWIDE CLASS[4]

A. DEFINITION

1. Legal Guardians[5] of Ohio residents born after March 16, 2000, who were medically diagnosed with opioid-related NAS[6] at or near birth and whose birth mother received a prescription for opioids or opiates prior to the birth and those opioids or opiates were manufactured, distributed, or filled by a Defendant or Purdue entity. Excluded from the class are any infants and children who were treated with opioids after birth, other than for pharmacological weaning. Also excluded from the class are legal guardianships where the State of Ohio or one of its political subdivisions, such as a public children services agency, has affirmatively assumed the duties of "custodian" of the child.

2. Legal Guardians[7] of Ohio residents born after March 16, 2000, who were medically diagnosed with opioid-related NAS[8] at or near birth and whose birth mother received and/or filled a prescription for opioids or opiates in the 10 months prior to the birth of said infant or child and those opioids or opiates were manufactured, distributed, or filled by a Defendant or Purdue entity.

B. DEFENDANTS

(1) MANUFACTURER DEFENDANTS

- Actavis Entities: Allergan PLC f/k/a Actavis PLC f/k/a Allergan, Inc.; Allergan Finance, LLC f/k/a Actavis, Inc. f/k/a Watson Pharmaceuticals,

[4] The Ohio statewide class is sought by putative Class Representatives Michelle Frost and Stephanie Howell.

[5] The term "Legal Guardian" is defined at fn. 2

[6] The term "NAS" is defined at fn. 3.

[7] The term "Legal Guardian" is defined at fn. 2.

[8] The term "NAS" is defined at fn. 3.

Inc.; Allergan Sales, LLC; Allergan USA, Inc.; Watson Laboratories, Inc.; Warner Chilcott Company, LLC; Actavis Pharma, Inc. f/k/a Watson Pharma Inc.; Actavis South Atlantic LLC; Actavis Elizabeth LLC; Actavis Mid Atlantic LLC; Actavis Totowa LLC; Actavis LLC; Actavis Kadian LLC; Actavis Laboratories UT, Inc. f/k/a Watson Laboratories, Inc.-Salt Lake City; Actavis Laboratories FL, Inc. f/k/a Watson Laboratories, Inc.-Florida.

- Cephalon Entities: Teva Pharmaceutical Industries Ltd.; Teva Pharmaceuticals USA, Inc.; Cephalon, Inc.
- Janssen Entities: Janssen Pharmaceuticals, Inc.; Janssen Pharmaceutica, Inc. n/k/a Janssen Pharmaceuticals, Inc.; Noramco, Inc.; Ortho-McNeil-Janssen Pharmaceuticals, Inc. n/k/a Janssen Pharmaceuticals, Inc.; Johnson & Johnson.
- Endo Entities: Endo Health Solutions Inc.; Endo Pharmaceuticals, Inc.; Par Pharmaceutical, Inc.; Par Pharmaceutical Companies, Inc. f/k/a Par Pharmaceutical Holdings, Inc.
- Mallinckrodt Entities: Mallinckrodt plc; Mallinckrodt LLC; SpecGx LLC.
- Insys Therapeutics, Inc.
- Depomed, Inc.
- Indivior, Inc.
- Co-Conspirator Purdue Entities: Richard S. Sackler; Jonathan D. Sackler; Mortimer D.A. Sackler; Kathe A. Sackler; Ilene Sackler Lefcourt; Beverly Sackler; Theresa Sackler; David A. Sackler; Rhodes Technologies; Rhodes Technologies Inc.; Rhodes Pharmaceuticals L.P.; Rhodes Pharmaceuticals Inc.; Trust for the Benefit of Members of the Raymond Sackler Family; The P.F. Laboratories, Inc.
- Non-Defendant, Co-Conspirator Purdue Entities: Purdue Pharma L.P.; Purdue Pharma Inc.; The Purdue Frederick Company, Inc.

(2) DISTRIBUTOR DEFENDANTS

- Cardinal Health, Inc.
- AmerisourceBergen Drug Corp.
- Mckesson Corporation
- Anda, Inc.
- H. D. Smith, LLC d/b/a HD Smith f/k/a H. D. Smith Wholesale Drug Co.; H. D. Smith Holdings, LLC; H. D. Smith Holding Company

- Discount Drug Mart, Inc.
- Prescription Supply, Inc.

(3) PHARMACY DEFENDANTS

- HBC Service Company
- CVS Health Corporation; CVS Indiana, LLC; CVS Rx Services, Inc.
- Rite Aid Corporation; Rite Aid of Maryland, Inc.; Rite Aid of Maryland, Inc. d/b/a Rite-Aid Mid-Atlantic Customer Support Center, Inc.
- Walgreen Co.; Walgreens Boots Alliance, Inc.; Walgreen Eastern Co.
- Wal-Mart Inc. f/k/a Wal-Mart Stores, Inc.
- Miami-Luken, Inc.
- Costco Wholesale Corporation

C. CLAIMS

1. First Cause of Action – Violation of RICO, 18 U.S.C. § 1961 *et seq.* – Opioid Marketing Enterprise (against only Defendants Cephalon Entities, Janssen Entities, Endo Entities, and Mallinckrodt Entities (the "RICO Marketing Defendants").

2. Second Cause of Action – Violation of RICO, 18 U.S.C. § 1961 *et seq.* – Opioid Supply Chain Enterprise (against only Defendants Cephalon Entities, Endo Entities, Mallinckrodt Entities, Actavis Entities, McKesson, Cardinal, and AmerisourceBergen (the "RICO Supply Chain Defendants").

3. Third Cause of Action — Negligence.

4. Fourth Cause of Action — Negligence *Per Se*.

5. Fifth Cause of Action — Civil Battery.

6. Sixth Cause of Action — Civil Conspiracy.

D. RELIEF REQUESTED – *See* ¶ I.D., *supra,* which is incorporated by reference.

III. CLASS 4 – CALIFORNIA STATEWIDE CLASS[9]

A. DEFINITION

1. Legal Guardians[10] of residents born after March 16, 2000, who were medically diagnosed with opioid-related NAS[11] at or near birth and whose birth mother received a prescription for opioids or opiates prior to the birth and those opioids or opiates were manufactured, distributed, or filled by a Defendant or Purdue entity. Excluded from the class are any infants and children who were treated with opioids after birth, other than for pharmacological weaning. Also excluded from the class are legal guardianships where a political subdivision, such as a public children services agency, has affirmatively assumed the duties of "custodian" of the child.

2. Legal Guardians[12] of California residents born after March 16, 2000, who were medically diagnosed with opioid-related NAS[13] at or near birth and whose birth mother received and/or filled a prescription for opioids or opiates in the 10 months prior to the birth of said infant or child and those opioids or opiates were manufactured, distributed, or filled by a Defendant or Purdue entity.

3. Legal Guardians[14] of California residents born after March 16, 2000, who were

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[9] The California statewjide class is sought by putative Class Representatives Jacqueline Ramirez, Roman Ramirez, and Melissa Barnwell.

[10] The term "Legal Guardian" is defined at fn. 2.

[11] The term "NAS" is defined at fn. 3.

[12] The term "Legal Guardian" is defined at fn. 2.

[13] The term "NAS" is defined at fn. 3.

[14] The term "Legal Guardian" is defined at fn. 2.

medically diagnosed with opioid-related NAS[15] at or near birth and whose birth mother received a prescription for opioids or opiates prior to the birth and those opioids or opiates were manufactured, distributed, or filled by a Defendant or Purdue entity.

B. DEFENDANTS – *See* ¶ II.B., *supra,* which is incorporated by reference.

C. CLAIMS

1. First Cause of Action – Violation of RICO, 18 U.S.C. § 1961 *et seq.* – Opioid Marketing Enterprise (against only Defendants Cephalon Entities, Janssen Entities, Endo Entities, and Mallinckrodt Entities (the "RICO Marketing Defendants").

2. Second Cause of Action – Violation of RICO, 18 U.S.C. § 1961 *et seq.* – Opioid Supply Chain Enterprise (against only Defendants Cephalon Entities, Endo Entities, Mallinckrodt Entities, Actavis Entities, McKesson, Cardinal, and AmerisourceBergen (the "RICO Supply Chain Defendants").

3. Third Cause of Action — Negligence.

4. Fourth Cause of Action — Negligence *Per Se*.

5. Fifth Cause of Action — Violations of the Unfair Competition Law.

D. RELIEF REQUESTED

1. Order Defendants to provide for the benefit of the Plaintiff Legal Guardians and the Putative Class Members ongoing medical monitoring, testing, intervention, provision of caregiver training and information, and medical referral, all of which are medically necessary for the NAS Children in their care, and all future medical care reasonably necessary to treat these children. Any injunctive relief to which Plaintiffs may justly show themselves entitled, including injunctive relief designed to reduce the incidence of children born with NAS.

[15] The term "NAS" is defined at fn. 3.

2. Order creation of a Science Panel.

3. Alternatively, all incidental compensatory damages and medical expenses incurred by Plaintiff Legal Guardians and the Putative Class Members in connection with their care of the NAS Children. It is expressly alleged that all compensatory damages sought in the alternative are incidental to the injunctive relief requested by Plaintiffs and the Class, and are for those caused by the *in utero* exposure to opioids and NAS diagnosis suffered by the NAS Children.

4. Disgorgement and other relief pursuant to the Unfair Competition Law.

5. Punitive damages.

6. Attorneys' fees and costs incurred by Plaintiff Legal Guardians and the Putative Class Members.

The following counsel will fairly and adequately represent the interests of the classes:

1. The Dann Law Firm (Class Counsel and Liaison Counsel);

2. Martzell, Bickford & Centola (Class Counsel);

3. The Bilek Law Firm, L.L.P. (Class Counsel); and

4. The Cooper Law Firm (Class Counsel).

Class Counsel are authorized to (a) represent the classes in settlement negotiations with Defendants; (b) sign any filings with this or any other Court made on behalf of the classes; (c) assist the Court with functions relevant to a class action, such as but not limited to executing a satisfactory notice program; and (d) represent the classes in Court.

Plaintiffs have satisfied the requirements of Fed. R. Civ. P. 23(a):

- The members of the classes are so numerous that joinder is impracticable;
- Membership in the classes is ascertainable and based on readily identifiable and objective criteria;
- The claims of the class members involve common questions of law and fact;

- The claims of the named Plaintiffs are typical of the claims of the other class members, and they will otherwise adequately represent the classes and have no conflicts of interest; and

- The putative class counsel will fairly and adequately represent the interests of the classes.

The proposed classes also satisfy Fed. R. Civ. P. 23(b)(2) and 23(b)(3):

- The parties opposing the classes have acted or refused to act on grounds generally applicable to the classes;

- Common questions of law and fact predominate over individual issues; and

- Class certification is superior to other available means of adjudication.

The Court accordingly certifies the two RICO claims against the four and seven Defendants, respectively, under Rule 23(b)(3). These identified Defendants encompass families of companies.

The Class Representatives' claims are typical of those of the classes, and the proposed Class Representatives will adequately represent the classes. The Court accordingly appoints Jacqueline Ramirez, Roman Ramirez, Melissa Barnwell, Michelle Frost, and Stephanie Howell as Class Representatives.

Class Counsel are ordered to provide to this Court class notice that will be sent to class members as directed by further order of this Court.

SO ORDERED on _____, 2020.

DAN AARON POLSTER
United States District Judge

UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF OHIO
EASTERN DIVISION

IN RE: NATIONAL PRESCRIPTION, OPIATE LITIGATION

MDL NO. 2804

Case No. 17-MD-2804

THIS DOCUMENT RELATES TO:

Judge Dan Aaron Polster

Salmons v. Purdue Pharma L.P., et al.
MDL Case #1:18-OP-45268;

Flanagan v. Purdue Pharma L.P., et al.
MDL Case #1:18-OP-45405

Doyle v. Purdue Pharma L.P., et al.
MDL Case No. #1:18-op-46327

Artz v. Purdue Pharma, L.P., et al.
MDL Case No. #1:19-op-45459

I, Marc Edward Dann, hereby state and declare as follows:

1. I am an attorney of law, duly licensed and admitted to practice law before the United States District Court for the Northern District of Ohio. I am over the age of 18.

2. I am a partner in the law firm of Dann Law, which serves as co-counsel for Plaintiffs Jacqueline Ramirez, Roman Ramirez, Melissa Barnwell, Jennifer Artz, Michelle Frost and Stephanie Howell ("Plaintiffs") in the matter of *In Re: National Prescription, Opiate Litigation*, No. 17-md-2804 (the "Action").

3. I have personal knowledge of the following facts, and I am competent to testify to the following facts upon my own personal knowledge. I make this declaration in support of Plaintiffs' Motion for Class Certification.

4. Plaintiffs' counsel are experienced attorneys who have handled many complex civil litigation matters including other class actions and would be adequate to serve as lead and liaison counsel.

5. I and the other nine attorneys at Dann Law ("Dann Law") have significant experience litigating consumer class actions on behalf of Ohio citizens with extensive experience litigating in the Northern District of Ohio. I previously served as Ohio Attorney General and the State's chief consumer protection enforcer. Further I served on the National Association of Attorneys General Committee overseeing the continued implementation of the National Tobacco Settlement. Under my Direction the State of Ohio prosecuted and settled claims for off label marketing of opioid pharmaceuticals against Perdue Pharmaceuticals. *See* Dann Law Firm Bio, attached hereto as **Exhibit 1**.

6. Thomas Bilek has substantial experience litigating with over 33 years of experience. Bilek has taken a position as one of the top plaintiffs' trial lawyers in Texas and is sought by other law firms to serve as co- or lead counsel in cutting-edge securities fraud, consumer protection, environmental, and occupational injury cases throughout the United States. *See* Bilek Firm Resume attached hereto as **Exhibit 2**.

7. Celeste Brustowicz is a partner with Cooper Law Firm in New Orleans, Louisiana who has extensive experience in litigating complex and class cases. *See* Cooper Law Firm Resume attached hereto as **Exhibit 3**.

8. Scott R. Bickford, a principal in Martzell, Bickford and Centola, APC, in New Orleans, Louisiana is an associate professor at Tulane Law School where he serves as co-director or the Law School's Trial Advocacy program. Bickford also has extensive experience in

complex litigation including several multi-district litigations as well as handling multiple class action cases. Bickford's resume is attached hereto as **Exhibit 4**.

9. The putative lead and liaison Counsel, Dann, Bilek, Brustowicz and Bickford have associated with a network of lawyers who represent guardians of NAS Babies throughout the United States and have sufficient resources to properly prosecute claims alleged in the third amended complaint on behalf of the Class. Evidence of the adequacy of resources is demonstrated by over thousands of hours of work already performed in researching claims alleged in the complaint and have retained the highly qualified and respected experts whose affidavits are offered in support of the Motion for Class Certification.

10. Attached hereto as **Exhibit 5** is the Curriculum Vitae and Declaration of Dr. Kanwaljeet S. Anand in support of Plaintiffs' Motion for Class Certification.

11. Attached hereto as **Exhibit 6** is the Curriculum Vita, Report, and List of Depositions of Dr. Charles L. Werntz III D.O. in support of Plaintiffs' Motion for Class Certification.

12. Attached hereto as **Exhibit 7** is the Curriculum Vitae and Declaration of Dr. Charles Vyvayan Howard in support of Plaintiffs' Motion for Class Certification.

13. Attached as **Exhibit 8** is "Increase in Prescription Opioid Use during Pregnancy among Medicaid-enrolled Women," Obstetrics and Gynecology, 123(5), 997-1002 (2014) R.J. Desai

14. Attached hereto as **Exhibit 9** is the NCHS Data Brief No. 329 "Drug Overdose Deaths in the United States 1999-2017" by Holly Hedegaard M.D., Arianldi M. Minino M.P.H. and Margaret Warner Ph.D., published November 2018.

15. Attached hereto as **Exhibit 10** is "Duties of a Guardian of the Person", https://www.courts.ca.gov/1211.htm (last visited Jan. 6, 2020).

16. Attached hereto as **Exhibit 11** is "Opioid use disorder in the United States: Diagnosed prevalence by payer, age, sex, and state", Stoddard Davenport and Katie Matthews (2018).

17. Attached hereto as **Exhibit 12** is "Cuyahoga County Announces How It'll Use $23 Million in Opioid Settlement Money on Treatment and Prevention Services," Vince Grzegorek, October 11, 2019, clevescene.com.

18. Attached hereto as **Exhibit 13** is "Ohio voters could decide constitutional amendment to split up opioid lawsuit cash," Darrel Rowland and Randy Ludow, The Columbus Dispatch, December 5, 2019.

I declare under penalty of perjury under the laws of the United States and the State of Ohio that the foregoing is true and correct.

EXECUTED in Cleveland, Ohio January 7, 2020

/s/ Marc E. Dann
Marc E. Dann

Marc Dann Declaration in Support of Motion for Class Certification

Exhibit 1

DannLaw Curriculum Vitae

DannLaw

DannLaw is a firm dedicated to consumer advocacy and prosecuting consumer protection claims through individual and Class Action claims. DannLaw's 10 attorneys bring an array of talents in areas which affect the day to day lives and finances of regular people. DannLaw assists clients with matters related to their mortgage servicing, consumer debts, student loans, foreclosure, data privacy and credit, disability access and other consumer claims. The firm often finds itself litigating before courts across the country. DannLaw has offices in New Jersey, New York, Cleveland, Columbus and Cincinnati Ohio and frequently join forces to co-counsel cases in cases throughout the country. Our firm is a leader in the prosecution of claims under RESPA, TILA, FDCPA, FCRA, ADA and related state law consumer protection statutes. DannLaw has brought and successfully resolved claims against every major mortgage loan servicer or bank servicer. DannLaw has substantial experience bringing claims as class actions in state and Federal Court, having brought matters against Wells Fargo, Inland Bank, Equifax, Sonic, Whole Foods, Intellos and Ken Jones and Associates.

Marc E. Dann

Areas of Practice: RESPA and TILA Litigation, Foreclosure Defense, Debt Collection Abuse, FCRA violations, Privacy Violations, FDCPA violations, TCPA violations, Unfair Acts and Practices Violations, Class Action Litigation, and Bankruptcy Law.

Education: Bachelor of Arts, History University of Michigan, 1984; Juris Doctorate Case Western Reserve University School of Law 1987.

Admissions: State of Ohio; United States District Court for the Northern District of Ohio; United States District Court for the Southern District of Ohio, Sixth Circuit Court of Appeals in addition to multiple district courts throughout the country.

Marc Dann is the Managing Partner of DannLaw. His practice focuses on representing clients who have been harmed by banks, debt buyers, debt collectors and other financial predators. He has fought for the rights of thousands of consumers and brought class actions lawsuits in both private practice and as Ohio's Attorney General.

As Ohio Attorney General, Marc Dann initiated securities fraud claims against the creators of mortgage-backed securities on behalf of Ohio's public pension funds. He assembled Ohio's Organized Crime Commission to mobilize Mortgage Fraud Task Forces in Ohio's major cities, challenging the standing of mortgage servicers to foreclose in cases where the State of Ohio was a party. Dann also worked with former Ohio Supreme Court Chief Justice Thomas Moyer to organize over 1,200 volunteer lawyers to represent homeowners in foreclosure.

After leaving the Attorney General's Office, Marc Dann began representing Ohio homeowners facing foreclosure pro bono. During this time, he recognized that the issues faced by individual homeowners represented patterns of practice throughout the mortgage servicing industry. In response, he mobilized a team and created The Dann Law Firm in order to fight for the rights of Ohioans.

Since The Dann Law Firm was founded, it has grown to represent clients facing a range of consumers' rights issues. While mortgage litigation practice remains the foundation of The Dann Law Firm, Marc Dann has developed a comprehensive collection of tools designed to help clients stay in their homes and to hold mortgage lenders accountable. He is a recognized national leader in the use of federal mortgage servicing regulations to hold servicers accountable for their actions. Utilizing these tools has lead Marc Dann to teach CLE approved seminars explaining these techniques to other attorneys. These working groups help to elevate the defense of foreclosures

and the prosecution of mortgage servicing and other consumer claims for clients across the nation while allowing attorneys to recognize patterns of practice that affect all citizens.

This collaborative spirit also applies to the communities of which The Dann Law Firm is a part. As a proud member of Midtown Cleveland, Marc Dann and the team members at the firm participate in community events, such as the annual Midtown clean-up. Marc Dann and The Dann Law Firm also support the Cleveland International Film Festival each year.

Dann prioritizes professional organizations as well, as a member of the American Bar Association, the Federal Bar Association, the Cleveland Metropolitan Bar Association, the Ohio State Bar Association, and the National Association of Consumer Bankruptcy Attorneys. He is a member of the Society of Attorneys General Emeritus, the Democratic Attorneys General Association.

Marc Dann is a regular contributor to Attorney at Law Magazine and the Cleveland Metropolitan Bar Association Magazine. His work has also been featured in NACBA's Consumer Bankruptcy Journal and Legal Ink Magazine.

Dann is admitted to practice in the United States Court of Appeals for the Sixth Circuit, United States District Court for the Southern District of Ohio, United States District Court for the Northern District of Ohio, United States District Court for the Northern District of Illinois, the United States District Court for the Western District of Tennessee and the Ohio Supreme Court. He has pro hac vice admission in Cook County, Illinois, United States District Court for the Southern District of Florida, United States District Court for the Middle District of Florida, United States District Court for the Northern District of Georgia, United States District Court in Nevada, United States District Court for the Western District of New York, United States District

Court for the Southern District of New York and the United States District Court for the District of New Jersey.

Dann has been appointed Liason Counsel in the In Re: Sonic Data Breach MDL and has been appointed lead coun

Donna Kolis

Areas of Practice: RESPA and TILA Litigation, Class Action Litigation, Personal Injury Law, Medical Malpractice and Probate Law

Education: *Bachelor of Arts,* Virginia Intermont College, Bristol, Virginia; *Juris Doctorate*, Cleveland-Marshall College of Law, Cleveland, Ohio

Admissions: State of Ohio, United States District Court for the Northern District of Ohio, United States for the Southern District of Ohio, and the United States District Court for the Northern District of Illinois.

Donna Taylor-Kolis is a senior attorney at DannLaw. With over thirty years of experience as a trial attorney, Attorney Kolis specializes in strategy and devising solutions to maximize recovery for her clients. Attorney Kolis utilizes a comprehensive approach to each and every case from the beginning phases of litigation to the end. With an aptitude for service to her clients, Attorney Kolis provides her undivided time and attention to each and every case that she works on.

For the last eight years Attorney Kolis has devoted her time to various aspects of medical malpractice litigation. She served on a Multi-District Litigation Committee for four product groups that included the coordination of scientists, physicians, pathologists, infectious disease specialists, academics, medical researchers, material engineers, economists and life planners. She has served on steering committees, science/expert committees and discovery committees in numerous Federal Court Multi-District Litigations, including, the “Transvaginal Mesh Litigation”

pending in both New Jersey State Court and the Federal Court in the Southern District of West Virginia.

Attorney Kolis served as the Post Settlement Administrator on MDL 1871 (Avandia); requiring her to meet with Third Party Administrators to ensure liens were taken out on payments and discuss how money would be distributed to parties. Attorney Kolis was also responsible for contacting and directing a select group of twenty lawyers across the country to prepare their plaintiffs on bellwether trials and synthesizing the information into aggregates and plaintiff groups.

Attorney Kolis has an extensive background in science and research. She utilizes a collaborative, proactive approach to all of her cases.

Emily White

Areas of Practice: Student Loan Law, Employment Discrimination, Disability Rights, RESPA and TILA Litigation, Foreclosure Defense, Debt Collection Abuse, FDCPA Violations, Unfair Acts and Practices Violations,

Education: *Bachelor of Arts,* University of Illinois at Urbana-Champaign, BA in Philosophy; City University of New York School of Law, JD.

Admissions: State of Ohio, United States District Court for the Northern District of Ohio, United States for the Southern District of Ohio, Sixth Circuit Court of Appeals, Supreme Court of Pennsylvania (inactive)

After spending nearly a decade as a public interest attorney, Emily White joined DannLaw. She is the Managing Partner of the firm's Columbus, Ohio office and the Director of the firm's Student Loan and Disability Rights Practice Groups.

Before attending law school she served as an AmeriCorps volunteer with Habitat for Humanity NYC. Emily received her law degree from the City University of New York School of Law, where she served on the editorial board of the New York City Law Review. Following law

school, she served for two years as a judicial law clerk to the Honorable Sylvia H. Rambo, U.S. District Court Judge for the Middle District of Pennsylvania.

In 2009 she joined the Legal Aid Society of Cleveland, where she represented low-income consumers during the historic recession and foreclosure crisis. While at Legal Aid she authored a chapter of Ohio Consumer Law focused on student loans and helped student loan borrowers resolve defaults and apply for student loan discharges.

In 2013 she joined Disability Rights Ohio as a staff attorney. In that role Emily represented individuals with disabilities in employment and higher education matters and offered advice about issues related to student loans and vocational rehabilitation services.

Brian D. Flick

Areas of Practice: RESPA and TILA Litigation, Foreclosure Defense, Debt Collection Abuse, FCRA violations, Privacy Violations, FDCPA violations, TCPA violations, Unfair Acts and Practices Violations, Class Action Litigation, and Bankruptcy Law.

Education: Bachelor of Arts, Adrian College; Juris Doctorate, Ohio Northern University Pettit College of Law.

Admissions: State of Ohio; State of Kentucky; United States District Court for the Northern District of Ohio; United States District Court for the Southern District of Ohio, in addition to multiple district courts throughout the country.

Brian Flick is the Managing Partner of DannLaw's Cincinnati office and is the director of the firm's Bankruptcy Practice Group and non-RESPA Consumer Litigation Practice Group. Brian is a tireless advocate for consumers across Ohio, Kentucky and the United States.

Brian prioritizes professional organizations as well. As an active member of the Cincinnati Bar Association, he serves as president of the CBA's Lawyer Referral Committee as well as sitting on the Unauthorized Practice of Law Committee. Brian is an active member of the National Association of Consumer Advocates as the Chair for the State of Ohio. Brian can also be

found regularly on the listservs for the National Association of Consumer Bankruptcy Attorneys where he is the Sixth Circuit moderator and has been a frequent presenter at NACBA seminars and webinars.

Brian is admitted to practice in the United States Court of Appeals for the Sixth Circuit, United States District Court for the Southern District of Ohio, United States District Court for the Northern District of Ohio, United States District Court for the Northern District of Illinois, the United States District Court for the Northern District of Indiana, the United States District Court for the Southern District of Indiana, the United States District Court for the Eastern District of Kentucky, the United States District Court for the Western District of Kentucky, the United States District Court for the Eastern District of Michigan, the United States District Court for the Eastern District of Tennessee, the United States District Court for the Western District of Ohio, the Kentucky Supreme Court and the Ohio Supreme Court. He has pro hac vice admission in the United States District Court for the Southern District of Florida, United States District Court for the Middle District of Florida, United States District Court for the Northern District of Georgia, United States District Court for the Southern District of New York, the United States District Court for the Eastern District of New York, the United States District Court for the District of Kansas, the United States District Court for the Western District of Missouri, the United States District Court for the Central District of California and the United States District Court for the Southern District of California.

Marc Dann Declaration in Support of Motion for Class Certification

Exhibit 2

THE BILEK LAW FIRM, L.L.P.

ATTORNEYS AT LAW

700 Louisiana, Suite 3950

Houston, Texas 77002

(713) 227-7720

FIRM RESUME

The Bilek Law Firm, L.L.P. is dedicated to the vigorous prosecution of plaintiffs' lawsuits in state and federal courts across the nation. With over 33 years of experience, Thomas Bilek has taken a position as one of the top plaintiffs' trial lawyers in Texas and is sought by other law firms to serve as co- or lead counsel in cutting-edge securities fraud, consumer protection, environmental, and occupational injury cases throughout the United States. Combined with Kelly Bilek's more than 26 years of class action, trial, and appellate expertise, the Firm's commitment to aggressive yet cost-effective counsel has frequently resulted in successful outcomes for its clients.

Commercial Litigation cases:

- Successfully represented shareholders as co-liaison counsel in the main securities fraud class action against *Enron Corporation, et al.* Settlement in excess of $7,200,000,000.00. (2008)

- Successfully represented plaintiffs as lead trial counsel in a federal nationwide securities class action against *Compaq Corporation*. Obtained a settlement in the amount of $28,650,000.00. (2003)

- Successfully represented a class of plan participants for ERISA violations by their employer, *El Paso Corporation*. Obtained a settlement in the amount of $17,000,000.00. (2008)

- Successfully represented an individual investor in state court actions against Deloitte Touche and the Adelphia outside directors arising out of the *Adelphia* securities fraud. Obtained confidential settlements for both cases. (2008)

- Successfully represented an individual investor in a state court action against Arthur Andersen relating to the sale of Sunbeam bonds. Obtained a confidential settlement. (2002)

- Successfully represented plaintiffs as liaison counsel for shareholders in a federal nationwide securities class action against *NCI Building Systems, Inc*. Obtained a settlement in the amount of $7,000,000.00. (2004)

- Successfully represented plaintiffs in a federal nationwide securities class action against *Cooper Industries*. Obtained a settlement in the amount of $6,850,000.00. (1999)

- Successfully represented Enron shareholders as class counsel in a nationwide class action filed in Texas state court arising out of the failed merger with *Dynegy*. Obtained a settlement in the amount of $6,000,000.00. (2003)

- Successfully represented plaintiffs in a securities class action against *Mitcham Industries*. Obtained a settlement in the amount of $2,700,000.00. (2002)

- Successfully represented a class of plan participants for ERISA violations by their employer, *RadioShack Corporation.* Obtained a settlement in the amount of $2,400,000. (2011)

- Successfully represented plaintiffs in a federal nationwide securities class action against *A Pea in the Pod*. Obtained a settlement in the amount of $2,150,000.00. (1997)

- Successfully represented a class of plan participants for ERISA violations by their employer, *Affiliated Computer Services, Inc.* Obtained a settlement in the amount of $1,500,000.00. (2008)

- Successfully represented a statewide class of California residents in their claims against an automobile manufacturer. (2007)

- Successfully represented shareholders of *Crestwood Midstream Partners LP* in its merger with Crestwood Equity Partners LP. The action resulted in additional disclosures to shareholders regarding the merger. (2016)

- Successfully represented shareholders of *Multimedia Games Holding Company, Inc.* in its merger with Global Cash Access Holdings, Inc. The action resulted in additional disclosures to shareholders regarding the merger. (2015)

- Successfully represented shareholders of *QR Energy LP* in its sale to Breitburn Energy Partners LP. The action resulted in additional disclosures to shareholders regarding the merger. (2015)

- Successfully represented shareholders of *MetroCorp Bancshares, Inc.* in its merger with East West Bancorp, Inc. The action resulted in a reduced termination fee and additional disclosures to shareholders regarding the merger. (2014)

- Successfully represented shareholders of *Crestwood Midstream Partners LP* in its merger with Inergy Midstream, L.P. The action resulted in additional disclosures to shareholders regarding the merger. (2014)

- Successfully represented shareholders of *HealthTronics, Inc.* in its merger with Endo Pharmaceuticals Holdings, Inc. The action resulted in additional disclosures to shareholders regarding the merger. (2010)

- Appointed lead counsel by Texas state court in a nationwide suit on behalf of shareholders in a breach of fiduciary duty class action against the former officers and directors of *Pennzoil-Quaker State Company*. (2007)

- Successfully represented *Dynacq Healthcare, Inc.* shareholders in a derivative action which resulted in greater board oversight of management of the company's accounting practices. (2003)

- Successfully represented shareholders of DTM in its merger with 3D Systems. The action resulted in the reduction of certain anti-takeover provisions and additional disclosures to shareholders in connection with the merger. (2003)

- Established significant legal precedent in Texas by successfully arguing creditor's (Lomas Bank USA) privilege from suit to impose liability for false statements negligently made to credit reporting agencies. *Lomas Bank USA v. Flatow*, 880 SW2d 52 (Tex. App.-San Antonio 1994, writ denied).

- Successfully defended First USA Bank against $27,000,000.00 claim involving the sale of various credit accounts. Case settled during trial for $50,000.00. (1995)

- Obtained summary judgment in favor of First USA Bank in two separate class action lawsuits both alleging false credit collection practices in violation of the Fair Credit & Reporting Act. Plaintiffs claimed damages in excess of $90,000,000.00. (1996)

- Successfully represented an employee in trial and appeal of wrongful termination action. Appellate decision was termed as "the most significant case in employment wrongful termination in Texas" during the 1990s. Case ultimately settled after affirmance by Texas Supreme Court. *Higginbotham v. Allwaste, Inc.*, 889 SW2d 411 (Tex. App.-Houston [14th Dist.] 1994, writ denied).

Environmental Litigation cases:

- Successfully represented plaintiffs in a class action regarding the Oil Spill by the Oil Rig "Deepwater Horizon" against *Halliburton Energy Services, Inc./Transocean, et al.* Settlement in excess of $1,200,000,000. (2015)

- Successfully represented plaintiffs in a class action regarding the Oil Spill by the Oil Rig "Deepwater Horizon" against *BP, P.L.C., et al*. Served as a Committee Chair in the matter, which ultimately settled for $7,800,000,000. (2012)

- Successfully represented Plaintiffs residing around a landfill in San Patricio County, Texas, whose property had been contaminated. Obtained total settlements of $12,500,000.00 after obtaining a verdict in favor of certain Bellwether plaintiffs in an eight-week jury trial. (2001 and 2004)

- Successfully represented plaintiffs residing in an oilfield in Brookhaven, Mississippi, whose property had been contaminated. Obtained a confidential settlement after obtaining a verdict in favor of certain Bellwether plaintiffs in a seven-week jury trial. (2002)

- Successfully defended hazardous waste disposal facility against environmental claims stemming from the disposal of wastes at the MOTCO superfund site. Plaintiff sought $27,000,000.00 solely from client for environmental clean-up costs. Retained to defend the action by Aetna, Hartford, Protective National, and National Automobile & Casualty. The action settled before trial for $125,000.00. (1996)

- Represented apartment tenants in action for damages resulting from chlordane exposure. Case settled before trial for in excess of $4,000,000.00. (1995)

BIOGRAPHIES

Partners:

Thomas E. Bilek, born Oakpark, Illinois, July 22, 1962; admitted to Texas bar, 1986. Admitted to practice before U.S. Supreme Court; U.S. Court of Appeals, Fifth Circuit; U.S. Claims Court; U.S. District Courts, Northern, Southern, Western, and Eastern Districts of Texas. Preparatory education: University of Texas (B.A. Economics, magna cum laude, Special Honors, 1983). Legal education: Southern Methodist University (J.D., 1986). Briefing Attorney to Chief Justice Brown, 14th Court of Appeals, 1986-87. Recipient, American Jurisprudence Awards, Real Property I and UCC Law, SOUTHWESTERN LAW JOURNAL, 1984-85. Author: "Accountant's Liability to Third Parties and Public Policy: A Calabresi Approach," 34 S.W.L.J. 689, 1985. Member: State Bar of Texas; Bar Association of the Fifth Federal Circuit; American Association for Justice. Life Member of Who's Who. Life Fellow of Texas Bar Foundation.

Kelly Cox Bilek, born Dallas, Texas, June 26, 1968; admitted to Texas Bar, 1993. Admitted to practice before U.S. Court of Appeals, Fifth Circuit, and U.S. District Courts, Northern, Southern, Eastern, and Western Districts of Texas. Preparatory education: Texas Christian University (B.A. History, PHI BETA KAPPA, magna cum laude, Departmental Honors, 1990). Legal education: The University of Texas School of Law (J.D., 1992). Research Assistant to Professor Jack Ratliff. Member, THE REVIEW OF LITIGATION and The Board of Advocates. Intern to Justice Raul A. Gonzalez, The Supreme Court of Texas. Member, The College of the State Bar of Texas.

Marc Dann Declaration in Support of Motion for Class Certification

Exhibit 3

COOPER LAW FIRM

1525 Religious Street
New Orleans, Louisiana 70130
Telephone: (504) 399-0009
Fax: (504) 309-6989
www.clfnola.com
Celeste Brustowicz
Licensed in LA-CA-MS
cbrustowicz@clfnola.com

Celeste Brustowicz

Cooper Law Firm
1525 Religious Street
New Orleans, LA 70130
January 2020

Education: Bachelor of Arts in Political Science, Louisiana State University (1985)
Juris Doctorate, Louisiana State University, Paul M. Herbert School of Law (1985)

Bar Admissions:

Louisiana	16835 (1985)
California	238686 (2007)
Mississippi	104041 (2011)

Bar Appointments: Louisiana Bar Examiner (Torts)

Significant Litigation:

Class Actions:

Adrian Caliste v Harry Cantrell, United States Court of Appeals for the Fifth Circuit, No. 17-30831 (Civil Rights);

Aguzin v. Bristol Meyers-Squibb, et al., United States Court of Appeals for the Fifth Circuit, No. 03-30377 (Torts/Negligence, Product Liability, Personal Injury);

Batiste-Swilley v. City of Baton Rouge et al., United States District Court, Middle District of Louisiana, No. 3:17-CV-00443 (Civil Rights);

Cain et al., v New Orleans City et al., United States District Court, Eastern District of Louisiana, No. 2:15-CV-04479 (Civil Rights);

Caliste et al v. Cantrell, United States District Court, Eastern District of Louisiana, No. 2:17-CV-06197 (Civil Rights);

Carlisle v. Normand, et al., United States District Court, Eastern District of Louisiana, No. 2:16-CV-03767 (Prisoner Rights/Civil Rights);

Crawford et al. v. Louisiana State et al., United States District Court, Eastern District of Louisiana, No. 2:14-CV-01190 (Civil Rights/Employment);

Imani et al., v. City of Baton Rouge et al., United States District Court, Middle District of Louisiana, No. 3:17-CV-00439 (Civil Rights);

John Kitchin, et al. v Bridgeton Landfill, et al., United States Court of Appeals for the Eighth Circuit, No. 19-8010 and *John Kitchin, et al. v. Bridgeton Landfill, et al.*, United States Court of Appeals for the Eighth Circuit, No. 19-2072 (Other Federal Statutes);

Kitchin et al v. Bridgeton Landfill, LLC, United States District Court, Eastern District of Missouri, No. 4:18-CV-00672 (Other Federal Statutes);

Jeff Quon, et al., v. Arch Wireless Inc., et al., United States District Court, Central District of California, No. 5:03-CV-00199 (Other Federal Statutes); (Went to US Supreme Court)

McGlone et al v. Centrus Energy Corp. et al., United States District Court, Southern District of Ohio, No. 2:19-CV-02196 (Class Action);

McKesson et al. v City of Baton Rouge et al., United States District Court, Middle District of Louisiana, No. 3:16-CV-00520 (Civil Rights);

Robert Bernhard et al., v. City of Ontario et al., United States District Court, Central District of California, No- 5:04-CV-01015 and *Robert Bernhard v. City of Ontario et al.*, United States District Court, Central District of California, No. 2:08-CV-05539 (Civil Rights);

Smith et al. v. City of Baton Rouge et al., United States District Court, Middle District of Louisiana, No. 3:17-CV-00436 (Civil Rights);

Steward et al. v. Honeywell International, Inc., United States District Court, Southern District of Illinois, No. 3:18-CV-01124 (Class Action);

Taylor Carlisle, et al., v. Newell Normand, et al., United States Court of Appeals for the Fifth Circuit, No. 18-30002 (Prisoner Rights, Civil Rights);

Taylor Carlisle, et al., v. Tracy Mussal, et al., United States Court of Appeals for the Fifth Circuit, No. 18-90004 (Appeals);

Tennart et al., v. Baton Rouge et al., United States District Court, Middle District of Louisiana, No. 3:17-CV-00179 (Civil Rights);

TruSouth Oil LLC v. Burlington Insurance Co. et al., United States District Court, Western District of Louisiana, No. 5:11-CV-00493 (Torts/Negligence, Personal Property, Property Damage Product Liability);

Wager v. Bristol-Myers Squibb, et al., United States District Court, Eastern District of Louisiana, No. 2:03-CV-00188 (Torts/Negligence, Personal Property, Property Damage Product Liability);

Mary Elizabeth Leger, et al., v. John N. Kent, D.D.S. et al., Civil District Court of Orleans Parish Louisiana, Division G, No. 1992-20925 (Medical Device);

Vajas, Judy Lucy v. Medical Center of Louisiana, Civil District Court of Orleans Parish Louisiana, Division I, No. 2003-13771 (Blood Transfusion);

MDL Litigation:

Bitetti v. Davol Inc., et al., United States District Court, Southern District of Ohio, No. 2:19-CV-00232) (Torts/Negligence, Product Liability, Personal Injury);

Goodale v. Davol, Inc., et al., United States District Court, Southern District of Ohio, No. 2:19-CV-03414 (Torts/Negligence, Product Liability, Personal Injury);

Kenny v. Davol, Inc., et al., United States District Court, Southern District of Ohio, No. 2:19-CV-03417 (Torts/Negligence, Product Liability, Personal Injury);

Perez v. Davol, Inc. et al., United States District Court, Southern District of Ohio, No. 2:19-CV-03424 (Torts/Negligence, Product Liability, Personal Injury);

Putman v. Davol, Inc. et al., United States District Court, Southern District of Ohio, No. 2:19-CV-03426 (Torts/Negligence, Product Liability, Personal Injury);

Sturgill v. Davol, Inc. et al., United States District Court, Southern District of Ohio, No. 2:19-CV-03428 (Torts/Negligence, Product Liability, Personal Injury);

In re: Davol, Inc./C.R. Bard, Inc. Polypropylene Hernia Mesh Products Liability Litigation, United States District Court, Southern District of Ohio, No. 2:18-MD-02846 (Torts/Negligence, Personal Injury, Other Federal Actions);

Major Environmental Representations:

Waste Services of Decatur LLC v. Decatur County, TN v. Waste Industries, LLC, United States District Court, Western District of Tennessee, No. 1:17-CV-01030 (Other Statutory Actions);

Michael Dailey, et al., v. Bridgeton Landfill, LLC, et al., United States District Court, Eastern District of Missouri, No. 4:17-CV-00024 (Other Statutory Actions);

Tamia Banks et al., v. Cotter Corporation, et al., Twenty-First Judicial Circuit of the State of Missouri, No. 18SL-CC00617-01 (Other Statutory Actions);

Marc Dann Declaration in Support of Motion for Class Certification

Exhibit 4

Scott R. Bickford
Martzell, Bickford & Centola
338 Lafayette St.
New Orleans, LA 70130
504-581-9065 January 2020 **Srb@mbfirm.com**

Education: B.A. in Political Science, Tulane University (1978)
Juris Doctorate, Tulane Law School (1982).

Bar Admissions:

Louisiana	01165
Texas	02295200
Colorado	021496

Publications:

"Restricting Lawyers' Solicitation of Victims," **ABA The Brief**, Vol. 25 No. 7, 1995.

Teaching Appointments:

Associate Professor Tulane Law School, Lecturer in Law and Co-Director of Trial Advocacy Program (Sept. 2014 to present);

Adjunct Professor of Trial Advocacy, Tulane Law School (2008 to 2014);

Litigation Appointments

Chair, Ad Hoc NAS Baby Committee, Purdue Bankruptcy.

NAS Representative and Class Attorney for INSYS Bankruptcy Medical Surveillance Certified Class;

Member Ad Hoc Lawyer Disciplinary Committee, US District Court Eastern District of Louisiana (2014 to present: DWH matters);

MDL Plaintiffs' Steering Committee member, *In Re: Pool Products Distribution Marketing Antitrust Litigation*, United States District Court, Eastern District of Louisiana, C.A. MDL No. 2328, Multi-District Litigation, Section R, Magistrate 2; (Consumer products/ Anti-trust litigation concerning distribution of swimming pool products) (2012 to 2016);

MDL Liaison Counsel Plaintiffs' Steering Committee, *In Re: Apple iPhone 3G and 3G-S "MMS' Marketing and Sales Practices Litigation*, United States District Court, Eastern District of Louisiana, C.A. 2:09-md-02116, Multi-District Litigation, Section J, Magistrate 1; (Consumer products litigation against Apple and AT&T) (2009 - 2012);

MDL Lead Trial Counsel, *In Re: Welding Fume Products Liability Litigation, Ernesto G. Solis v. Lincoln Electric Company, et al,(*welding fume litigation alleging brain damage to welders) United States District Court, Northern District of Ohio, Eastern Division, C.A. No. 1:04-CV-17363, MDL Docket No. 1535;

Plaintiff Steering Committee, Co-Trial Chair in *Patrick Joseph Turner, et al. v. Murphy Oil USA, Inc.*, United States District Court, Eastern District of Louisiana, C.A. No. 05-4206, Section L, Magistrate 2 (environmental oil spill at Murphy Refinery in St. Bernard Parish, Louisiana, following Katrina);

Court Appointed Receiver, for Louisiana Interests, Inc. (The OZ Bar), *John L. Chisholm, Jr. vs. Doyle G. Yeager, et al*, Civil District Court, New Orleans, LA, C.A. No. 13-6325 (2013-2014);

Court Appointed Special Master, *Billieson, et al. v. City of New Orleans, et al.*, Civil District Court, New Orleans, LA, C.A. No. 94-19231 (class action of hundreds of lead poisoned children) (2013-2016);

Court Appointed Special Master, *Alvendia vs. Alvendia*, (Domestic Dispute/ Distribution of Legal Fees) Civil District Court, New Orleans, LA, C.A. No 2006-452; (2010-2011);

Expert witness in re *Sigma Delta, LLC, et al v. Eric R. George, M.D., et al*, (Expert on Attorney Fees) United States District Court, Eastern District of Louisiana, C.A. No. 07-5427, Section "K", Magistrate "I" (2009);

Expert Witness in re AAA Case No. 69 180 00011 01 - *LeBlanc & Waddell, L.L.C. v. F. Gerald Maples and F. Gerald Maples, A Professional Association* - New Orleans, Louisiana c/w AAA Case No. 69 180 00239 01 - *F. Gerald Maples, P.A. - A Professional Law Corp. v. Jules B. LeBlanc, III; J. Burton LeBlanc, IV; Cameron R. Waddell* (2002) (Expert on Attorney Fees);

Court Appointed Liquidator, Ardoin & Tanet (liquidation of a plaintiffs' law firm/fee distribution);

Assistant Bar Examiner, Louisiana State Bar Association, Code I (1990 to Present);

Committee Member, Creditors Committee, Babcock and Wilcox Bankruptcy (2001 to 2008).

Significant Litigation:

Lead Trial Counsel, *In Re: Welding Fume Products Liability Litigation, Ernesto G. Solis v. Lincoln Electric Company, et al,(*welding fume litigation alleging brain damage to welders) United States

District Court, Northern District of Ohio, Eastern Division, C.A. No. 1:04-CV-17363, MDL Docket No. 1535;

Co-Lead Trial Counsel, *Patrick Joseph Turner, et al. v. Murphy Oil USA, Inc.*, United States District Court, Eastern District of Louisiana, C.A. No. 05-4206, Section L, Magistrate 2 (environmental oil spill at Murphy Refinery in St. Bernard Parish, Louisiana, following Katrina);

USA vs. Edwin Edwards, et al, United States District Court, Eastern District of Louisiana, C.A. No. 85-078, (criminal representation of Marion Edwards);

United States of America v. Donald L. Beckner, (Beckner was indicted former US Attorney) United States District Court, Middle District of Louisiana, C.A. No. 93-0060-1, Section B;

State of Louisiana vs. Texaco, et al (Counsel for Sen. Russell Long/ Lawton Family Interests), United States District Court, Middle District of Louisiana, State of Louisiana suit to recover unpaid oil and gas royalties by Texaco. Resulted in over a 2 Billion Dollar settlement. C.A. No. 88-998-A;

Lead Counsel, *Clara Provosty Johnson, et al vs. Ashland Oil, Co., et al.*, 16th JDC for the Parish of St. Mary, State of Louisiana, C.A. No. 89517, Division A (filed March 2, 1992) leading to the decision to exempt mesothelioma from workman compensation coverage and allow tort suits;

Lead Counsel, *Louis "Woody" Jenkins vs. Secretary of State, et al.* (Counsel for Senator-Elect Mary Landrieu) (Election Contest involving Senator-Elect Mary Landrieu) (1996 - 19th JDC Baton Rouge);

Counsel, In re: *United States Senate in the Matter of the Senate Seat from Louisiana*, 105th Congress (1997) (Counsel for Senator-Elect Mary Landrieu);

Lead Trail Counsel, *Dennis Mullins, et al. v. Treasure Chest Casino, LLC*, U. S. Court of Appeals for the Fifth Circuit, Case No. 97-31189 - 186 F.3d 620, 5th Cir.(La.) (Certified Class Action of indoor smoke environmental case for crew members on Treasure Chest Casino);

Lead Trial Counsel, *Roshto v. Transocean*, LLC, United States District Court, Eastern District of Louisiana, C.A. No. 2:10- C.V.-01156 (First filed case from Deepwater Horizon involving the death of a crewman) (2010);

Counsel, *In the Matter of P&E Boat Rentals*, 872 F.2d 642 (1989).

Major Environmental Representations:

Oil Spill Task Force, MDL- 2179, Deepwater Horizon Oil Spill (2010 to 2013) took multiple depositions of principal witnesses;

Plaquemines Parish, Louisiana - Lead Special Appointed Counsel for parish-wide damages arising from Deepwater Horizon Spill (also counsel for the Port of Plaquemines; Plaquemines Parish School Board; the Town of Grand Isle, Louisiana; and Cameron Parish Louisiana) (2011 to present) USDC, Eastern District of Louisiana, CA. No. 10-2771;

Lafourche Basin Levee District - Marsh Damage/Land Loss/Oilfield Waste, *Lafourche Basin Levee District v. Texaco*, 17th JDC CA No. 81,858 D (1997);

West Jefferson Levee District - Marsh Damage/Land Loss/Oilfield Waste (1997);

Plaquemines Parish, Louisiana - Special appointed counsel for parish- wide litigation of oil field waste (2002 to present); 24th JDC CA No. 48-080 (A); 24th JDC CA No. 48-614 (A); 24th JDC CA No.53-387;

Lafourche Parish School Board - Marsh Damage/Land Loss/Oilfield Waste (1998);

St. Mary Parish School Board - Marsh Damage/Land Loss/Oilfield Waste (2001);

Vermilion Parish School Board - Oil Royalties Litigation (2005 to Present);

Oil Spill Class Litigation, Lead Class Counsel: *Tinson v. Bass*, USDC , Eastern District of Louisiana, CA. No. 2005-4512; *Barasich v. Shell*, USDC Eastern District of Louisiana, CA No. 2005-4180; *Blanchard vs. Sundown Energy*, CA No. 2005-4198; *Cvitanovich v. Shell Pipeline Co.*, USDA, Eastern District of Louisiana, CA. No. 2008-312.

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Exhibit 5

CURRICULUM VITAE

Kanwaljeet S. Anand

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12/7/2019

CURRICULUM VITAE

Name: **Kanwaljeet S. Anand**

Address: 770 Welch Road, #435, Palo Alto, CA 94304

Education:

1981	M.B.B.S.	Mahatma Gandhi Memorial Medical College, University of Indore, Indore, India.
1986	D.Phil.	Jesus College, University of Oxford, Oxford, U.K.
1991	F.A.A.P.	American Academy of Pediatrics, Elk Grove Village IL, USA
1997	F.R.C.P.C.H.	Royal College of Pediatrics and Child Health, London, U.K.
1998	F.C.C.M.	American College of Critical Care Medicine, Anaheim CA, USA.

Postdoctoral Training:

1980 - 1980	Intern, Maharaja Yeshwantrao Hospital, Indore, India
1980 - 1981	Intern, Hindu Rao Hospital, Delhi, India
1981 – 1982	House Officer, Department of Pediatrics, Maharaja Yeshwantrao Hospital, Indore, India
1982 - 1983	Senior House Officer, Special Care Baby Unit, Department of Paediatrics, John Radcliffe Hospital, Oxford, U.K.
1988 - 1991	Internship and Residency in Pediatrics, Department of Medicine, Children's Hospital, Boston, Massachusetts, U.S.A.
1991 – 1993	Clinical Fellow, Neonatal and Pediatric Intensive Care Units, Massachusetts General Hospital, Boston, Massachusetts, U.S.A.

Licensure and Certification:

1981	Registered Medical Practitioner, Madhya Pradesh Board, Bhopal, India.
1982	Limited Registration, General Medical Council, London, U.K.
1988	Massachusetts Board of Registration in Medicine, Boston, MA, (License No. 75047)
1991	Board Certification in Pediatrics, American Board of Pediatrics (valid 1991-1998)
1993	Composite State Board of Medical Examiners, Atlanta, GA (License No. 037123)
1993	Controlled Substance Registration, Drug Enforcement Administration, U.S. Department of Justice (License No: BA2998687, expires June 30, 2018)
1994	Board Certification, Sub-Board in Pediatric Critical Care, American Board of Pediatrics (Re-certified in 2004 and 2014, expires December 31, 2023)
1994	Basic Life Support (BLS Certification), American Heart Association (expires August, 2019)
1994	Pediatric Advanced Life Support (PALS Certification), American Heart Association (expires August, 2019)
1995	Advanced Cardiac Life Support (ACLS Certification), American Heart Association (expires August, 2019)
1997	Arkansas State Medical Board, Little Rock, Arkansas (License No. E-1508)
2009	Board of Medical Examiners, Nashville, Tennessee (License No. MD045154)

2015	The Medical Board of California, Sacramento, CA (License No. C138692)
2016	Advanced Trauma Life Support, American College of Surgeons (No. 644546) (expires April 16, 2020).

Academic Appointments:

1983 - 1985	Rhodes Scholar and Research Fellow, University Department of Paediatrics, University of Oxford, Oxford, U.K.
1985 - 1988	Research Fellow in Anesthesia, Harvard Medical School, Boston, MA.
1988 - 1991	Clinical Fellow in Pediatrics, Harvard Medical School, Boston, MA.
1991 - 1993	Fellow in Pediatrics, Harvard Medical School, Harvard University, Boston, MA.
1993 - 1997	Assistant Professor of Pediatrics and Anesthesia, Emory University School of Medicine, Atlanta, GA.
1994 - 1997	Assistant Professor of Psychiatry and Behavioral Sciences, Emory University School of Medicine, Atlanta, GA.
1994 - 1997	Director for Critical Care Research, Department of Pediatrics, Emory University School of Medicine, Atlanta, GA.
1995 - 1996	Interim Director, Office for Research Promotion, Department of Pediatrics, Emory University School of Medicine, Atlanta, GA.
1997 - 2000	Associate Professor of Pediatrics and Anesthesiology, College of Medicine, University of Arkansas for Medical Sciences, Little Rock, Arkansas.
1997-2003	Section Chief, Critical Care Medicine, Department of Pediatrics, University of Arkansas for Medical Sciences, Little Rock, Arkansas.
1998 - 2000	Associate Professor of Anatomy & Neurobiology, College of Medicine, University of Arkansas for Medical Sciences, Little Rock, Arkansas.
2001-2009	Professor of Pediatrics, Anesthesiology, Pharmacology, Neurobiology & Developmental Sciences, College of Medicine, University of Arkansas for Medical Sciences, Little Rock, Arkansas.
2001-2009	Morris & Hettie Oakley Endowed Chair for Critical Care Medicine, University of Arkansas for Medical Sciences, Little Rock, Arkansas.
2009-2014	St. Jude Chair for Excellence in Critical Care Medicine; St. Jude Children's Research Hospital, Memphis, TN.
2009-2015	Professor of Pediatrics, Anesthesiology, Anatomy & Neurobiology, Principal Investigator, UT Neuroscience Institute, University of Tennessee Health Science Center, Memphis, TN.
2015-2016	Division Chief, Pediatric Critical Care Medicine, Department of Pediatrics, Stanford University School of Medicine, Palo Alto, CA.
2015-present	Professor of Pediatrics, Anesthesiology, Perioperative & Pain Medicine, Stanford University School of Medicine, Palo Alto, CA.

Professional Awards

1982-1985	Rhodes Scholarships for India, University of Oxford, U.K.
1986	***Dr. Michael Blacow Award*** for the Best Paper presented at the 58th Annual Meeting of the British Paediatric Association, York, U.K.
1989	The ***Von L. Meyer Award for Research*** at Children's Hospital, Boston.
1992	***Pediatric Resident Research Award***, American Academy of Pediatrics

1994	Inaugural recipient, ***Young Investigator Award in Pediatric Pain***, International Association for the Study of Pain, Special Interest Group for Pain in Children, Philadelphia, PA.
1995	6th Annual ***Dr. Fred J. Vlazny Humanitarian Award*** and Visiting Professorship, Medical College of Wisconsin, Milwaukee WI.
2000	***Jeffrey Lawson Award for Advocacy in Children's Pain Relief***, 19th Annual Scientific Meeting, American Pain Society
2001	Inaugural Recipient, ***Morris & Hettie Oakley Endowed Chair for Critical Care Medicine***, University of Arkansas for Medical Sciences and Arkansas Children's Hospital, April 13th, 2001.
2007	The ***Father Joseph Biltz Award*** from JCCA (formerly the NCCJ of Arkansas) for promoting inter-faith harmony in Arkansas.
2007	***Joan M. Cranmer "Mentor of the Year" Award***, Department of Pediatrics, University of Arkansas for Medical Sciences.
2008	***"Salute to Greatness" Individual Award*** from the Dr. Martin Luther King Commission, State of Arkansas, January 18th, 2008.
2006-2008	**Vice-Chair and Chair of the Research Committee**, Society of Critical Care Medicine
2009	***The Nils Rosén von Rosenstein Award*****,** an international award given to Pediatricians every 5 years by the Swedish Society of Medicine & Swedish Paediatric Society, April 23, 2009.
2010	Inaugural recipient, ***The St. Jude Chair of Pediatric Critical Care Medicine***, University of Tennessee Health Science Center and St. Jude Children's Research Hospital, March 31st, 2010.
2011	***Mentor Award***, School of Graduate Studies, University of Arkansas for Medical Sciences, July 2011.
2013	9th Annual ***"In Praise of Medicine Award"***, Erasmus University Centenary Celebration, Faculty of Medicine, Rotterdam, The Netherlands; October 4, 2013.
2015	***Journées Nationales de Néonatologie,*** Keynote Address at The Pasteur Institute, Paris, France; March 26th, 2015.
2015	***Respect for Nursing Award*** from the PICU Nurses and Nursing Leadership, Lucile Packard Children's Hospital, Palo Alto, CA.
2016	***Nightingale Excellence Award***, the only physician who has received this honor by Stanford Children's Healthcare and Lucile Packard Children's Hospital, Stanford University, Palo Alto, CA; October 25th, 2016.
2019	***Honorary Doctorate***, Faculty of Medicine and Health, University of Örebro, Örebro, Sweden.

Honors and Professional Recognition:

1968-1974	Merit Certificates, The Daly College, Indore, India
1975	M.P. State Science Talent Scholarship, Madhya Pradesh, India
1977-1978	Merit Students Scholarship, University of Indore, India
1977	University Gold Medal for Anatomy, University of Indore, India
1987	Listed in ***American Men and Women in Science***
1988	Honorary Life Membership in the National Neonatology Forum, India.
1989	Keynote Address: First European Conference on Pediatric Pain, June 1989,

	Maastricht, The Netherlands
1990	Keynote Address: 44th Annual Congress, Svensk Forening for Anesteshioch Intensivvard, Huddinge, Sweden.
1990	Keynote Address: 4th Annual John Lind Symposium, Trollhattan, Sweden.
1991	Who's Who Among Rising Young Americans, Citation Directories, USA.
1992	Men of Distinction, Cambridge University Press, Cambridge, U.K.
1993	International ***Who's Who in Medicine***
1993	International Scientific Committee, 3rd International Meeting of Pediatric Intensive Care, Padova, Italy.
1993	Scientific Planning Committee, Symposium on Pain and Stress in the Newborn, National Institute of Child Health and Human Development.
1994	Co-Chair, NICHD Symposium on "Neonatal Pain: Physiology and Management", June 1994, Philadelphia PA, U.S.A.
1995	Moderator for Maternal and Newborn Health Symposium in Child Health 2000, 2nd World Congress & Exposition, May 30 - June 3, 1995, Vancouver, Canada
1995	Keynote Address: Nordic Congress on Children and Pain, September 7-9 1995, Stockholm, Sweden.
1995	Keynote Address: XVII Annual Congress of the Dutch Paediatric Association, November 1, 1995, Veldhoven, The Netherlands.
1996	International Scientific Committee, 2nd World Congress on Pediatric Intensive Care, June 1996, Rotterdam, The Netherlands.
1996	Plenary Lecturer in Pediatric Pain, 8th World Congress on Pain, International Association for the Study of Pain, August 17-22 1996, Vancouver (B.C.).
1997	International Scientific Advisory Committee, 4th International Symposium on Pediatric Pain, International Association for the Study of Pain, Helsinki, Finland.
1997	Member of the U.S. Rhodes Scholars Selection Committee, State of Arkansas.
1997	Member, International Selection Committee for the 2nd Young Investigator Award for Pediatric Pain, Special Interest Group on Pediatric Pain, International Association for the Study of Pain.
1997	Elected to Fellowship, Royal College of Paediatrics & Child Health, U.K.
1998	Elected to Fellowship of the American College of Critical Care Medicine.
1998	Listed in Marquis' *Who's Who in Science and Technology*
1999	Chairman, 2nd International Consensus Conference on Guidelines for Procedural Pain Management in Infants, August 21, 1999; Baden, Austria.
1999	Keynote Address : International Symposium on "Basic Mechanisms and Recent Advances in Pediatric Pain", German Pediatric Association, University of Erlangen, Kloster Weltenberg, Germany, October 29-31, 1999.
1999	Keynote Address: IIIrd Congreso Internacional De Clinica Del Dolor Y Cuidados Paliativos, Asociacion Mexicana De Algologia A.C., Ciudad y Puerto de Veracruz, Veracruz, México, October 31st to November 2nd, 1999.
1999	Keynote Address: Fifth Greater Tulsa Area Pain Conference, University of Oklahoma, Tulsa OK, October 1, 1999.
1999	Plenary Podium Presentation: 52nd Annual Meeting, American Academy of Pediatrics, Washington DC, October 9th to 15th, 1999.
1999	Member, Board of Directors, Arkansas Children's Hospital Research Institute
2000	Keynote Address: International Symposium on Infant Pain, Karolinska

Institute, Stockholm, Jan 25th, 2000.

2000 Keynote Address: Danish Pediatric Society, University Hospital of Copenhagen, Denmark, Jan 21st, 2000.

2000 Keynote Speaker: "Pain in Children: Conquering the Hurt", The Hospital for Sick Children, Pain Awareness Week, Toronto, March 31st, 2000.

2000 Co-Chair, Pharmacology, Pain & Sedation Track, 3rd World Congress of Pediatric Intensive Care, Montreal, Canada, June 24-29, 2000.

2000 Plenary Lecture, 5th International Symposium on Pediatric Pain, Special Interest Group for Pain in Children, International Association for the Study of Pain, London, U.K., June 19th, 2000.

2000 Public Lecture, The European Institute of Health and Medical Sciences at the University of Surrey, Chertsey, Surrey, U.K.; June 21st, 2000.

2000 Plenary Speaker, 3rd World Congress on Pediatric Intensive Care, Montreal, Canada; June 26th-29th, 2000.

2000 ***Baxter Plenary Speaker***, 6th Annual Meeting of the Society for Pediatric Anesthesia, Sanibel, FL.

2001 Keynote Address: 10th Annual Symposium on Neonatal-Perinatal Medicine, University of Michigan, Ann Arbor, MI; April 26th, 2001.

2001 Listed in ***Strathmore's Who's Who***, 2001-2002 Edition

2001 Plenary Presentation, 14th Annual Meeting of the Canadian Pain Society, Montreal, Canada, May 10th, 2001.

2001 Keynote Speaker, 3rd Nordic Congress on Pain in Children, Stockholm, Sweden, Sept 12th, 2001.

2002 Honorary Secretary, U.S. Rhodes Scholarships Selection Committee, State of Arkansas

2002 Steering Committee Member, National Summit on Race 2002, Little Rock

2002 Editorial Board, *Critical Care Medicine,* Williams & Wilkins Publishers

2002 Editorial Board, *Biology of the Neonate,* Karger A.G. Publishers

2002 Pfizer Visiting Professorship in Pain Medicine, Department of Pediatrics, Wayne State University and Detroit Children's Hospital, Detroit, MI, June 3-6, 2002.

2002 Member of the National Planning Group, NICHD/FDA Newborn Drug Development Initiative

2002 Plenary Speaker, 18th European Congress of Perinatal Medicine, June 19 – 22, 2002, Oslo, Norway.

2002 Keynote Speaker, 28Th Annual Congress, German Society of Neonatology and Pediatric Intensive Care, June 27 – 29, 2002, Mainz, Germany.

2002 Keynote Speaker, 4th International Forum on Pediatric Pain, September 19 - 22, 2002, White Point Beach, Nova Scotia, Canada.

2002 Keynote Speaker, International IPOKRaTES Seminar on "Neonatal Comfort and Care" Oct 10-12, 2002, Gmunden, Austria.

2002 ***Lesley Cooper Memorial Lecture***, 20th Neonatal Course for Senior Paediatricians, Imperial College of Medicine, November 25-29, 2002, London, England.

2003 Member of the Research Committee, Society of Critical Care Medicine.

2003 Pfizer Visiting Professorship in Pain Medicine, Department of Pediatrics, Baylor University and Texas Children's Hospital, Houston TX, Feb 19-21, 2003.

2003 ***Arnold J. Rudolph Memorial Grand Rounds***, Department of Pediatrics, Baylor University and Texas Children's Hospital, Houston, TX.

2003 ***Chairman, Neonatal Pain Task Force***, FDA/NICHD Newborn Drug Development Initiative

2003 Keynote Address, Opening Ceremony of the EURAIBI (Europe Against Infant Brain Injury) Congress, June 6, 2003, Siena, Italy (live broadcast of opening ceremony to 125 countries by Reuters International).

2003 ***Chairman, Pharmacology, Analgesia & Sedation Track***, 4th World Congress on Pediatric Intensive Care, Boston MA, June 16-20, 2003.

2003 Listed in ***Who's Who in America***, 58th Edition, Marquis Who's Who, Inc.

2003 Member, Pediatric Pharmacology Research Study Section (ZHD1 DSR-A-01), National Institute for Child Health and Human Development

2003 Keynote Address: Annual Meeting of the Perinatal Research Society, Charleston SC, September 12-14, 2003.

2003 Member, Pediatrics Subcommittee Study Section (ZHD1 CHHD-A-01), National Institute for Child Health and Human Development

2004 ***Windermere Honorary Lecturer*** (presented to Her Royal Highness Princess Anne), 8th Spring Meeting, Royal College of Paediatrics and Child Health, York (UK).

2004 Expert Witness, U.S. Supreme Court, Department of Justice for the Partial-Birth Abortion Ban Act of 2003, April 6th, 13th and 15th, 2004.

2004 Keynote Speaker, 4th Nordic Congress on Children and Pain, Linköping, Sweden; May 5-7, 2004.

2004 Member, Loan Repayment Program Study Section (ZHD1 DSR-A LRP), National Institute for Child Health and Human Development.

2004 Keynote Speaker, 10th International Postgraduate Course in Neonatal Intensive Care, Buenos Aires, May 17-19, 2004.

2004 ***Laurie Edmunds Keynote Speaker***, University of Massachusetts Medical School, June 2, 2004, Marlboro, MA.

2004 International Editorial Board, ***Anestesia Pediatrica e Neonatale*** (Pediatric and Neonatal Anesthesia)

2004 Elected to membership of the ***American Pediatric Society***

2005 Listed in ***Who's Who in America***, 2005 (59th Edition), Marquis' Who's Who, Inc.

2005 Editorial Board, ***Pain,*** official journal of the International Association for the Study of Pain.

2005 John S. Liebeskind Visiting Professorship, Departments of Pediatrics, Medicine, Psychology, History, Sociology, Anthropology, University of California at Los Angelis, April 29th, 2005.

2005 ***"World News Tonight" for ABC News*** Interviewed for the latest research on pain in infants and children, May 10th, 2005.

2005-2006 **Vice-Chair, Research Committee, Society of Critical Care Medicine**.

2005 Faculty Advisor, Graduate School of Studies, University of Arkansas for Medical Sciences

2005 VIP Member, *Continental Who's Who* registry of National Business Leaders.

2005 Arkansas Hospital Association, Judges' Merit Award in Advertising (3rd place in the Special Visuals Category for Dr. Martin Luther King Day lecture).

2005 Expert Witness testimony in relation to the **Unborn Child Pain Awareness**

Act of 2005 (H.R. 356), before the Subcommittee on the Constitution, U.S. House Committee on the Judiciary, 109th U.S. Congress, November 1st, 2005.

2005 ***Gregory Mark Taubin Distinguished Lecturer*** at Children's National Medical Center, Department of Pediatrics, George Washington University School of Medicine, Washington DC, December 7th, 2005.

2006 ***Inaugural Visiting Professor***, University of Utah School of Pharmacy, Department of Pharmaceutics, January 10th, 2006.

2006 Pfizer Visiting Professor in Pain Medicine, Department of Pediatrics, University of Utah and Primary Children's Hospital, Salt Lake City, January 10-12, 2006.

2006 Member of the ALSDAC Committee of the Food & Drug Administration (FDA), U.S. Public Health Service, Department of Health & Human Services

2006 Chairman, Special Task Force for Anesthesia & Analgesia Drugs, National Institute for Child Health & Human Development.

2006 Study Section Member, National Institute for Mental Health

2006 Study Section Member, Clinical Trials Division, National Heart, Lung & Blood Institute

2006 Keynote Speaker, 12th Annual Ruth Rappaport Seminar on Pediatric Pain Management: The Technion: Israel Institute of Technology, Haifa, Israel.

2006 Keynote Address, 2006 Annual Meeting, Society for Pediatric Anesthesia, Chicago, IL.

2006 Research work cited by Dr. Jane Qiu in ***Nature*** 444(9): 143-145, 2006.

2007 Member, Special Emphasis Panel, NIH/National Center for Research Resources

2007 Member, Future of Research Task Force, Society of Critical Care Medicine

2007 The Medical Home Model for Children After Life-threatening Illness or Injury: Member of a National Experts' Panel

2007 Member, Special Emphasis Panel, NIH/National Institute for Neurological Disorders and Stroke

2007-2013 ***American Board of Pediatrics***, Sub-Board of Critical Care Medicine, 6-year term (2007-2013).

2007 Featured speaker, ***The 'Child in Mind' Project*** for training Pediatric Faculty by The Royal College of Pediatrics & Child Health

2007-2013 Listed in *America's Top Pediatricians*, Consumers' Research Council of America

2007 Featured speaker, "Dispatches" Program: *Abortion - What We Need to Know,* reported by Deborah Davies, BBC Channel 4 on October 17th, 2007.

2008 Board Member, Critical Care Educational & Research Foundation, Society for Critical Care Medicine

2008 Keynote Speaker, Special Meeting of the British Parliament (House of Commons) on January 28th, 2008.

2008 Study Section Reviewer, National Institute of Neurological Disorders and Stroke, ZNS1 SRB-M(57), March 10th, 2008.

2008 The **National Academy of Sciences**, Institute of Laboratory Animal Research, Expert Consultant for "Recognition and Alleviation of Pain in Laboratory Animals".

2009 **Keynote Speaker**, Pediatric Palliative Care Conference, University Hospital, University of Medicine and Dentistry of New Jersey, Newark, NJ; October 10,

2009

2009 **6th Annual Josephine Templeton Honorary Lecture**, The Children's Hospital of Philadelphia, Department of Anesthesiology & Critical Care Medicine, Philadelphia, PA; September 24, 2009.

2009 Expert Consultant, Pediatric Analgesic Clinical Trials, Division of Analgesia, Anesthesia, and Rheumatology Products, Center for Drug Evaluation and Research, Food and Drug Administration, Baltimore, MD; December 3, 2009.

2010 Shelby County and Memphis City Council, Certificates of Appreciation for humanitarian service in Haiti, presented on February 16th, 2010.

2010 House of Representatives, State of Tennessee, Joint resolution No. 868: recognizing service in Haiti, passed on May 20th, 2010.

2010 Keynote Speaker, 1st Annual Mississippi Perinatal Association Conference on July 8, 2010.

2010 Community Service Award, ***Memphis Rotary Club***, March 30, 2010.

2010 ***Study Section Member***, Loan Repayment Program, National Institute for Neurological Disorders & Stroke (NINDS), July 2010.

2010 Keynote Speaker, 8th Annual Ron Lemire Symposium on Contemporary Pediatric Critical Care Medicine, University of Washington and Seattle Children's Hospital, August 27th, 2010.

2010 Invited Speaker, "Open Hearts, Open Minds, & Fair Minded Words", International Conference on Life and Choice in the Abortion Debate, Princeton University, October 16, 2010.

2010 Keynote Speaker, Frontiers in Pain Research Lecture Series, McGill University and Alan Edwards Centre for Research on Pain, November 4, 2010.

2011 ***Summit Level Award*** at the MSQPC Quality Award Ceremony, **Greater Memphis Chamber of Commerce**, February 24, 2011

2011 Keynote Speaker, Brain Awareness Week, UT Neuroscience Institute and The Urban Child Institute, March 24, 2011

2011 Member of the Executive Council, Special Interest Group on Pain in Children, International Association for the Study of Pain

2011 Keynote Speaker, Premature Newborn Symposium, Mayanei HaYeshua Medical Center, Bnei Brak, Tel Aviv, Israel, May 10, 2011

2011 ***Scientific Expert***, Anesthetic and Life Support Drugs Advisory Committee (ALSDAC), Center for Drug Evaluation and Research, U.S. Food & Drug Administration

2011 ***AMA Seed Research Grant Award***, received by Dr. Bonny Bardhan from the American Medical Association.

2011 ***Chair, Selection Committee, Distinguished Investigator Award in Pediatric Pain***, on behalf of International Association for the Study of Pain, Special Interest Group for Pain in Children

2011 Keynote Speaker, International Cardiac Surgery Conference, Fortis Escorts Heart Institute & Research Center, New Delhi, India; December 28, 2011

2012 Keynote Speaker, Danish International Conference on Pediatric Trauma in Odense, Denmark; January 16, 2012

2012 ***Inaugural Address***, 2nd International Obstetrie & Neonatologie Congress, Máxima Medisch Centrum Hospital, Veldhoven, The Netherlands, March 8, 2012

2012 ***Sujit & Uma Pandit Visiting Professorship***, Department of Anesthesiology,

University of Michigan Health Systems, Ann Arbor, MI; March 29, 2012

2012 Keynote Speaker, 48th Annual Meeting of the Japanese Society of Perinatal & Neonatal Medicine; Saitama, Japan, July 8 - 10, 2012.

2013 Listed in ***Who's Who in America*** 2002-2013, Marquis Who's Who, Inc.

2013 Listed in *America's Top Doctors,* Castle Connolly Medical, Ltd.

2013 Listed in *Best Doctors in America*, Best Doctors, Inc.

2013 ***Dr. Digby Leigh Distinguished Speaker***, 51st Clinical Conference in Pediatric Anesthesia, University of Southern California and Children's Hospital Los Angeles, Anaheim, CA; February 9, 2013

2013 ***Dr. Jackson Rees Distinguished Lecture***, 14th Jackson Rees Symposium, Sophia Children's Hospital, Rotterdam, The Netherlands; October 5, 2013.

2013 Dean's Faculty Advisory Committee, College of Medicine, University of Tennessee Health Science Center, Executive Dean and Vice Chancellor, Dr. David M. Stern.

2013 Chair, Promotion & Tenure Committee, Department of Pediatrics, University of Tennessee Health Science Center.

2014 Annual Neonatology Keynote, Pediatrics Section, Combined Sections Meeting of the American Physical Therapy Association (APTA), Las Vegas, Nevada; February 4-6, 2014.

2014 Keynote Speaker, 3rd Annual Neonatal & Pediatric Pearls (NAPP) Conference, UCLA Department of Pediatrics and Mattel Children's Hospital, Mumbai, India; February 8-9, 2014.

2014 5th Annual ***Dr. I. David Todres, MD Grand Rounds***, Department of Pediatrics, Harvard Medical School and Massachusetts General Hospital, Boston, MA; June 2-3, 2014.

2014 Keynote Speaker, Health Beliefs and Practices Forum, Health Ministry Network of the Mid-South, Catholic Center, Memphis TN. August 14, 2014.

2014 ***Chair, Selection Committee, Distinguished Investigator Award in Pediatric Pain***, on behalf of International Association for the Study of Pain, Special Interest Group for Pain in Children

2014 Listed in ***Who's Who in America***, Marquis Who's Who, Inc.

2014 Listed in ***America's Top Doctors,*** Castle Connolly Medical, Ltd.

2014 Listed in ***Best Doctors in America***, Best Doctors, Inc.

2014 Keynote Speaker, 33rd Annual Neonatal & Perinatal Conference, Chile Association of Pediatrics, Santiago, Chile; August 21-23, 2014.

2014 Member, NIH Study Section (CSR) ZRG1 SBIB-V (82), National Institutes of Health, Center for Scientific Review, October 23rd, 2014.

2014 14th Annual ***Dr. John J. Fangman Lectureship,*** Department of Pediatrics, Children's Hospital and Clinics – Minneapolis, MN; October 27-28, 2014.

2015 International Advisory Group, Leading Causes of Life: *Towards an Integrative Paradigm of Health*; Wake Forest University, Winston-Salem, NC; February 24-27, 2015.

2015 Appointed as **Fellow of the Leading Causes of Life Initiative**, Wake Forest University, Winston-Salem, NC.

2015 10th International Symposium on Pediatric Pain, International Association for the Study of Pain, Distinguished Investigator Award Presentation, Seattle, WA; May 31-June 4, 2015.

2015 Keynote Speaker, XIV International Congress of Intensive Care Medicine,

	Belo Horizonte, Brazil; May 21-23 2015.
2015	Member, Special Emphasis Panel for STTR Applications, *Eunice Kennedy Shriver* National Institute for Child Health & Human Development/NIH, October 29th, 2015.
2015	Executive Committee Member for the Pediatric Pain Research Network (PPRN), the Pediatric Section of the ACTTION Network.
2016	*Ad hoc* Member, NICHD Study Section, Special Emphasis Panel/Scientific Review Group 2016/01 ZHD1 DSR-K (90)
2016	*Ad hoc* Member, Center for Scientific Review 2016/10 ZRG1 PSE-D (90), Neurological, Aging & Musculoskeletal Epidemiology (NAME) Study Section
2017	Co-Chair, International Conference on *"Collaborations for the Ideal Village"*, Stanford University School of Medicine, June 17th, 2017.
2017	*Ad hoc* Member, Center for Scientific Review, 2018/01 SBIB-H82, Clinical Fetal & Pediatric Applications Study Section, February 10th, 2017.
2017	Member, Pediatric Pain Consensus Task Force, Ethical Guidelines for Pediatric Pain Research, The MayDay Fund, August-December, 2017.
2017	Master of Ceremonies, 50th Anniversary Gala Dinner, The Sikh Foundation International, Asian Art Museum, San Francisco, CA; May 5th, 2017.
2017	Chair, Healthcare Panel, International Conference "Advancing Sikhs through Education", Stanford University, Palo Alto, CA; May 7th, 2017.
2017	Member, Center for Scientific Review, 2018/01 SBIB-H82, Study Section, Clinical Fetal & Pediatric Applications, October 11th, 2017.
2017	***Chief Guest***, 37th Annual Meeting of the National Neonatology Forum Conference Inauguration, December 8th, 2017.
2017	Member, Consensus Task Force, Ethical Guidelines for Pediatric Pain Research, The MayDay Fund
2018	Co-Chair, International Conference on *"Empowerment of Women for the Ideal Village"*, Stanford University School of Medicine, June 26th, 2018.
2018	***NIH Study Section Chair***, Center for Scientific Review, 2018/02 SBIB-H82, Clinical Fetal & Pediatric Applications
2019	***Honorary Doctorate***, Faculty of Medicine and Health, University of Örebro, Örebro, Sweden (conferred on February 9th, 2019)
2019	Co-Chair, 4th Annual Ideal Village Conference on *"Corporate Social Responsibility"*, Stanford University, June 25th, 2019.

Scientific Groups:

Life Member	National Neonatology Forum, India
Fellow	American Academy of Pediatrics
Fellow	Royal College of Paediatrics & Child Health
Fellow	American College of Critical Care Medicine
Fellow	Leading Causes of Life Initiative
Member	American Pediatric Society
Member	Society of Critical Care Medicine
Member	International Association for the Study of Pain (IASP)
Member	American Association of Rhodes Scholars

Current Positions:

- Professor of Pediatrics, Anesthesiology, Perioperative & Pain Medicine

- Director, Pain Neurobiology Laboratory, Women & Child Health Research Institute, Stanford University School of Medicine

- Attending Intensivist, Lucile Packard Children's Hospital
- Director, Jackson Vaughan Critical Care Research Fund
- Section Editor, ***Pediatric Research***

Research Grants Awarded:

1983 Co-Investigator: "Hormonal and metabolic effects of surgery and anesthesia in the human newborn infant". National Medical Research Fund (U.K.). P.I.: Dr. Albert Aynsley-Green: $18,000 (Jan. 1984 - June 1985).

1983 Laboratory research training grant, The Rhodes Trust (U.K.), $2,200 (Oct. 1982 - Sept. 1985).

1983 Principal Investigator: Microanalytical methods for measurement of hormones and intermediary metabolites." Medical Research Fund, University of Oxford (U.K.) $1,500, (Aug. 1983 - June 1984).

1984 Principal Investigator:: "Glucose homeostasis in premature newborn infants undergoing surgery." Mason Medical Research Fund (U.K.), $3,000. (October 1984 - October 1985).

1984 Co-investigator: "Amino acid metabolism and acute phase reactants related to perioperative metabolism in neonates". Peel Medical Research Fund (U.K.) P.I.: Dr. Albert Aynsley-Green: $2,000 (June 1984 - May 1985).

1984 Principal Investigator: "Micromethods for insulin and glucagon radioimmunoassays in human plasma." Locally Organized Research Grant, Oxfordshire Health Authority, Oxford (U.K.) $2,600 (March 1984 - June 1985).

1985 Principal Investigator: "Evaluation of neonatal anesthetic techniques by measurement of stress responses.: Locally Organized Research Grant, Oxfordshire Health Authority, Oxford (U.K.) $2,400 (July 1985 - Dec. 1985)

1986 Co-Investigator: "Effects of high-dose opioids on the physiological responses of neonates undergoing cardiac surgery." Janssen Research Foundation, P.I.: Paul R. Hickey, M.D. $60,000 (Jan. 1986 - Dec. 1987)

1989 Principal Investigator: "Assessment of pain in premature neonates." The Von L. Meyer Research Fund, Children's Hospital, Boston MA. $1,500 (Sept. 1989).

1993 Principal Investigator: "Developmental physiology of pain in newborn infants." U.S. Sprint, Inc.: $20,000 (July 1993 - June 1995)

1993 Principal Investigator: "Neurobiological effects of pain and stress during fetal and neonatal development." Emory Egleston Children's Research Center, $330,000

(July 1993 - June 1996).

1994 Principal Investigator: Unrestricted research funds. International Association for the Study of Pain and Astra Pain Control AB, Sweden; $10,000 (Oct. 1994-Oct. 1995).

1994 Mentor: "Design and development of a prospective database of analgesic practices in term and preterm neonates." American Academy of Pediatrics, Resident Research Grants, 1994, Applicant: Joel D. Selanikio, M.D. $2,000 (Fall 1994).

1995 Co-Investigator: The Measurement and Assessment of Pain in Infants and Children less than 3 years: the development of an instrument in relation to hormonal stress responses and morphine plasma levels. (P.I.'s: Prof. Dick Tibboel & Prof. J. Passchier) Dutch Medical Research Council, D.fl. 510,425 (March 1995 - February 1998).

1995 Principal Investigator: "Treatment of pain in newborn infants." U.S. Sprint Foundation, Inc.: $15,000 (July 1995 - June 1996)

1996 Mentor: "Does the severity of surgical stress predict clinical outcome in surgical neonates and children?" Summer Research Fellowships, Emory University School of Medicine, Applicant: Bryan Wall (M1), $ 4,000 (May-August, 1996)

1996 Principal Investigator: "Neurobiologic and behavioral effects of neonatal pain"; National Institutes of Child Health & Human Development (HD01123), $ 210,424 (Sept 1996-Aug 1999).

1996 Co-Investigator: "The Assessment of Pain in Severely and Profoundly Mentally Retarded Children". (P.I.'s: Prof. Huda H. Abu-Saad, Prof. Dick Tibboel) Dutch Organization for Scientific Research, D.fl. 537,660 (October 1996 - September 2001).

1998 Mentor: "Long-term effects of pain and self-regulation of behavior in preterm neonates" (P.I.: Marlene Walden, RNC,Ph.D., NNP) Faculty Scientist Award, Nell Hodgson Woodruff School of Nursing, Emory University, Atlanta, $120,000 (September 1998 to April 2000).

1998 Principal Investigator: "Tissue Cryo-sectioning: the Gateway to Laboratory Bench Research" (Shared equipment grant), Competitive Research Grants, CUMG Research Fund, University of Arkansas for Medical Sciences, $ 14,693 (September 1998 to August 1999).

1998 Co-Investigator: "Ultra-cold Freezer Storage of Research Samples" (Shared equipment grant, PI: Dr. Farrar), Competitive Research Grants, CUMG Research Fund, University of Arkansas for Medical Sciences, $ 15,000 (September 1998 to August 1999).

1999 Principal Investigator: "Neurologic Outcomes & Pre-emptive Analgesia in

Neonates" (The NEOPAIN Multicenter Trial) 1R01 HD36484, National Institute of Child Health & Human Development, $ 1,513,766 (June 1999 to May 2004).

1999 Principal Investigator: How do neonatal experiences alter brain development and subsequent behavior? Blowitz-Ridgeway Foundation, $100,000 (Oct 1999-2001).

2000 Principal Investigator: Does neonatal isolation lead to apoptosis in the developing brain? Medical Research Endowment Fund, University of Arkansas for Medical Sciences, $15,000 (Jan - Dec 2000).

2000 Principal Investigator: Methadone analgesia in full-term neonates: an assessment of pharmacokinetics and pharmacodynamics. Children's University Medical Group, University of Arkansas for Medical Sciences; $19,218 (7/1/2000 – 5/31/2001).

2000 Mentor: Effects of neonatal isolation on apoptosis during brain development. Arkansas Perinatal Board (P.I.: Adnan Bhutta, M.D.; $1,000 (9/1/2000 – 8/31/2001)).

2001 Mentor: "Cerebral Autoregulation in Preterm Infants" (P.I.: Jeffrey R. Kaiser, MD, MA) Clinical Investigator Development Award (K23 NS43185 Grant), NINDS/NIH, $ 684,760 (Jun 2002 to May 2007).

2001 Applicant: Proposal for building a state-of-the-art Pediatric Intensive Care Unit at Arkansas Children's Hospital, Donald W. Reynolds Foundation (Other Applicants: David T. Berry, Jonathan R. Bates, M.D.; $8,540,000 (9/1/2001 – 08/31/2003).

2002 Program Support: Arkansas Center for Pain Research, Initiated Act I funds to Arkansas Children's Hospital Research Institute; $300,000 (July 2001 - 2004).

2003 Mentor: *"Effects of adverse neonatal experience on cortical subplate neurons"* (Principal Investigator: Barbara Clancy, Ph.D.; University of Central Arkansas) Faculty Summer Grant, Arkansas Biomedical Research Infrastructure Network. $ 16,700 (May-August, 2003).

2003 Co-Investigator: *"Impact of Adverse Early Experience on Mental Health"* (Principal Investigator: Delia Vazquez, M.D.; University of Michigan at Ann Arbor) National Institute for Mental Health (1R21 MH068489-01) Direct Costs: $ 688,500 (July 2003 – June 2006).

2003 Mentor: *"The assessment of chronic arthritis pain in patients with dementia"* (P.I.: Pao-Feng Tsai, RN, Ph.D.) John A. Hartford Post-Doctoral Fellowship, Building Academic Geriatric Nursing Capacity Scholar Fund, John A. Hartford Foundation Grant number: 03-204; $100,000 (July 2003-June 2005).

2003 Mentor: *"Acquisition of a Three-Dimensional Neuroanatomical Analysis System"* (P.I.: Barbara Clancy, Ph.D.) Arkansas BRIN Equipment Grant, $27,257 (July 2003 – June, 2004).

2003 Mentor: *"Mechanisms of repetitive pain-induced neuronal cell death"* (Principal Investigator: Deborly Wade, Ph.D.; Central Baptist College) Faculty Grant, Arkansas Biomedical Research Infrastructure Network. $16,667 (September, 2003 – June, 2004).

2003 Mentor: *"Equipment grant for Molecular Biology methods"* (Principal Investigator: Deborly Wade, Ph.D.; Central Baptist College) Faculty Grant, Arkansas Biomedical Research Infrastructure Network. $25,331 (September, 2003 – December, 2003).

2004 Co-Investigator: *"The Effect of Tai Chi on Cognitive Function in Elders with Dementia and Pain"* (P.I.: Pao-Feng Tsai, RN, Ph.D.) Alzheimer Disease Center UAMS: $45,779 (April 2004-March 2005).

2004 Mentor: Center for Translational Neuroscience, COBRE Project III: *"Early Pain Experience and Pre-attentional Mechanisms"* National Center for Research Resources (1P20 RR018765) $10,439,884 (September 2004 to August 2009).

2004 Co-Investigator: *"The Effect of Tai Chi on Cognitive Function in Elders with Dementia and Pain"* (P.I.: Pao-Feng Tsai, RN, Ph.D.) Alzheimer Disease Association: $199,997 (Oct 2004-Sept. 2006).

2004 Mentor: *"Effects of Adverse Perinatal Experiences on Cortical Organization"* (P.I.: Barbara Clancy, Ph.D.) INBRE Summer Research Fellowship, $8,334 (June 2004 – October, 2005).

2004 Principal Investigator: *"PCCM Network: Remedies for Opioid Tolerance & Withdrawal"* National Institute for Child Health and Human Development (NIH# 1U10 HD050009-01), $1,987,796 (May 2005 – November 2009)

2004 Principal Investigator: *"Inflammatory changes in the Immature Brain following Perinatal Pain"* SURF (SILO Undergraduate Research Fellowship for UCA student: Shannon Palmer), $ 3,900 (Jan. – August, 2005).

2005 Principal Grantee: Pfizer Visiting Professorship in Pain Medicine Grant ($7,500) to invite Professor John van den Anker, Professor of Pediatrics, Pharmacology, Physiology; George Washington University School of Medicine and Health Sciences; Children's National Medical Center, Washington, DC.

2005 Mentor for Project #8: *"Effects of Adverse Perinatal Experiences on Cortical Organization Mechanisms";* Arkansas INBRE Grant *"Cellular Signaling, Growth, and Differentiation"*, (P.I.: Lawrence E. Cornett, Ph.D.) NIH/National Center for Research Resources (2 P20 RR016460-04; $ 16,908,508; June 2005 to May 2010).

2006 Principal Investigator: *"Use of Acupuncture to reduce Inflammatory Pain in Infants: A translational approach"* Arkansas Biosciences Institute $ 49,869 (October 2006 – June 2008).

2006 Principal Investigator: *"Near-continuous, Non-invasive Blood Pressure Monitoring to improve outcomes in Pediatric Transport"* Dean's Research Development Fund $ 14,919 (January 2006 – December 2007).

2006 Principal Investigator: *"Pain Assessment in Cognitively Impaired, Functionally Impaired Children (PACIFIC Study)"* Children's University Medical Group Seed Grant; $30,000 (January 2007 – December 2008).

2007 Co-Principal Investigator: (P.I. Hugo Lagercrantz) *"NeoOpioid Consortium: No pain during childhood by adapting off-patent medicines"*, European Commission FP7 Program: HEALTH-2007-4.2-1: Adapting off-patent Medicines for Paediatric populations (Euro 2,300,000; October, 2008 to October, 2013).

2008 Principal Investigator: *"Safety and Efficacy of Acupuncture for Relieving Pain in Newborn Infants"*, The Mayday Fund, ($401,884; July, 2008 to December, 2013).

2008 Principal Investigator: *"Assessment of the Pharmacokinetics, Pharmacodynamics, and Neurotoxic Effects of an Anesthetic in Infants undergoing various Surgical Procedures"* Safety of Key Inhaled and Intravenous Drugs in Pediatrics (SAFEKIDS), Food & Drug Administration, FDA-SOL-08-SAFEKIDS, Clinical Project 003 ($308,000; October, 2008 to September, 2012).

2008 Primary Mentor: *"Goal-directed Resuscitative Interventions during Pediatric Inter-facility Transport (the GRIPIT Trial)"* (P.I.: Michael H Stroud, M.D.) *Eunice Shriver Kennedy* National Institute for Child Health & Human Development, Pediatric Research LRP Program, $44,924.64 (July 1, 2008 – June 30, 2012).

2011 Principal Investigator: *"Development of the newborn brain and exposure to anesthetic agents"* The Oxnard Foundation ($ 75,859.92 – July 01, 2011 to June 30, 2014).

2011 Primary Mentor: *"Steroids for Pediatric Acute Lung Injury Trial"* (P.I.: Bonny Bardhan, M.D.; 2nd Year Fellow), American Medical Association Foundation, Seed Grant Research Program, $2,500.00 (April 1, 2011 – March 30, 2013).

2013 Mentor: *"The role of 2-pore domain potassium channel Trek-1 in Acute Lung Injury"*, (P.I.: Dr. Andreas Schwingshackl), American Lung Association (ALA) Biomedical Research Grant ($80,000; October, 2013 – October, 2015).

2013 Site P.I.: *"Multiple Medical Therapies for Pediatric TBI – A Comparative Effectiveness Approach"* (P.I.: Mike Bell), National Institute for Neurological Disorders & Stroke (NIH/NINDS), Cooperative Agreement grant (U01 NS081041, July, 2013 – June, 2018).

2014 Co-Mentor: *"The role of 2-pore domain potassium channels in Acute Lung Injury"*, (P.I.: Dr. Andreas Schwingshackl), National Heart, Lung & Blood

Institute (NIH/NHLBI) Mentored Clinical Scientist Development Award (1 K08 HL118118: $676,890, February, 2014 to January, 2019).

2014 Principal Investigator: *"Science to Survival: Innovative Strategies for Critically Ill or Injured Children"*; National Institute for Child Health & Human Development, $1,522,280 (1 UG1 HD083173: Approved by NICHD Council, awaiting allocation of funds, Dec. 2014 – Nov. 2019).

2014 Co-Mentor: *"Morphine Pharmacogenomics to Predict Risk of Respiratory Depression in Children"*, (P.I.: Dr. Vidya Chidambaran), *Eunice Kennedy Shriver* National Institute for Child Health & Human Development (NIH/NICHD) Mentored Patient-Oriented Research Career Development Award (K23) (5K23HD082782: $655,425; July 2014 to June 2019).

2015 Principal Investigator: *"Biomarkers for Risk and Resilience in Critically Ill Children"*; Anand Lab Startup Fund, Department of Pediatrics, Stanford University School of Medicine, $1,500,000 (Oct. 2015 – Nov. 2020).

2017 Primary Mentor: *"Measuring Pain in Newborn Infants: Developing objective approaches at the bedside"*, (P.I.: Dr. Iris Morag), Feldman Family Foundation Visiting Professorship to Stanford University ($50,000; August 2017 to 2018).

2017 Principal Investigator: *"Biomarkers of Risk and Resilience in Preschool Children"* Maternal & Child Health Research Institute, Stanford University (Total costs $34,999.56).

2018 Co-Principal Investigator: STTR Grant Proposal: *"Measuring Infant Pain Objectively using Sensor Fusion & Machine Learning Algorithms"*, in response to RFA-DA-18-013, NIH/NIDA "Development of a Device to Objectively Measure Pain (R41/R42)"; in collaboration with Autonomous Healthcare, Inc. (1 R41 DA046983; Total Costs: $224,999; Stanford sub-contract: $ 118,958; Dates: September 01, 2018 to August 31, 2020).

2019 Co-Investigator: Research Instrumentation Grant: *"Xevo TQ-XS Triple Quadrupole Mass Spectrometer System"* (P.I. Allis Chien) NIH Office of the Director (1 S10 OD026962-01; Total Costs: $527,209; Dates: February 01, 2019 to January 31, 2020).

2019 Principal Investigator: R01 Grant Proposal: *"Do Hair Cortisol and Hair Oxytocin represent the Stressful and Supportive Experiences of Preschool Children?" Eunice Kennedy Shriver* National Institute for Child Health & Human Development (NIH/NICHD) (1 R01 HD099296-01; Budget: $2,494,333; Dates: August 01, 2019 to May 31, 2023).

Teaching and Lab Supervision:

High School Seniors:

1. Brandon Mack (June – August, 2002)
2. Russell Saltz (June – August, 2002)

3. Sarah Bransford (June – August, 2002)
4. Julie Holt (June – August, 2002)
5. Carrie Acrey (June – August, 2002)
6. Michael Reid (June – August, 2002)
7. RaElle Jackson (June to August, 2003)
8. Jerry Choate (August 2003 to May 2004)
9. Nisha Kunapalli (July to Nov., 2005)
10. Gail Khaidakov (July 2005 to Jan. 2006)
11. Janelle Vircks (March-Dec, 2011)
12. Aidan Rubio (June-August, 2017)
13. Ginikachi Ozioma Amuzie (June-August, 2017)
14. Herman Saini (June-August, 2019)

Undergraduate Students:

1. Hosefa Divan (May - Sept, 1994)
2. Sheela Bavikatty (Sept 1994 – Apr 1995)
3. Jaime E. Estrada (Apr – Dec, 1995)
4. Peter Kim (June – Aug, 1997)
5. Sarah Hopkins (May – Dec, 1997)
6. Matthew Saltz (June - Aug, 1999 & 2000)
7. Kendra Williams (June – Aug, 1999)
8. Michael Bishop (June – Aug, 2000)
9. Robin Morris (June – Aug, 2000)
11. Stephen Baker (June – Aug, 2001)
10. Drew Newton (June – Aug, 2001)
11. Patrick Kennedy (June – Aug, 2002)
12. Brandy Tharp (June – Aug, 2002)
13. Michael Reid (May to August, 2003)
14. Julie Carter (June to Sept., 2003, 2004)
15. Brian Bowden (June - Sept., 2003, 2004)
16. Debbie Sollener (June-Sept, 2003, 2004)
17. Amanda Plummer(Jun-Sep, 2003, 2004)
18. Kate Street (June to Sept., 2003, 2004)
19. Danny Glassman (June-Sept 2003, 2004)
20. Lauren Leach (June to Sept., 2004)
21. Brian Ray (June to Sept., 2004)
22. Blythe Bowman (June to Sept., 2004)
23. Jason Fletcher (June to Sept., 2004)
24. Sarabeth Bailey (June to Sept., 2004)
25. Whitney Tharp (June to August, 2005)
26. Brandon Kersh (June to August, 2005)
27. Shannon Palmer (Jan. to August, 2005)
28. Sarasijha Desikan (June to August, 2006)
29. Jessie Rose (January, 2007, Tufts Univ.)
30. Jamie Waldron (June to August, 2007)
31. Cemeka Augbaum (June-August, 2007)
32. Sarah Latham (May to August, 2008)
33. Greg O'Ryan-Johnson (May-Aug, 2012)
34. Stephanie Allen (May to August, 2013)
35. Anqi Zheng (June to Sept., 2014)
36. Yannick Boni (June to August, 2015)
37. Hannah Todd (May-June, 2017)
38. Noor Singh (June to August, 2018)
39. Emily Mendonsa (June-Dec., 2019)

Graduate Students:

1. Yasmeen Golzar (Wellesley College, Wellesley, MA; January to August, 1999)
2. John Frank (University of Central Arkansas, Biology Program, Fall 2003 – Summer 2004)
3. Tiffany Wallace (University of Arkansas for Medical Sciences, Neuroscience Program, July to October, 2003)
4. Ross Brown (University of Arkansas for Medical Sciences, Neuroscience Program, July 2006 to May 2007)
5. Chaoxuan Dong, (University of Arkansas for Medical Sciences, Neuroscience Program, July 2007 to May 2011)
6. Jitka Hiscox (Stanford School of Engineering, Civil and Environmental Engineering Department, January 2019 to June 2022)

Medical Students:

1. Howard Silverboard (June – August, 1994), University of Alabama at Birmingham
2. Bryan Wall (May – August, 1996), Emory University School of Medicine
3. Charles Weber (June – Nov, 1999), University of Arkansas for Medical Sciences

4. John Haltom (May – Aug, 2000), University of Arkansas for Medical Sciences
5. Sukhvir K. Chana (Oct-Nov, 2000), University College London, London (UK)
6. Chi Ling Sarah Cheung (Oct 2001-July 2002) Erasmus University School of Medicine, Rotterdam, The Netherlands
7. Matthew Saltz (M2) (May – July, 2002), University of Arkansas for Medical Sciences
8. Robin Morris (M1) (May – July, 2002), University of Arkansas for Medical Sciences
9. Stephen Baker (M2) (May – July, 2003), University of Arkansas for Medical Sciences
10. Dana Jo Coker (M1) (January 2005-July, 2006), University of Arkansas for Medical Sciences
11. Paulomi Mehta (M2), (May 2007 to 2010), University of Arkansas for Medical Sciences
12. Karmen McPherson (M2) (June to August, 2012) University of Tennessee Health Science Center
13. Aaron Kala (M1, M2, M3) (February to August 2013, June-August 2014, December 2014-January 2015), University of Tennessee Health Science Center
14. Anna Zeidman (M1) (December 2019 – May, 2020), Stanford University School of Medicine
15. Janelle Clarise Chavez (June-August 2020), Stanford University School of Medicine

Post-Doctoral Fellows:

1. **Thomas Bruns**, M.D., Post-doctoral fellow in Pediatric Emergency Medicine, Emory University Department of Pediatrics, January 1994 to April 1995. Project: "Comparison of the efficacy, adverse effects, costs and patient outcomes in a randomized trial of histoacryl blue vs. suturing for skin closure of lacerations in pediatric patients."
2. **Joel D. Selanikio**, M.D., Resident in Pediatrics, Emory University Department of Pediatrics, December 1993 to June 1995. Project: "Analysis of institutional data from a survey of pain and analgesia in neonates."
3. **Sylvia Garcia**, M.D., Resident in Pediatrics, Emory University Department of Pediatrics, December 1993 to June 1995. Project: "The clinical basis for monitoring central venous oxygen saturations in critically ill pediatric patients."
4. **Volkan Coskun**, M.D., Doctoral graduate of Ankara University, Turkey. December 1995 to August 1997. "Factors determining opioid receptor development using immunohistochemical techniques."
5. **Markus Sogl**, Medical Technical Analyst from Vienna University and Vienna General Hospital, Austria. July to September 1995. Project: "Cognitive testing in adult rats exposed to repetitive pain in the neonatal period."
6. **Mandana Ghodrat**, Pharm.D., Clinical Pharmacist, Emory-Egleston Pediatric Care Foundation, Emory University School of Medicine, December 1995 to July 1996. Project: "Impact of Patient-Controlled Analgesia on the Behavioral Responses of Children undergoing Lumbar Puncture".
7. **William Lariviere**, Doctoral student, Department of Psychology, McGill University, Montreal, Canada. June to August, 1997. Project: "Fos expression in the developing rat brain associated with noxious stimuli."
8. **Devika Kommineni**, M.D., Visiting Scholar, Department of Pediatrics, Emory University School of Medicine, January to August, 1997. Project: "Analgesic practices for Neonatal I.C.U.'s in U.K.".
9. **Umesh Narsinghani**, M.D., Critical Care Medicine Fellow, Department of Pediatrics, University of Arkansas for Medical Sciences, July 1999 to June 2001. "Changes in brain development resulting from repetitive neonatal pain."

10. **Adnan Bhutta**, M.D., Critical Care Medicine Fellow, Department of Pediatrics, University of Arkansas for Medical Sciences, January 1999 to December 2001. "Apoptosis following isolation in the developing rat brain."
11. **Jing-Gen Liu**, Ph.D., Postdoctoral Fellow, Pain Neurobiology Laboratory, Arkansas Children's Hospital Research Institute, December 1998 to January 2000. "Changes in opioid receptor signal transduction associated with repetitive neonatal pain."
12. **Sarita Garg**, Ph.D., Postdoctoral Fellow, Pain Neurobiology Laboratory, Arkansas Children's Hospital Research Institute, February 2001 to December 2003. "Regulators of neuronal cell death following inflammatory pain."
13. **Lingling Zhang**, Ph.D., Postdoctoral Fellow, Pain Neurobiology Laboratory, Arkansas Children's Hospital Research Institute, May 2005 to present. "Use of Acupuncture to reduce Inflammatory Pain in Infant Rats."
14. **Micheal Stroud,** M.D., Critical Care Medicine Fellow, Department of Pediatrics, University of Arkansas for Medical Sciences, July 2004 to June 2007. "Near-continuous, non-invasive monitoring of pediatric transport patients."
15. **Muayyad Tailounie,** M.D., Critical Care Medicine Fellow, Department of Pediatrics, University of Arkansas for Medical Sciences, December 2006 to June 2009. "Neuroprotective effects of Ketamine for patients with traumatic brain injury."
16. **Bonny Bardhan**, M.D., Critical Care Medicine Fellow, Department of Pediatrics, University of Tennessee Health Science Center, July 2009 to June 2012. "Randomized placebo-controlled trial of steroids for acute lung injury (ALI)/ acute respiratory distress syndrome (ARDS)."
17. **Kandiss Dukes**, Pharm.D., Pharmacy Resident, University of Tennessee Health Science Center, October 2009 to October 2010. "Use of Methadone and Lorazepam for weaning sedation in PICU patients."
18. **Audra Rouster**, M.D.: Senior Resident and Pediatric Gastroenterology Fellow, Le Bonheur Children's Hospital and New Orleans Children's Hospital, August 2010 to December 2011. "Grantsmanship and Career Planning; Application for the LRP Program Grant funding from NIH/NICHD".
19. **Fabio Savorgnan**, M.D., Critical Care Medicine Fellow, Department of Pediatrics, University of Tennessee Health Science Center, July 2010 to June 2013. "Randomized controlled trial of inhaled Nitric Oxide: early versus late use."
20. **Chaoxuan Dong**, M.D., Ph.D.; Postdoctoral Fellow in Neuroscience, UT Neuroscience Institute, September 2011 to August 2013. "Neurotoxicity of Anesthetic and Analgesic Agents in Neonatal Neural Stem/Progenitor Cells."
21. **Radomir Slominski**, M.D. Postdoctoral Fellow, University of Tennessee Health Science Center, Sept. 2014 to June 2015. "Biomarkers for Early Childhood Stress in Hair Samples."
22. **Rajshri Babeoram Panday**, M.D. Vrije Universiteit Medical Center, Amsterdam, The Netherlands; Research Internship, University of Tennessee Health Science Center, July to December 2015, "Novel Assays for measuring Cytokines in hair samples from children".
23. **Dane Jacobson**, M.D. PCCM Clinical Fellow, Stanford University School of Medicine, Jan 2016 to June 2018, "Prevalence of delirium in Pediatric ICU patients".
24. **Urs Naber**, M.D. PCCM Clinical Fellow, Stanford University School of Medicine, July 2016 to June 2017, "Measurement of infant pain using EEG and other monitors".
25. **Reshma Aramanadka**, M.D. PCCM Clinical Fellow, Post-Graduate Institute for Research & Medical Education, Chandigarh, India; January 2019.

26. **Monica Osbelia Ruiz**, M.D. PCCM Clinical Fellow, Stanford University School of Medicine, July 2019 to June 2022, "Measurement of anxiety in preschool children".

Pediatric Critical Care Medicine Fellows:

1. Sharon Holloway, M.D.
2. Amirah Daher, M.D.
3. Atul Vats, M.D.
4. Nandkishore Raghuram, M.D.
5. Karl Serrao, M.D.
6. Venu Devabhaktuni, M.D.
7. Ronald Sanders, Jr., M.D.
8. Umesh Narsinghani, M.D.
9. Adnan Bhutta, M.D.
10. Patricia Wankum, M.D
11. Adriana Lopez, M.D.
12. Brian Eble, M.D.
13. Basem Al-Saati, M.D.
14. Jay Duncan, M.D.
15. Micheal Stroud, M.D.
16. Thomas Bannister, M.D.
17. Meredith Denton, M.D.
18. Muyyad Tailounie, M.D.
19. Laura Ortmann, M.D.
20. Katherine Clement, M.D.
21. David Smith, M.D.
22. Jonathan Byrnes, M.D.
23. Bonny Bardhan, M.D.
24. Rebecca Shappley, M.D.
25. Kimberley Ingram, M.D.
26. Fabio Savorgnan, M.D.
27. Rajat Pareek, M.D.
28. Astrid Gutierrez-Zepeda, M.D.
29. Cody Tigges, M.D.
30. Paige Klingborg, M.D.
31. Patricia Alleyne, MD
32. Peter "Mike" Mangubat, MD
33. Catherine Taylor, MD
34. Camille Immanuel, MD, MPH
35. Jagila Wesley, MD
36. Mindy Ju, MD
37. Katherine Kruse, MD
38. Catherine Ross, MD
39. Dane Jacobson, MD
40. Zahidee Rodriguez, MD
41. Daniel Tawfik, MD
42. David Werho, MD
43. Lindsey Troy, MD
44. Urs Naber, MD, PhD
45. Meghna Patel, MD
46. Mais Yacoub, MD
47. Lara Murphy, MD

Thesis Advisor / Reviewer:

1. **Bjorn Larsson, M.D**.: Ph.D. Thesis, Karolinska Institute, Stockholm, Sweden (awarded September, 1994).
2. **Sarah Hopkins**: M.S.P.H. Thesis Advisor, Rollins School of Public Health, Emory University, Atlanta (awarded May, 1997).
3. **Ronald Cary Sanders, Jr. M.D.**: M.S. (Physiology) Thesis Advisor and Fellowship Director, University of Arkansas for Medical Sciences (awarded May, 2000).
4. **Nancy Boumeester, M.D.**: Ph.D. Thesis Advisor, Erasmus University, Rotterdam, The Netherlands (awarded October, 2002).
5. **Sayid M. Maleki, MBBS**: M.D. Thesis Examiner, Department of Pediatrics, Yazd University of Medical Sciences, Yazd, Iran (awarded November, 2002).
6. **Lena Bergqvist, M.D**.: Ph.D. Thesis Advisor, Karolinska Institute, Stockholm, Sweden (currently ongoing).
7. **C.L. Sarah Cheung**: M.D. Thesis Advisor, Erasmus University Medical College, Rotterdam, The Netherlands (passed November 2003).
8. **Cameron Good, M.S.**: Ph.D. Thesis Committee, Neuroscience Program, University of Arkansas for Medical Sciences, Little Rock, Arkansas (passed October 2005).

9. **John Frank, B.S.**: M.S. (Biology) Thesis Advisor and Laboratory Mentor, Biology Program, University of Central Arkansas, Conway, Arkansas (Passed September 2004).
10. **Ross Brown, B.S.**: M.S. (Neuroscience), Thesis Advisor and Laboratory Mentor, University of Arkansas for Medical Sciences, Little Rock, Arkansas (Graduated May, 2007).
11. **Chaoxuan Dong, M.D.**: Ph.D. in Neuroscience, University of Arkansas for Medical Sciences, Little Rock, Arkansas (Graduated May, 2011).

Mentorship for Local / Visiting Faculty:

1. **Steen Hertel**, M.D., Consultant Neonatologist and Anesthesiologist from the Hilleroed Hospital, Hilleroed, Denmark. (visit: Sept-Oct, 1996)
2. **Sunit Singhi**, M.D., Director of Pediatric Critical Care Medicine, Associate Professor, Postgraduate Institute for Medical Education and Research, Chandigarh, India (visit: Nov-Dec, 1997).
3. Research Mentorship for faculty colleagues in the Department of Pediatrics, Emory University School of Medicine: David McLario, M.D.; Rita Helfand, M.D.; Dale Nordenberg, M.D.; Harold Simon, M.D.; Benjamin Gold, M.D.; William Zempsky, M.D.
4. **Marlene Walden**, RNC, Ph.D.; Assistant Professor of Nursing Science, Nell Hodgson Woodruff School of Nursing, Emory University, Atlanta, GA (visit: Feb-March, 1999).
5. Research Mentorship for faculty colleagues in the Department of Pediatrics, UAMS: Mark H. Heulitt, M.D.; Mick Tilford, Ph.D.; Craig Rowlands, Ph.D.
6. **Jeffrey Kaiser**, M.D., Assistant Professor of Pediatrics, University of Arkansas for Medical Sciences.
7. **Mohd. Ilyas,** M.D., Assistant Professor of Pediatrics, University of Arkansas for Medical Sciences.
8. **Barbara Clancy**, Ph.D., Assistant Professor, Department of Biology, University of Central Arkansas.
9. **Shalini Khurana**, M.D., Instructor in Pediatrics, University of Arkansas for Medical Sciences
10. **Deborly Wade**, Ph.D., Faculty member, Department of Biology, Central Baptist College, Conway, AR.
11. **Adnan T. Bhutta**, M.D., Instructor in Pediatrics, University of Arkansas for Medical Sciences
12. **R. Whit Hall,** M.D., Assistant Professor of Pediatrics, University of Arkansas for Medical Sciences
13. **Pao-Feng Tsai,** RN, Ph.D., Assistant Professor of Geriatric Nursing, College of Nursing, University of Arkansas for Medical Sciences
14. **Michelle Schober**, M.D., Assistant Professor of Pediatrics (Critical Care Medicine), University of Utah School of Medicine and Primary Children's Hospital, Salt Lake City, UT.
15. **Ana Theresa Stochero,** M.D., M.S., Assistant Professor of Pediatrics (Neonatology), National University of Sao Paulo, Sao Paulo, Brazil.
16. **Martin Blakely,** MD, FACS, Assistant Professor of Surgery, University of Tennessee Health Science Center
17. **Samir H. Shah,** MD, MBA, FRCPC, Associate Professor of Pediatrics, University of Tennessee Health Science Center
18. **Andreas Schwingshackl,** MD, Ph.D., Assistant Professor of Pediatrics, University of Tennessee Health Science Center
19. **Marie Mazel,** MD, Assistant Professor of Pediatrics, University of Tennessee Health Science Center

20. **Ignasio Federico Nievas,** MD, Assistant Professor of Pediatrics, University of Tennessee Health Science Center
21. **Dai Kimura,** MD, Assistant Professor of Pediatrics, University of Tennessee Health Science Center
22. **Hitesh S. Sandhu,** MD, Assistant Professor of Pediatrics, University of Tennessee Health Science Center
23. **Arun K. Saini,** MD, Assistant Professor of Pediatrics, University of Tennessee Health Science Center
24. **Iris Morag**, MD, Ph.D., Associate Professor of Pediatrics (Neonatology), Tel Aviv University, Israel.
25. **Jorina Elbers**, MD; Assistant Professor of Neurology and Pediatrics, Stanford University School of Medicine, Palo Alto, CA.
26. **Azadeh Fayazi**, MD, Assistant Clinical Professor of Pediatrics, Stanford University School of Medicine, Palo Alto, CA.
27. **Jean-Michel Roue**, MD; Associate Professor of Pediatrics, Brest University Hospital, and University of Western Brittany, Brest, France.

Honors/Awards to mentored fellows, students and faculty:

1. Umesh Narsinghani, M.D., FAAP.: Education Scholarship Award, 30th International Scientific Symposium of the Society for Critical Care Medicine, Feb 13th, 2001.
2. Adnan Bhutta, M.D.: Young Investigator Grant Award, Arkansas Perinatal Society, 2000.
3. Umesh Narsinghani, M.D., FAAP.: First Prize Winner, Annual Student Research Day, University of Arkansas for Medical Sciences, Little Rock; March 22nd, 2001.
4. Umesh Narsinghani, M.D., FAAP.: First Prize Winner, Annual Fellows Day, Department of Pediatrics, University of Arkansas for Medical Sciences, Little Rock; May 9th, 2001.
5. Brandon Mack, Arkansas School for Math & Science: First Place in Medicine and Health at the *West Central Regional Science Fair* (2003)
6. Brandon Mack, Arkansas School for Math & Science: Second Place in Medicine and Health at the *West Central Regional Junior Academy of Sciences* (2003)
7. Brandon Mack, Arkansas School for Math & Science: Awarded the "Clinical Lab Association Best Life Science Project" at the *West Central Regional Junior Academy of Sciences* (2003)
8. Brandon Mack, Arkansas School for Math & Science: "Arkansas State Science Fair Achievement Award" for First Place in Medicine and Health at the *Arkansas State Science Fair* (2003)
9. Brandon Mack, Arkansas School for Math & Science: Awarded the "Society for Neuroscience Achievement Award" by the Society of Neuroscience Arkansas Chapter (2003)
10. Brandon Mack, Arkansas School for Math & Science: State Intel Science and Engineering Fair (ISEF) Finalist Award (2003)
11. Brandon Mack, Arkansas School for Math & Science: "Scientific American" Award for Outstanding Achievement in Science Education of America (2003)
12. Brandon Mack, Arkansas School for Math & Science: *Arkansas State Science Fair* " Best in State: Second Place Award" (2003).
13. Ronald Sanders, Jr., M.D.: Clinical Investigator Development Award (K08), National Institutes of Health (2003): 1K08 HL074128 – *"Hemangioblastic Progenitors in Acute Lung Injury"*.

14. Adnan Bhutta, M.D.: 2004 CHCA National Benchmarking Award. Reducing the incidence of blood-stream infection in the PICU.
15. Glenda Hefley, RN, MNSc..: Society of Pediatric Nurses, Annual Meeting April 2004, Research Poster Award: Parent Bed Spaces in the PICU: Perceived Benefits and Concerns of Staff.
16. Michelle Schober, M.D.: Pediatric Critical Care Medicine Scientist Development Award (K12), National Institutes of Health (2004): *"Neurotoxicity from Fentanyl Therapy in Infant Rats".*
17. Amanda Plummer: Arkansas Biomedical Research Infrastructure Network, Annual Research Day, 2nd Prize for Undergraduate Research Posters.*"Consequences of Neonatal Pain on Neurodevelopment"*.
18. Shannon Palmer: Scholars Undergraduate Research Fellowship, 2005 (SURF Grant $ 3,900) "*Inflammatory changes in the Immature Brain following Perinatal Pa*in".
19. Shannon Palmer: Barry A. Goldwater Scholarship, 2005.
20. Brian Bowden: UCA Student of the Year, 2004.
21. Brian Bowden: Rotary International Fellowship, 2005.
22. Tiffany Wallace: Committee on Women in Neuroscience (C-WIN) Graduate Student Travel Award from the Society for Neuroscience to attend the SFN Annual Meeting, November 12-16, 2005.
23. Michael Stroud. Importance of noninvasive blood pressure monitoring during pediatric transport. Received 1st Prize for the Best Fellow's Day Presentation at the UAMS College of Medicine Fellow's Day, May 16th, 2006.
24. Michael H. Stroud: Near-continuous, non-invasive monitoring of pediatric transport patients. First Prize for Fellows' Presentation, American Academy of Pediatrics, Section of Transport Medicine, October 11th, 2006.
25. Michael H. Stroud: Accelerated non-invasive monitoring of blood pressure in pediatric transport patients: a randomized trial. Fellows Clinical Research Award, ***Society for Pediatric Research (SPR)***, Pediatric Academic Societies' Meeting, May 7th, 2007.
26. Michael H. Stroud, M.D.; R21 Exploratory /Developmental Research Grant Award, *Eunice Kennedy Shriver* National Institute for Child Health & Human Development.
27. Bonny Bardhan, M.D.; 2nd Year Fellow in Pediatric Critical Care: "Steroids for Pediatric Acute Lung Injury Trial" nationally competitive award from the Seed Grant Research Program by the American Medical Association Foundation.
28. Stephanie Allen, undergraduate student: First Place – Science Award, National Conference of Alpha Chi Honors Society, St. Louis, 2014.

BIBLIOGRAPHY:

Peer-Reviewed Publications

See complete list on Scopus at: http://www.scopus.com/authid/detail.url?authorId=7101749758

1. **Anand KJS**, Rovnaghi CR, Rigdon, JR, Qin FF, Tembulkar S, Murphy LE, Barr DA, Gotlib IH, Tylavsky FA. Demographic and psychosocial factors associated with Hair Cortisol Concentrations in preschool children. ***Pediatric Research***, 2019, (in press).
2. **Anand KJS**, Rigdon, JR, Rovnaghi CR, Qin FF, Tembulkar S, Bush N, LeWinn K, Tylavsky FA, Davis R, Barr DA, Gotlib IH. Measuring socioeconomic adversity in early life. ***Acta Paediatrica***, 2019, Jan 7. DOI: 10.1111/apa.14715. PMID: 30614554.
3. Bearer C, Agostoni C, **Anand KJS**, et al. Toward the elimination of bias in Pediatric Research. ***Pediatric Research***, 2019; doi: 10.1038/s41390-019-0583-5. PMID: 31533126
4. **Anand KJS**. Discovering pain in newborn infants. ***Anesthesiology*** 2019; 131:392–5. PMID: 31233407 DOI: 10.1097/ALN.0000000000002810.
5. Slopen N, Roberts AL, LeWinn KZ, Bush N, Rovnaghi CR, Tylavsky F, **Anand KJS**. Maternal experiences of trauma and cortisol production in early childhood in a prospective cohort. ***Psychoneuroendocrinology***, 2018; 98: 168–76. PMID: 30170311 DOI: 10.1016/j.psyneuen.2018.08.027
6. Rovnaghi CR, **Anand KJS**. Pathways from adverse childhood experiences to nervous system dysregulation. ***Internal Medicine Review*** 2018; 4(10): 1-20 (https://www.internalmedicinereview.org/index.php/imr/article/download/773/pdf).
7. Walco GA, Kopecky EA, Weisman SJ, Stinson J, Stevens B, Desjardins P, Berde CB, Krane EJ, **Anand KJS**, Yaster M, Dampier CD, Dworkin R, Gilron I, Lunn, Maxwell L, McDermott M, Raja SN, Schactel B, Turk D. Clinical Trial Designs and Models for Analgesic Medications for acute pain in neonates, infants, toddlers, children, and adolescents: ACTTION recommendations. ***Pain*** 159(2): 193-205, 2018. PMID: 29140927; PMCID: PMC5949239.
8. Berger JT, Villalobos ME, Clark AE, Holubkov R, Pollack MM, Berg RA, Carcillo JA, Dalton H, Harrison R, Meert KL, Newth CJL, Shanley TP, Wessel DL, **Anand KJS**, Zimmerman JJ, Sanders RC Jr, Liu T, Burr JS, Willson DF, Doctor A, Dean JM, Jenkins TL, Nicholson CE; *Eunice Kennedy Shriver* National Institute of Child Health and Human Development Collaborative Pediatric Critical Care Research Network. Cognitive development one year after infantile critical pertussis. ***Pediatric Critical Care Medicine*** 19(2): 89-97, 2018. PMID: 29117060; PMCID: PMC5796844.
9. Katewa A, **Anand KJS**, Sahu B. One stage repair of aortic pseudo-aneurysm following central shunt and Tetralogy of Fallot with single pulmonary artery. ***World Journal of Congenital Heart Surgery***, 2018. doi: 10.1177/2150135117750566. [Epub ahead of print]. PMID: 29614910.
10. Elbers J, Rovnaghi CR, Golianu B, **Anand KJS**. Clinical profile associated with Adverse Childhood Experiences: The advent of nervous system dysregulation. ***Children*** 2017; 4 (11). pii: E98. doi: 10.3390/children4110098. PMID: 29140276 PMCID: PMC5704132.
11. **Anand KJS**. Defining Pain in Newborns: Need for a new taxonomy? ***Acta Paediatrica*** 2017; 106(9): 1438-1444. doi: 10.1111/apa.13936, PMID: 28556311.
12. Schwingshackl A, **Anand KJS**. Work-Life Balance: Essential or Ephemeral? ***Frontiers in Pediatrics*** 2017; 5:108. doi: 10.3389/fped.2017.00108. PMID: 28540286.

13. McGuire JK, Schwingshackl A, **Anand KJS**. Pediatric ARDS –"Reaching for the horizon". ***Frontiers in Pediatrics*** 2017; 15 (5): 100. DOI: 10.3389/fped.2017.00100. PMID: 28555176.
14. **Anand KJS**, Eriksson M, Boyle EM, Avila-Alvarez A, Andersen RD, Sarafidis K, Polkki T, Matos C, Lago P, Papadouri T, Attard-Montalto S, Ilmoja ML, Simons S, Tameliene R, van Overmeire B, Berger A, Dobrzanska A, Schroth M, Bergqvist L, Courtois E, Rousseau J, Carbajal R; EUROPAIN survey working group of the NeoOpioid Consortium. Assessment of continuous pain in newborns admitted to NICUs in 18 European Countries. ***Acta Paediatrica*** 2017, 106(8): 1248-1259. DOI: 10.1111/apa.13810. PMID: 28257153.
15. Carcillo JA, Dean JM, Holubkov R, Berger J, Meert KL, **Anand KJS**, Zimmerman JJ, Newth CJL, Harrison R, Burr J, Willson DF, Nicholson C, Bell MJ, Berg RA, Shanley TP, Heidemann SM, Dalton H, Jenkins TL, Doctor A, Webster A, Tamburro RF; *Eunice Kennedy Shriver* National Institute of Child Health and Human Development (NICHD) Collaborative Pediatric Critical Care Research Network (CPCCRN). Interaction between 2 nutraceutical treatments and host immune status in the Pediatric Critical Illness Stress-Induced Immune Suppression comparative effectiveness trial. ***J Parenter Enteral Nutr.*** 41(8): 1325-1335, 2017. PMID: 27660289.
16. Lago P, Frigo AC, Baraldi E, Pozzato R, Courtois E, **Anand KJS**, Rambaud J, Carbajal R. Sedation and analgesia practices at Italian Neonatal Intensive Care Units: Results from the EUROPAIN study. ***Italian Journal of Pediatrics*** 43(1):26, 2017. doi: 10.1186/s13052-017-0343-2. PMID: 28270167.
17. Mitchell AJ, Hall, RW, Golianu B, Yates C, Williams DK, Chang J, **Anand KJS**. Does Noninvasive Electrical Stimulation of Acupuncture Points (NESAP) reduce heelstick pain in neonates? ***Acta Paediatrica*** 105(12):1434-1439, 2016. DOI: 10.1111/apa.13581. PMID: 27607517.
18. **Anand KJS**. Revisiting a dilemma: repetitive pain vs. opioid exposures? ***Acta Paediatrica*** 105(7): 736-7, 2016. doi: 10.1111/apa.13442. PMID: 27272629.
19. Kimura D, Saravia J, Rovnaghi CR, Meduri GU, Schwingshackl A, Cormier SA, **Anand KJS**. Plasma Biomarker Analysis in Pediatric ARDS: Generating Future Framework from a Pilot Randomized Control Trial of Methylprednisolone: A Framework for Identifying Plasma Biomarkers Related to Clinical Outcomes in Pediatric ARDS. ***Frontiers in Pediatrics*** 4:31, 2016. doi: 10.3389/fped.2016.00031. PMID: 27066464
20. Carcillo JA, Dean JM, Holubkov R, Berger J, Meert KL, **Anand KJS**, Zimmerman JJ, Newth CJ, Harrison R, Burr J, Willson DF, Nicholson C, Bell MJ, Berg RA, Shanley TP, Heidemann SM, Dalton H, Jenkins TL, Doctor A, Webster A; Eunice Kennedy Shriver National Institute of Child Health and Human Development (NICHD) Collaborative Pediatric Critical Care Research Network (CPCCRN). Inherent risk factors for nosocomial infection in the long stay critically ill child without known baseline immunocompromise: A *post hoc* analysis of the CRISIS Trial. ***Pediatric Infectious Diseases Journal*** 35(11): 1182-1186, 2016. PMID: 27753764; PMCID: PMC5089838.
21. Dong CE, Rovnaghi CR, **Anand KJS**. Ketamine exposure during embryogenesis inhibits cellular proliferation in rat fetal cortical neurogenic regions. ***Acta Anaesthesiologica Scandinavica*** 60 (5): 579-587, 2016. doi: 10.1111/aas.12689. PMID: 26822861.

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37. Shah SH, West AN, Sepanski RJ, Hannah D, May WN, **Anand KJS**. Clinical risk factors for Central Line-Associated Venous Thrombosis (CLAVT) in children: A study of 3,258 central venous lines. ***Frontiers in Pediatrics*** 2015; 3:35. doi: 10.3389/fped.2015.00035. PMID: 26000265.
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39. Jardine D, Emond M, Meert KL, Harrison R, Carcillo JA, **Anand KJS**, Berger J, Newth CJ, Willson DF, Nicholson C, Dean JM, Zimmerman JJ; NICHD Collaborative Pediatric Critical Care Research Network. A single nucleotide polymorphism in the corticotropin receptor gene is associated with a blunted cortisol response during pediatric critical illness. ***Pediatric Critical Care Medicine*** 2014; 15(8): 698-705. PMID: 25055195
40. Dong CE, Rovnaghi CR, **Anand KJS**. Ketamine affects the neurogenesis of rat fetal neural stem progenitor cells via the PI3K/Akt-p27 signaling pathway. ***Birth Defects Research (BDRB)*** 101(5): 355-363, 2014. PMID: 25231110.
41. Hall RW, **Anand KJS**. Pain management in newborns. ***Clinics in Perinatology*** 41: 895-924, 2014. PMID: 25459780.
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87. Hefley, G. C., Smith, A., **Anand, K.J.S.** (April 2005). Parent Bed Spaces in the PICU: Effect on Parental Stress. Paper presented at the meeting of the 15th Annual Conference of the Society of Pediatric Nurses. Philadelphia, Penn.
88. Hefley, G. C., Smith, A., **Anand, K.J.S.** (April 2005). Parent Bed Spaces in the PICU: Effect on Parental Stress. Paper presented at "Evidence for Practice 2005" Research Conference. Little Rock, AR.
89. Hefley, G. C., Belote, C., **Anand, K.J.S.** (April 2005). Methods of changing vasoactive infusion lines: Quick switch or double pump? Poster presentation, 15th Annual Conference, Society of Pediatric Nurses. Philadelphia, PA.
90. Sallassi-Scotter, M., Schexnayder, S., White, K., **Anand, K.J.S.**. Creating a PICU environment to promote "Caring through all seasons". Poster presentation, National Association of Children's Hospitals and Research Institutes, NACHRI Spring Conference, March 12-14, 2005, New Orleans, LA.
91. Hall RW, Wallace T, **Anand KJS**, Garcia-Rill E. Pain, stress, and attentional dysfunction in ex-preterm adolescents. Pediatric Academic Societies' 2006 Annual Meeting, April 29-May 3, 2006, San Francisco, CA.

92. Boyle E, Freer Y, Teunisse S, McIntosh N, **Anand KJS**. Research in neonates – International differences in consent. Pediatric Academic Societies' 2006 Annual Meeting, April 29-May 3, 2006, San Francisco, CA.
93. Stroud MH, Fiser RT, Moss MM, **Anand KJS**. Near-continuous, noninvasive blood pressure monitoring during pediatric transport. American Academy of Pediatrics, National Convention & Exhibition, October 8-12, 2006. **Received AAP Young Investigator's Award from Section of Critical Care Medicine**.
94. Stroud MH, Fiser RT, **Anand KJS**. Importance of noninvasive blood pressure monitoring during pediatric transport. Abstract presented at the UAMS College of Medicine Fellow's Day, May 16th, 2006. **Received 1st Prize for the Best Fellow's Day Presentation**.
95. Bhutta AT, **Anand KJS**, Schmitz ML, Lindquist D. Ketamine as a neuroprotective agent in children undergoing cardiac surgery: Results of Magnetic Resonance Spectroscopy- Presented as poster presentation at 11th Annual Update on Pediatric Cardiovascular Disease, Feb 6-10, 2007; Scottsdale, AZ.
96. Stroud MH, Fiser RT, Prodhan P, Moss M, **Anand KJS**. Near-Continuous Blood Pressure (BP) Monitoring during Transport Improves Outcomes in P.I.C.U. Patients: A Randomized Controlled Trial. Abstract presented at the Pediatric Academic Societies' Annual Meeting, Toronto, Canada, May 5-8, 2007. **Fellows' Clinical Research Award, SPR**.
97. Bhutta AT, Rovnaghi CR, **Anand KJS**. Use of low dose Ketamine: Effect on neuronal activation and neuronal degeneration in neonatal rats. Poster presentation at the 5th World Congress on Pediatric Critical Care, June 24-28, 2007; Geneva, Switzerland.
98. Zhang LL, Rovnaghi CR, **Anand KJS**. Acupuncture reduces inflammatory hyperalgesia in newborn rats. Poster presentation at the 5th World Congress on Pediatric Critical Care, June 24-28, 2007; Geneva, Switzerland.
99. Zhang LL, Rovnaghi CR, **Anand KJS**. Acupuncture reduces brain cell death following neonatal inflammatory pain. Oral presentation at the 5th World Congress on Pediatric Critical Care, June 24-28, 2007; Geneva, Switzerland.
100. Rovnaghi CR, Venkatesan AK, **Anand KJS**. Neonatal pain alters adult cognitive performance & brain cytokine expression. Poster presentation at the 5th World Congress on Pediatric Critical Care, June 24-28, 2007; Geneva, Switzerland.
101. Hall RW, Rovnaghi CR, **Anand KJS**. Ketamine normalizes the neuroexcitatory response and decreases cell death after inflammatory pain in the amygdaloid region of the rat model. Oral presentation at the 5th World Congress on Pediatric Critical Care, June 24-28, 2007; Geneva, Switzerland.
102. Lantz SM, Frank JC, Bratton GN, Palmer SH, Rovnaghi CR, **Anand KJS**, Clancy B. Behavioral effects of Ketamine at birth are evident at late adulthood. Annual Meeting, Arkansas Chapter of the Society for Neuroscience, October 23, 2007.
103. Brown RC, Venkatesan AK, Rovnaghi CR, Hall, RW, **Anand KJS**. Behavioral Effects of Ketamine at Birth are Evident at Late Adulthood. Neurosci Abstr (2007)
104. **Anand KJS**. Exposure to neonatal pain may set the life-span patterns of pain processing. Canadian Pain Society Conference: "Pain Through The Ages - Common Themes", May 27-30, 2008, Victoria (BC), Canada.
105. Bhutta AT, Schmitz ML, James LP, Jaquiss RDB, Imamura M, Lindquist D, Glasier C, Wardbegnoche W, **Anand KJS**. Ketamine as a neuroprotective agent for children undergoing cardiac surgery: Results of a pilot randomized controlled trial. Platform presentation at Society of Pediatric Research/Pediatric Academic Societies Annual

Meeting, May 2-6, 2008, Honolulu, Hawaii.

106. McJunkins A, Green A, **Anand KJS**. Pain Assessment in Cognitively Impaired, Functionally Impaired Children (PACIFIC): A Pilot Study. Presented at Society of Pediatric Nurses Annual Convention in Denver, CO April 2008. Also presented at UAMS Research Day, Little Rock, AR, April 2008.
107. McJunkins A, Green A, **Anand KJS**. Pain Assessment in Cognitively Impaired, Functionally Impaired Children (PACIFIC): A randomized comparison of two pain assessment tools. Presented at Society of Pediatric Nurses Annual Convention in Atlanta, GA, April 2009, also presented at UAMS Research Day, April 2009.
108. Mehta P, **Anand KJS**, Bhutta AT, McCracken A. Does exposure to opioids in the early infancy lead to long-term opioid tolerance? Results of a Case-Control Study. 2009 National Conference and Exhibition, American Academy of Pediatrics.
109. Dong C, Rovnaghi CR, **Anand KJS**. Repetitive Pain and Ketamine Analgesia activate Inflammatory Mediators in the Newborn Brain. Presented at the 8th International Symposium on Pediatric Pain, International Association for the Study of Pain, March 10-13, 2010 in Acapulco, Mexico.
110. Dong C, Rovnaghi CR, **Anand KJS**. Ketamine damages the proliferation of Neural Stem/Progenitor Cells (NSPCs). Presented at the 8th International Symposium on Pediatric Pain, International Association for the Study of Pain, March 10-13, 2010 in Acapulco, Mexico.
111. Shappley RKH, Bardhan B, Ingram K, Storgion SA, Arnold SR, **Anand KJS**, Shah SH. Determinants of Pediatric Intensive Care Unit (PICU) Length of Stay (LOS) in Children with H1N1 Influenza A Infection. PAS Annual Meeting, Vancouver (BC), May 2010.
112. Millfors P, **Anand KJS**, Bergqvist LL. Effects of paracetamol during first days of life. Poster presentation at the 16th World Congress of Basic and Clinical Pharmacology, WorldPharma2010 *"Bridging Basic and Clinical Pharmacology"*, July 17-23, Copenhagen, Denmark.
113. Dong C, Rovnaghi CR, **Anand KJS**. Ketamine exposure alters the fate of cortical neural stem progenitor cells (NSPCs) isolated from the embryonic rat brain. Pediatric Academic Societies and Asian Society for Pediatric Research Joint Meeting, PAS Poster Presentation, Denver, CO., April 30 - May 3, 2011.
114. Shah SH, Scwingshackl A, Figueroa M, Knott-Craig CJ, **Anand KJS**. Development of a post pediatric cardiac surgery cardiac arrest (ppcs-ca) management flow process pathway. Poster presentation, Pediatric Academic Societies PAS, Denver, CO., April 30 - May 3, 2011.
115. Sepanski RJ, Brinkley K, Summerall C, Giles K, Storgion SA, **Anand KJS**. Race/ethnicity associated with increased mortality among Pediatric Intensive Care Unit (PICU) patients. Pediatric Academic Societies and Asian Society for Pediatric Research Joint Meeting, PAS Platform Presentation, Denver, CO., April 30 - May 3, 2011.
116. Dukes KM, Bobo KS, **Anand KJS**. Evaluation of Weaning Methadone and Lorazepam in Pediatric Patients. Presented at the 19th Pediatric Pharmacy Conference and 2010 Annual Meeting, Pediatric Pharmacy Advisory Group, October 7-10, 2010; Saint Charles, MO.
117. **Anand KJS**. Development of the pain in the fetus and neonate. Platform presentation, 48th Annual Meeting of the Japanese Society of Perinatal & Neonatal Medicine; Saitama, Japan on July 8 - 10, 2012.
118. **Anand KJS**. Management of pain in the neonate: current practice and novel options.

Platform presentation, 48th Annual Meeting of the Japanese Society of Perinatal & Neonatal Medicine; Saitama, Japan on July 8 - 10, 2012.

119. **Anand KJS**. Love, Pain, and Intensive Care. Workshop presentation, 48th Annual Meeting of the Japanese Society of Perinatal & Neonatal Medicine; Saitama, Japan on July 8 - 10, 2012.
120. Dong C, **Anand KJS**. No functional NMDA receptor determines the resistance of neural stem progenitor cells to ketamine-induced cell death. Poster presentation, Annual Meeting of the Society for Critical Care Medicine, Puerto Rico, January 27-31, 2013.
121. Millfors P, Bai L, **Anand KJS**, Bergqvist LL. Effects of paracetamol during first days of life. Poster presentation, 9th International Symposium on Pediatric Pain, Stockholm June 17-20, 2013.
122. Sundell I, Carbajal R, **Anand KJS**, Eriksson M. National guidelines for neonatal pain management – occurrence and content. Poster presentation, 9th International Symposium on Pediatric Pain, Stockholm June 17-20, 2013.
123. **Anand KJS**, Hall RW, Grunau RVE, Tibboel D. Opioid therapy in neonates: Long-term effects & functional outcomes. Workshop presentation, 9th International Symposium on Pediatric Pain, Stockholm, Sweden; June 17-21, 2013.
124. **Anand KJS**. Pain in Infancy: From Stress to Society. 9th Annual "In Praise of Medicine" Public Address, Erasmus University MC, Sophia Children's Hospital, Rotterdam, The Netherlands, October 4, 2013.
125. Bardhan B, Meduri, G, Rovnaghi CR, **Anand KJS**. Methylprednisolone infusion in pediatric Acute Lung Injury (ALI/ARDS): Interim results from a double-blind, placebo-controlled randomized trial. SCCM poster #974, Jan. 19-23, 2013; San Juan, Puerto Rico.
126. Shah SH, Hannah D, Pickard S, May W, **Anand KJS**. Clinical risk factors for central line associated venous thrombosis (CLAVT) in children. Poster presentation, Pediatric Academic Societies' Meeting, Washington DC, May 3-7, 2013.
127. **Anand KJS**, Rovnaghi CR, McPherson KD, Moore AP, Tylavsky FA. Maternal traumatic life events but not parenting stress regulate hair cortisol levels in early childhood. Platform presentation, Pediatric Academic Societies' Meeting, Washington DC, May 3-7, 2013.
128. Boni Y, Rovnaghi CR, **Anand KJS**. Racial Differences in salivary levels of IL-2 and cortisol: Candidate biomarkers for detection of HPA axis changes in the developing brain. 2015 Annual Biomedical Research Conference for Minority Students (ABRCMS), November 11-14 2015, Washington State Convention Center, Seattle, WA.
129. Kimura D, Saravia JS, Rovnaghi C, Schwingshackl A, Meduri G, Cormier SA, Anand KJS. 669: The Effect of Low Dose Methylprednisolone on Biomarker Levels in Early Pediatric ARDS. Critical Care Medicine. 2015; 43 (12 Suppl 1):169. doi: 10.1097/01.ccm.0000474497.21863.8a. PubMed PMID: 26570330.
130. **Anand KJS**, Slominki R, Boni Y, Zheng A, Rovnaghi C. 502: Magnetoencephalography scanning alters salivary cortisol, ACTH, and S100beta in pre-school children. Critical Care Medicine. 2015; 43(12 Suppl 1):127. doi: 10.1097/01.ccm.0000474330.20558.0f. PubMed PMID: 26570163.
131. Kimura D, Rovnaghi CR, Drago BB, Meduri U, **Anand KJS**, Schwingshackl A. Differential regulation of inflammatory biomarkers by methylprednisolone in early pediatric ARDS. Critical Care Medicine. 2016; 46 (Suppl 1):183.
132. **Anand KJS**, Cochrane JR, Cutts T, Gunderson G. Changing Health Care: From pathology to generativity; Workshop on *'The Leading Causes of Life',* 14th International Conference

on Communication, Medicine, and Ethics (COMET), Aalborg University, Denmark, July 4-6, 2016.

133. Carbajal R, Courtois E, Eriksson M, Boyle E, Avila-Alvarez A, Andersen RD, Sarafidis K, Polkki T, Matos C, Lago P, Papadouri T, Montalto SA, Ilmoja ML, Simons S, Tameliene R, van Overmeire B, Berger A, Dobrzanska A, Schroth M, Bergqvist L, Lagercrantz H, **Anand KJS** on behalf of the EUROPAIN Survey Working Group. Pain assessment in ventilated and non-ventilated neonates in NICUS across Europe: Results from the EUROPAIN study. Presented at the 16th World Congress on Pain, International Association for the Study of Pain (IASP), September 26-30, 2016, Yokohama, Japan.

134. Amuzie GO, Rigdon J, Qin FF, Rovnaghi CR, **Anand KJS**. Development of the Family Poverty Index (FPI): a novel index to measure socioeconomic status. Presented at the12th Annual Symposium for STEP-UP HS program, supported by National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK), National Institutes of Health, Grant number: 2R25DK078382-12; August 6-10, 2017, Bethesda, MD.

135. Rubio A, Rovnaghi CR, **Anand KJS**. What are normal cortisol values for young children? Presented at the12th Annual Symposium for STEP-UP HS program, supported by National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK), National Institutes of Health, Grant number: 2R25DK078382-12; August 6-10, 2017, Bethesda, MD.

136. Krasinska KM, Rovnaghi CR, Anand KJS, Chien A. Quantitative LC-MS/MS analysis of cortisol and cortisone in children's hair. Comparison with cortisol ELISA assay. American Society of Mass Spectrometry, June 2018 San Diego, CA.

Editorial Activities

1. ***Ad Hoc* Manuscript Reviewer**:

Acta Paediatrica
Anesthesiology
Archives of Disease in Childhood
American Journal of Public Health
Biology of the Neonate
Brain Research
British Medical Journal
Clinical Investigation
Clinical Journal of Pain
Critical Care Medicine
European Journal of Pediatrics
Epidemiology
Frontiers in Pediatrics
JAMA
JAMA Pediatrics
Journal of Pain
Journal of Pediatrics
Journal of Perinatology
Lab Animal (Nature)
New England Journal of Medicine
Pain
Pediatrics
Pediatric Critical Care Medicine
Pediatric Pulmonology
Pediatric Research
The Lancet

2. Appointed as Specialty Chief Editor for ***"Frontiers in Pediatric Critical Care"***, a section of ***Frontiers in Pediatrics***, Nature Publishing Group; has appointed 24 Associate Editors and 107 Review Editors.

3. **Member of the Editorial Boards of:**
   Frontiers in Pediatrics (2012 – present)

Frontiers in Pediatric Critical Care (Editor-in-Chief, 2013 – present)
Pain (2005-2015)
Critical Care Medicine (2002-2012)
Pediatric and Neonatal Anesthesia *www.anestesiapediatrica.it* (2004-2012)
Pediatric Critical Care Medicine (2005-2009)
The Suffering Child (*www.thesufferingchild.net*) (2002-2004)
Biology of the Neonate (2002-2004)
Indian Journal of Critical Care Medicine (2003-2005)

Grant Reviewer

1. **National Institutes of Health:**
   - National Institute for General Medical Sciences (NIGMS), Surgery, Anesthesiology & Trauma Study Section (*ad hoc* reviewer, 1989).
   - National Institute for Child Health and Human Development (NICHD), Maternal & Child Health Study Section-A (*ad hoc* reviewer, 1992).
   - National Institute for Child Health and Human Development (NICHD), Maternal & Child Health Study Section-B (*ad hoc* reviewer, 1997).
   - National Institute for Child Health and Human Development (NICHD), Small Grants Program (R03) on Health Services Research (Member, 2001).
   - National Institute for Child Health and Human Development (NICHD), Pediatric Pharmacology Research Study Section (ZHD1 DSR-A-01), (October, 2003).
   - National Institute for Child Health and Human Development (NICHD), Member of the Child Health & Human Development-A Pediatrics Study Section (ZHD1 CHHD-A-01), (October, 2003).
   - National Institute for Child Health and Human Development (NICHD), Loan Repayment Program, applications (ZHD1 DSR-A LRP Study Section) (April, 2004)
   - National Institute for Child Health and Human Development (NICHD), *ad hoc* reviewer (K12 Grant awards for Critical Care Medicine, May, 2004)
   - National Institute for Child Health and Human Development (NICHD), (ZHD1 DSR-A Loan Repayment Program Study Section) (Member, 2005)
   - National Institute for Mental Health (NIMH), NIH Roadmap Initiative: review of Interdisciplinary Training Grant applications (July, 2005)
   - National Institute for Child Health and Human Development, Special Emphasis Panel for the NICHD Neonatal Network (November, 2005)
   - National Institute for Child Health and Human Development (NICHD), Pediatrics Sub-Committee (CHHD-A) (October, 2005)
   - National Institute for Child Health and Human Development (NICHD), ZHD1 DSR-A Loan Repayment Program Committee (March-April, 2006)
   - National Heart, Lung and Blood Institute (NHLBI), Clinical Studies and Training Scientific Review Group (CLTR Study Section, June, 2006)
   - Center for Scientific Review, National Institutes of Health, BBBP - Biobehavioral & Behavioral Processes IRG, Child Psychopathology & Developmental Disabilities (CPDD) Study Section; Ad hoc Reviewer (June, 2006)
   - National Center for Research Resources (NCRR), ZRR1 CR-3 (01), Loan Repayment

Program Committee (March-April, 2007)

- National Institute of Neurological Disorders and Stroke (NINDS), ZNS1 SRB-M-948 (01), Loan Repayment Program Committee (April, 2007)
- National Institute of Neurological Disorders and Stroke (NINDS), Special Emphasis Panel ZNS1 SRB-M (75), April 2010.
- Center for Scientific Review (CSR), NIH Study Section ZRG1 SBIB-V (82), National Institutes of Health, October 2014.
- Member, Special Emphasis Panel, STTR applications for RFA: "Safe and Effective Instruments and Devices for Use in Neonatal and Pediatric Care Settings (R41/R42)" and "Non- or Minimally-Invasive Methods to Measure Biochemical Substances for Neonatal and Perinatal Clinical Care and Research (R41)", October 2015.
- Member, *Eunice Kennedy Shriver* National Institute of Child Health & Human Development (NICHD/NIH), Special Emphasis Panel/Scientific Review Group 2016/01 ZHD1 DSR-K (90), March 2016.
- *Ad hoc* Member, Center for Scientific Review 2016/10 ZRG1 PSE-D (90), Neurological, Aging & Musculoskeletal Epidemiology (NAME) Study Section, June 2016.
- Member, Center for Scientific Review SBIB H (82), Clinical Fetal & Pediatric Applications Study Section, February 2017.
- Member, Center for Scientific Review SBIB H (82), Clinical Fetal & Pediatric Applications Study Section, October 2017.

2. **National Science Foundation:**
   - Directorate for Social, Behavioral, and Economic Sciences, Division of Behavioral and Cognitive Sciences (Neuroendocrinology Study Section, *ad hoc* Reviewer, 2004, 2012).

3. **Non-Federal and Foreign National Agencies:**
   - Medical Research Council of Canada (1987, 1991)
   - The Wellcome Trust, United Kingdom (1996, 1999, 2001, 2004)
   - Hospital for Sick Children Foundation, Toronto, Canada (1995, 1997)
   - Career Scientist Development Program, Ministry of Health, Canada (1996, 1998)
   - Austrian Federal Ministry of Education, Science and Culture (Division of Life Sciences) (2002)
   - Dutch Organization for Scientific Research, The Netherlands (1995, 2001)
   - The Blowitz-Ridgeway Foundation, "Neuroscience Grants" (2001, 2002, 2004)
   - Society of Critical Care Medicine, "Patient Safety Grants" (2003, 2004)
   - Swiss National Science Foundation, Division of Biology and Medicine, Bern, Switzerland: "Stress Neurobiology Grants" (2003)
   - Society of Critical Care Medicine, Vision Grants Review (2005, 2006, 2007)
   - German Ministry of Health, German Aerospace Center Department of Health Research, Long-term Studies in Health Research (September 2007).
   - Spanish Ministry of Health and Consumer's Affairs, Invited grant evaluator for the National Programme of Cooperative Research (March, 2008)

Peer Reviews

1. **External Reviewer, Faculty Promotion Committees:**

- **Dr. Ruth V.E. Grunau** for Assistant Professor, Department of Pediatrics, University of British Columbia, Vancouver BC, Canada.
- **Dr. Joseph D. Tobias** for Associate Professor with Tenure, University of Missouri, Columbia, Missouri.
- **Dr. Patricia A. McGrath** for Professor with Tenure, University of Western Ontario, London, Ontario, Canada.
- **Dr. Bonnie Stevens** for Associate Professor with Tenure, University of Toronto, Toronto, Ontario, Canada.
- **Dr. Steven J. Weisman** for Professor of Anesthesiology, Medical College of Wisconsin, Milwaukee, Wisconsin.
- **Dr. Linda S. Franck** for Associate Professor, Department of Family Health Care Nursing, School of Nursing, University of California, San Francisco, CA.
- **Dr. Myron Yaster** for Tenured Professor, Department of Anesthesiology and Critical Care Medicine, Johns Hopkins University School of Medicine, Baltimore, MD.
- **Dr. G. Allen Finley** for Full Professor with tenure, Department of Anesthesiology, Dalhousie University, Halifax, Nova Scotia, Canada.
- **Dr. William Zempsky** for Associate Professor, Department of Pediatrics, University of Connecticut Health Center, Farmington, CT.
- **Dr. Santhanam Suresh** for Associate Professor in the Department of Anesthesiology, Feinberg School of Medicine, Northwestern University, Chicago, IL.
- **Dr. Marianne Garland** for Associate Professor in the Department of Pediatrics, Columbia University College of Physicians and Surgeons, New York, NY.
- **Dr. Natan Noviski** for Associate Professor, Department of Pediatrics, Harvard Medical School and MassGeneral Hospital for Children, Boston, MA.
- **Dr. Ruth Grunau** for Professor, Department of Pediatrics, University of British Columbia, Vancouver BC, Canada.
- **Dr. Michael Agus** for Associate Professor, Department of Anesthsiology & Critical Care Medicine, Harvard Medical School, Children's Hospital, Boston, MA.
- **Dr. Michael Bell** for Professor, Department of Critical Care Medicine, University of Pittsburgh, UPMC Children's Hospital of Pittsburgh, Pittsburgh, PA.
- **Dr. I. Federico Fernandez-Nievas** for Assistant Professor, University of Cleveland, Cleveland Clinic, Cleveland, OH.
- **Dr. Emilie Courtois**, Member of l'Académie des Sciences, Bourses françaises L'Oréal-UNESCO Pour les Femmes et la Science, Paris, France.
- **Dr. Umesh Narsinghani** for Professor, Department of Pediatrics, Mercer University School of Medicine, Macon, GA.
- **Dr. Andreas Schwingshackl** for Associate Professor In-Residence, Department of Pediatrics, David A. Geffen School of Medicine, University of California Los Angeles, Los Angeles, CA.
- **Dr. Jason Custer** for promotion to Associate Professor (non-tenure track), Department of Pediatrics, University of Maryland, Baltimore, MD.
- **Professor Ricardo Carbajal** for promotion to Professor and Chair, Division of General Pediatrics, University Hospital of Geneva, Geneva, Switzerland.

2. **Scientific Reviewer for:**

- 3rd International Meeting of Pediatric Intensive Care, June 1993, Padova, Italy.
- Conference on Pediatric Pain: Challenges, Innovations, and Costs, Emory University School of medicine and Egleston Children's Hospital, Atlanta GA, November 1995.
- 2nd World Congress on Pediatric Intensive Care, June 1996, Rotterdam, The Netherlands.
- 4th International Symposium on Pediatric Pain, July 1997, International Association for the Study of Pain, Helsinki, Finland.
- 3rd World Congress on Neonatal and Pediatric Intensive Care, June 2000, Montreal, Canada.
- 2005 Pediatric Academic Societies' (SPR/APS/APA/AAP) Annual Meeting, May 2005, Baltimore, MD.
- 5th International Symposium on Pediatric Pain, March 2010, International Association for the Study of Pain, Acapulco, Mexico.
- Workshop Reviewer, Pediatric Academic Societies' Annual Meeting, May 2012, Boston, MA.
- Workshop & Abstract Reviewer, Pediatric Academic Societies' Meeting, May 2013, Washington DC.
- Workshop & Abstract Reviewer, Pediatric Academic Societies' Meeting, May 2014, Vancouver, BC (Canada).
- Workshop & Abstract Reviewer, Pediatric Academic Societies' Meeting, April-May 2015, San Diego, CA.
- Workshop Proposal Reviewer, Pediatric Academic Societies' Meeting, May 2015, Baltimore, MD.

3. Member, Promotions & Tenure Committee, Department of Pediatrics, University of Tennessee Health Science Center (2009-2015) and Chair, Promotions & Tenure Committee, Department of Pediatrics, University of Tennessee Health Science Center, 2013

Academic Leadership Activities:

1. Moderator, Symposium on "Pain and Stress Responses in Children": for the 1st World Congress of Pediatric Intensive Care, June 1992, Baltimore MD, U.S.A.
2. Moderator, Symposium on "Pain Control in the Intensive Care Nursery": Special Ross Conference on "Hot Topics in Neonatology 1992", December 1992, Washington DC, U.S.A.
3. Moderator, Symposium on "Analgesia and Sedation in the Pediatric I.C.U.": The 3rd International Meeting on Pediatric Intensive Care, June 1993, Padova, Italy
4. Chairman, "Neonatal Outcome and Prolonged Analgesia in Newborn ICUs": Protocol Discussion Meeting for the NOPAIN Trial, held in conjunction with "Hot Topics in Neonatology 1993" December 1993, Washington DC, U.S.A.
5. Organizer and Co-Chairman, National Institute of Child Health and Human Development Symposium on "Neonatal Pain: Physiology and Management", supported by the NICHD Center for Research for Mothers and Children, June 1994, Philadelphia PA, U.S.A.
6. Moderator for a Workshop on "Pain during Critical Illness: Management Principles", 3rd International Symposium on Pediatric Pain, IASP Special Interest Group on Pain in Children, June 1994, Philadelphia PA, U.S.A.

7. Course Director, International Symposium on "Pain in Infants: Assessment and Management" Emory University School of Medicine and Egleston Children's Hospital, October 20, 1994, Atlanta GA, U.S.A.
8. Moderator, Symposium on Maternal and Newborn Health "Pain in Newborns: Revolutionary impact on N.I.C.U. care", CHILD HEALTH 2000: Second World Congress & Exposition, May 30 - June 3, 1995, Vancouver (B.C.), Canada.
9. Course Director, "Pediatric Pain: Challenges, Innovations and Costs" Emory University School of Medicine and Egleston Children's Hospital, November 4, 1995, Atlanta GA, U.S.A.
10. Moderator, Symposium on "Intensivists as Change Agents", in Survival Strategy for Pediatric Intensivists under Managed Care, Egleston Children's Health Care System and Emory University, March 14-15, 1996, Atlanta GA, U.S.A.
11. Chairman, Committee on Pain in Newborns and Infants, Project funded by the Maternal and Child Health Bureau, Department of Health & Human Services, U.S. Government, 1996-98.
12. Moderator, Poster Symposium on Analgesia and Sedation in the Pediatric I.C.U., 2nd World Congress on Pediatric Intensive Care, Rotterdam, The Netherlands, June 23-26, 1996.
13. Presented a proposal to the Site Selection Committee for getting the 3rd World Congress of Pediatric Intensive Care to Atlanta in July 2000.
14. Fourth International Pediatric Pain Symposium, Special Interest Group on Pediatric Pain, International Association for the Study of Pain, July 1-4, 1997, Helsinki, Finland. Chairperson, Scientific Symposium 5: Clinical Pharmacology of Analgesics in Children.
15. Chairman, International Consensus Conference on "Pain and Pain Management during Infancy", Nice, France, April 21-23, 1998.
16. Co-Chairman, Symposium on "Pain Management in Neonatal and Pediatric Intensive Care", 9th Annual Meeting, European Society of Pediatric Intensive Care, Stockholm, Sweden, September 6-9, 1998.
17. Moderator, Symposium on "Philosophical and Scientific Bases for the Definition of Pain", 17th Annual Scientific Meeting, American Pain Society, San Diego, CA, November 5-8, 1998.
18. Chairman, International Consensus Conference on "Pain Management Guidelines for Infant", Baden-Baden, Austria, August 20-21, 1999.
19. Moderator, Session on "Pharmacological Management", 27th Neonatal & Infant Symposium, University of California at Irvine, College of Medicine, Vail, Colorado; March 19-23, 2000.
20. Chairman, Pharmacology, Pain & Sedation Track, at the 3rd World Congress on Pediatric Intensive Care, Montreal, Canada, June 24-29, 2000.
21. Moderator of the Plenary Session, Pharmacology, Pain & Sedation Track, 3rd World Congress on Pediatric Intensive Care, Montreal, Canada, June 24-29, 2000.
22. Chairman, State-of-the-Art Plenary Session on Pediatric Pain, PAS 2002 Meeting, Baltimore MD, May 3-7, 2002.
23. Chairman, Plenary Session on Pain, 18th European Congress of Perinatal Medicine, June 19 – 22, 2002; Oslo, Norway.
24. Chairman, Plenary Session, 8th Biennial Congress, European Society for Developmental Pharmacology (ESDP), October 27th, 2002; Liège, Belgium.
25. Chairman, Pharmacology, Analgesia & Sedation Track, 4th World Congress on Pediatric Intensive Care, Boston MA, June 16-20, 2003.
26. Chairman, NICHD/FDA Task Force for Neonatal Anesthesia, Analgesia and Sedation, Newborn Drug Development Initiative from the Best Pharmaceuticals for Children Act, February 10th, 2003.

27. Expert Witness for the U.S. Department of Justice, defendants of the Partial Birth Abortion Ban Act of 2003. Provided expert testimony on the development of fetal pain in the Supreme Courts for the District of Nebraska, Southern District of New York, and Northern District of California.
28. Chairman, Neonatal Pain Control Working Group, Newborn Drug Development Initiative Workshop, March 29th and 30th, 2004; Baltimore, MD.
29. Research Competition Judge, 11th Annual Residents' Day, Department of Anesthesiology, University of Arkansas for Medical Sciences, February 12th, 2005; Little Rock, AR.
30. Moderator for the Brain Injury Poster Symposium Session, Saturday, PAS Annual Meetings, Washington DC, May 14th, 2005.
31. Chairman, 11th World Congress on Pain held in Sydney, Australia, workshop on "Impact of Neonatal Pain on Subsequent Pain Processing, Pain Thresholds and Responses to Analgesia".
32. Hosted a meeting of the NIMH-funded Maternal-Fetal Network (Impact of Adverse Fetal and Neonatal Experience on Child and Adolescent Mental Health, "Salient Environmental Signals and Learning Systems: the LHPA Axis") in Little Rock, October 5-7, 2006.
33. 36th SCCM Critical Care Congress, Orlando, FL; February 17-21, 2007; Chaired the Annual Meeting of the SCCM Research Committee.
34. Social Issues Roundtable, Society for Neuroscience Meeting, San Diego CA, November 11-16, 2007. Multi-disciplinary discussion on: "Can the Neuroscience of Fetal Pain and Human Consciousness inform Social Issues, Current Policies or Pending Legislation?"
35. Moderator, ***Neonatal Clinical Trials: Nutrition, Development and Pulmonary Outcomes***, PAS Original Science Abstracts - Platform Session, Saturday, 5/4/2013; Washington Convention Center, Washington DC.
36. Chairman, ***Community, Family, Health and Genetics: Risk Factors for Socio-emotional Development in Urban Children***, PAS Topic Symposium; Monday, 5/6/2013; Washington Convention Center, Washington DC.
37. Chairman, Workshop on ***Opioid Therapy in Neonates: Long-term Effects & Functional Outcomes***, 9th International Symposium on Pediatric Pain, Stockholm, Sweden; June 17-21, 2013.

(Dr. Anand has continued to play leadership roles in various national and international meetings since June 2013, but stopped recording these roles since they were too numerous to count and were offered due to his preeminence in the fields of neonatal pain and pediatric critical care.)

National Research Committees:

- Data & Safety Monitoring Committee, NIH Grant to University of Pittsburgh (clinical trial of hypothermia for critically ill children with head trauma - NINDS): 1999-2003
- Consultant, G. D. Searle & Co., Planning Committee for Pediatric Trials of COX-2 Inhibitors: 2000-2002
- Consultant, The Vermont-Oxford NICU Network, NIC/Q 2002 Collaborative: 2002-2003
- Research Committee, Society of Critical Care Medicine: 2003-2006; Vice Chair: 2005-2006; Chairman: 2006-2007.
- NICHD/FDA (National Institute of Child Health and Human Development / Food and Drug Administration, Center for Drug Evaluation and Research) Newborn Drug Development Initiative, Member of the National Planning Group 2003-2004

- NICHD/FDA Newborn Drug Development Initiative, Chairman of the Neonatal Pain Control Working Group: 2003-2005
- Data Safety and Monitoring Board for an NHLBI-supported program "Re-engineering Clinical Research in Critical Care" 2005-2008.

COMMITTEE APPOINTMENTS:

Stanford University School of Medicine
- Division Chiefs Committee, Department of Pediatrics, Stanford University (2015-2016)
- Search Committee for Director, Non-invasive Cardiac Imaging Lab, Department of Pediatrics and Lucile Packard Children's Hospital (2016-2017)

Lucile Packard Children's Hospital Stanford
- Service Chiefs Committee (2015-2017)
- Medical Executive Committee (2015-2016)
- Medical Director, Pediatric Intensive Care Unit (June-November, 2016)
- PICU Governance Committee (2015-2016)
- Quality Improvement Council (2015-2016)
- Clinical Improvement Committee (2015-2016)
- Pediatric I.C.U. Local Improvement Team (LIT) Committee (2015-2016)
- Critical Care Daily Management Oversight Committee (2015-2016)
- Packard 2.0-Growing Together: Operations & Transition Planning Committee (2015-2016)

International Association for the Study of Pain:
Selection Committee for the "Young Investigator Award in Pediatric Pain": 2011, 2014, 2017
Member of the Governing Council, Special Interest Group for Pediatric Pain (2010-2017)
Chair, Selection Committee for the "Distinguished Investigator Award in Pediatric Pain", International Association for the Study of Pain: 2011, 2013, 2015

Society for Critical Care Medicine
Research Committee: Member (2001-2006), Vice-Chair (2006-2007), Chair (2007-2008)
SCCM Research Foundation, Board Member (2009-2014)

***Previous Committee Appointments*:**

Egleston Children's Hospital at Emory University:
Pediatric Intensive Care Unit Committee: 1993-1997
Care Pathways Task Force: 1994-1996.
Asthma Care Pathway Development Task Force: 1994-95
Nursing Research Council, Pediatric I.C.U.: 1994-1997
Bereavement Council, Pediatric I.C.U.: 1995-1997
Re-engineering of Intensive Care Services: Aug 1995 - June 1996
Chairman, Research Office Development Task Force: 1996

Department of Pediatrics, Emory University School of Medicine:

Departmental Executive Committee: 1995-96
Division Director's Committee: 1995-96
Goddard Faculty Scholar Selection Committee: 1995
Long-Term Research Planning Committee: 1995-96

Emory University School of Medicine:
Planning Committee, Problem-Based Learning Course: 1995-96
Committee for the Care and Use of Fetal and Newborn Animals: 1995

U.A.M.S. College of Medicine:
- Section Heads Committee, Department of Pediatrics: 1997 to June, 2003
- Program Directors Subcommittee, Graduate Medical Education Committee: 1998 to 2003
- Search Committee for Chairman of the Anatomy Department: 1998-99
- Research Advisory Committee, General Clinical Research Center: 1999 to 2001
- College of Medicine Research Committee (Grants Review): 1999
- Summer Science Student Selection Committee, Department of Pediatrics: 2000
- Chairman, Pediatric Endocrinology Search Committee, Department of Pediatrics: 1999-2000
- Chairman, Research Strategic Planning Committee, Department of Pediatrics: 2000
- Member, GME Appeals Board, UAMS: 2002 to 2004
- Member, Genetics Senior Scientist Search Committee: 2002
- Chair, Faculty Mentoring Committees for Mark Heulitt, M.D. (1999-2001); Mohd. Ilyas, M.D. (2001-to present); R. Whit Hall, M.D. (1999-to present)
- Faculty Mentoring Committees for Craig Rowlands, Ph.D. (1999-2001); Shalini Khurana, M.D. (2003-2005), Adnan Bhutta, M.D. (2002-to present), Ritu Sachdeva, M.D. (2003-to present); Jeffrey R. Kaiser, M.D. (2001-2005); Regina Gargus, M.D., MPH (2005-to present)
- Recruitment Committee for Department of Anatomy and Neurobiology: 2002-2004
- Member, Search Committee for Chief of Pediatric Genetics & Genomics, 2004 – 2005.
- Interviewer for Department of Pediatrics Residency Program candidates, 2002, 2003, 2004.
- Member, Biostatistics Steering Committee, Department of Pediatrics 2004-2005
- CCM Fellows Scholarship Committees, Department of Pediatrics, 2004 – to present.
- Member, Developmental Biology Core Scientists Search Committee, 2005 – to present.
- Campus-wide Criterion 4 Committee, University of Arkansas for Medical Sciences: 2005
- Faculty Advisor, UAMS Graduate School of Studies: 2005
- Member, Special Ad Hoc Evaluation Committee on College-Wide Events, UAMS College of Medicine

U.A.M.S. College of Nursing:
- Member, Nursing Scholars Mentoring Committee
- NIH Grant Review Committee, Dr. Pao-Feng Tsai, August, 2004.

Arkansas Children's Hospital:
- Space Committee: 1997 to 2000
- PICU-CQI Committee: 1997 to 2006
- Multidisciplinary Mortality & Morbidity Review Committee: 1997 to 2001

- Chairman, Task Force on Analgesia for Withdrawal of Life Support: 1998-99
- Intensive Care Committee: 1998 to 2003
- Corporate Compliance Executive Committee: 1999 to 2003
- Nitric Oxide Therapy Task Force: 2000
- Pain Management QI Team: 2000 to 2001
- Pediatric Intensive Care Unit Planning Team, 2001 to 2003

Arkansas Children's Hospital Research Institute

- Research Council: 1997 to 2009.
- Board of Directors: 1999 to 2008
- Chairman, Clinical Research Advisory Committee: 1999 to 2002
- Co-Chair, Faculty Research Conference, 2001 to 2009
- Vice-Chair, Search Committee for the President of ACHRI: April to Sept., 2003
- ACHRI Research Council task force: Definition of focus areas, September – December 2004.

University of Tennessee Health Science Center:

- Dean's Faculty Advisory Committee 2013-2015.
- Member, Promotions & Tenure Committee, Department of Pediatrics 2009-2015.
- Chair, Promotions & Tenure Committee, Department of Pediatrics, 2013
- Division Directors Committee, Department of Pediatrics 2009-2014
- Curriculum Re-design Committee: Basic Science, College of Medicine 2010-2012
- Research Committee, Children's Foundation Research Center 2009-2014
- Search Committee for the Executive Dean, College of Medicine 2011-2012
- Search Committee for the Dean, College of Pharmacy 2012-2013
- Research Development Advisory Committee, Clinical & Translational Science Institute 2009-2012

Le Bonheur Children's Hospital:

- Senior Leadership Council 2009-2014
- Physician Advisory Group 2010-2012
- Quality Council 2009-2013
- Hospital Ethics Committee 2009-2014
- Hospital Operations Move Committee 2009-2010
- Critical Care Safety & Quality Committee 2009-2014
- Disaster Preparedness Task Force 2010-2012
- Neuro-ICU Design Committee 2012-2013
- Pediatric Burns Task Force 2009-2012
- CLABSI Reduction Task Force 2010-2015
- CVICU Physician Leadership Committee 2009-2013
- Organ Transplant Advisory Committee 2012-2014
- Pharmacy & Therapeutics Committee 2010-2015

St. Jude Children's Research Hospital:

- Critical Care Committee 2009-2014

- Tower 2 Planning Committee 2011-2013
- GME Committee, *ad hoc* consultant for simulation studies 2012-2013

Methodist Le Bonheur Healthcare System:
- System-wide Ethics Committee, 2011-2015
- Critical Care Study Group, 2010-2013
- Senior Fellow, Center of Excellence in Faith & Health, 2010-2013

The Urban Child Institute:
- Principal Investigators Steering Committee, 2009-2015

INVITED PRESENTATIONS:

1983

4th Annual Conference, National Neonatology Forum, December, 1983, Indore, India. "The stress response of neonates to surgical trauma."

1984

International Symposium on Surgery and Support of the Premature Infant, September, 1984, Dublin, Ireland. "Metabolic changes following thoracotomy in preterm neonates."

Symposium on Perspectives in Neonatology, November, 1984, Newcastle upon Tyne, UK. "The metabolic and endocrine responses of the human newborn to surgical stress."

Nuffield Department of Surgery Seminars, University of Oxford, February, 1984, Oxford, UK. "Response of the neonate to the stimuli of surgical stress."

Post-Graduate Lectures, Janeway Childhealth Center, Memorial University of Newfoundland, August, 1984, St. John's, Canada. "The beneficial and harmful effects of endocrine-metabolic changes in neonates undergoing surgery."

Department of Anaesthesia Seminars, The Brompton Hospital, November,1984, London, UK. "The neonatal stress response to surgery: Is it a physiological or pathological phenomenon?"

Post-Graduate Seminars, Nuffield Department of Anaesthetics, University of Oxford, November, 1984, Oxford, UK. "Pathophysiology of the neonatal stress response to anaesthesia and surgery."

1985

1st Joint Meeting, The Neonatal Society and British Association of Perinatal Paediatrics, July, 1985, Dundee, UK. "The endocrine and metabolic response of preterm neonates to ligation of a patent ductus arteriosus."

Ciba Foundation Symposium on "Pain and the Fetus" (Ciba Foundation), October, 1985, London, UK. "Does the newborn infant need anaesthesia during surgery?"

6th Annual Conference, National Neonatology Forum, November, 1985, Calcutta, India. "Total parenteral nutrition in newborn infants undergoing surgery."

Paediatric Post-Graduate Lectures, Department of Paediatrics, University of Leicester, February, 1985, Leicester, UK. "Regulation of metabolic homeostasis in the neonatal surgical patient and its practical implications."

Grand Rounds, Department of Anesthesia, children's Hospital, Harvard Medial School, April, 1985, Boston, MA. "Features of the neonatal stress response to anaesthesia and surgery."

Paediatric Cardiology Seminars, Department of Child Health, University of Newcastle upon Tyne, May, 1985, Newcastle upon Tyne, UK. "Practical management of the newborn infant undergoing cardiac surgery in relation to the body's stress response."

Post-Graduate Lectures, Nuffield Department of Anaesthetics, University of Oxford, November, 1985, Oxford, UK. "Randomised control trials of halothane and fentanyl anaesthesia in neonates undergoing surgery."

Guest Lectures, Department of Paediatrics, Post-Graduate Institute for Medical Education and Research, November,1985. Chandigarh, India. "Does the newborn infant really need anesthesia?"

Guest Lectures, Department of Surgery, Post-Graduate Institute for Medical Education and Research, November, 1985, Chandigarh, India. "Measuring the severity of surgical stress in newborn infants."

1986

International Symposium on "Analgesia for Neonates", The Association of Anaesthestists of Great Britain and Ireland, July, 1986, London, UK. "Is the stress response in the newborn different to that in the adult?"

Anesthesia Grand Rounds, Children's Hospital, February, 1986, Boston, MA. "An overview of neonatal stress response."

Cardiac Anesthesia Seminars, Department of Anesthesia, Massachusetts General Hospital, February, 1986, Boston, MA. "Clinical implications of the neonatal stress response."

Paediatric Grand Rounds, Department of Child Health, University of Newcastle upon Tyne, April, 1986, Newcastle upon Tyne ,UK. "Endocrine and metabolic changes in newborn infants undergoing anaesthesia and surgery."

Surgical Grand Rounds, Department of Surgery, Children's Hospital, May, 1986, Boston, MA.

"Measuring the severity of surgical stress in neonates and small infants."

Neonatology Grand Rounds, Department of Paediatrics, University of Oxford, John Radcliffe Hospital, July, 1986, Oxford, UK. "An overview of the neonatal stress responses to surgery."

Anesthesiology Grand Rounds, Department of Anesthesiology, Tufts University, New England Medical Centre Hospitals, December 1986, Boston, MA. "Does the neonate feel pain?"

Pain Clinic Seminars, Children's Hospital, December, 1986, Boston, MA. "Pain perception in the human newborn infant."

1987

International Symposium on Paediatric Surgical and Neonatal Intensive Care, September, 1987, Paris, France. "Randomised trials of fentanyl and halothane - Is anaesthesia necessary for the human newborn infant?"

Third International Symposium on Paediatric Surgical and Neonatal Intensive Care, September, 1987, Paris, France. "Measurement of the degree of surgical stress in newborn infants by a novel scoring method."

First Annual Conference, Society for Pediatric Anesthesia, October, 1987, Atlanta, GA. "Stress response to surgery in the newborn."

International Symposium on 'Opiate Receptors and Pain Management', November, 1987, New Orleans, LA. "Effects of high-dose sufentanil anesthesia on the mortality of neonates undergoing cardiac surgery."

Cardiology Grand Rounds, Department of Pediatrics, Children's Hospital, January, 1987, Boston, MA. "Neonatal stress responses and their practical implications."

Neuropathology Research Seminars, Department of Neurosciences, Harvard Medical School, January, 1987, Boston, MA. "Pain perception in the human fetus and newborn: present data and future research."

Neonatology Seminars, Children's Hospital, March, 1987, Boston, MA. "Pain perception and use of narcotics in preterm and term neonates."

NICU Clinical Conference, Joint Program of Neonatology, Brigham and Women's Hospital, March, 1987, Boston, MA. "Does the newborn baby feel pain and what can we do about it?"

Surgical Grand Rounds, Department of Surgery, Children's Hospital, June, 1987, Boston, MA. "Fundamental statistics for medical research."
Anesthesia Grand Rounds, Department of Anesthesia, Massachusetts General Hospital, July, 1987, Boston, MA. "Neonatal stress responses."

Post-Graduate Seminars, Department of Paediatrics, University of Cambridge, Addenbrooke's Hospital, August, 1987, Cambridge, UK. "Pain perception in the human newborn infant."

Joint Colloquium, Departments of Paediatrics, Surgery & Anesthesia, Christian Albrechts University of Kiel, Universitats-Kinderklinik, September, 1987, Kiel, FRG. "Neonatal stress responses and their relation to pain."

Neonatal Grand Rounds, Department of Paediatrics, Montreal Childrens Hospital, October, 1987, Montreal, Canada. "Does the newborn baby feel pain?"

1988

International Symposium on 'Pain after Surgery and Trauma', May, 1988, Meran, Italy. "Postoperative pain in infants and children."

Symposium on 'Emotional & Physical Needs of the Newborn', June, 1988, London, UK. "Pain perception in preterm and term neonates."

1st International Symposium on Pediatric Pain, July, 1988, Seattle, WA.. "Pain and its effects in the human neonate."

B.P.A. Diamond Jubilee Paediatric Conference, Royal College of Physicians of London, October, 1988, London, UK. "The ontogeny of pain perception in the human fetus and neonate."

Second Annual Conference, Society for Pediatric Anesthesia, October, 1988, San Francisco, CA. "The stress response - how is the newborn different?"

Joint Conference of the American Pain Society & Canadian Pain Society, November, 1988, Toronto, Canada. "Physiological responses to pain in neonates".

Anesthesia Grand Rounds, Department of Anesthesiology and Critical Care Medicine, The Johns Hopkins Hospital, January, 1988, Baltimore, MD. "Effects of anesthesia on the neonatal stress responses."

Neonatology Grand Rounds, Department of Pediatrics, Stanford University Medical Center, January, 1988, Palo Alto, CA. "Pain perception in preterm and term neonates."

Pediatric Grand Rounds, Department of Pediatrics, The Johns Hopkins Hospital, January, 1988, Boston, MA. "Pain and stress responses in neonates."

Anesthesia Grand Rounds, Department of Anesthesia, Beth Israel Hospital, February, 1988, Boston, MA. "Randomised trial of sufentanil anesthesia in neonates undergoing cardiac surgery."

Clinical Conference, Joint Program in Neonatology, Brigham & Women's Hospital, May, 1988, Boston, MA. "Mechanisms of pain and the ontogeny of nociception in the human fetus and neonate."

Anesthesia Grand Rounds, Department of Anesthesiology, Children's Hospital National Medical Center, George Washington University, June, 1988, Washington, DC. "Pain and stress in surgical neonates: The role of anesthesia."

Anesthesia and Surgery Combined Grand Rounds, Departments of Anesthesia and Surgery, Children's Hospital of Eastern Ontario, June, 1988. Ottawa, Canada. "Anesthetic requirements for neonates."

Anesthesia Grand Rounds, The Children's Hospital, Boston, September, 1988, Boston, MA.. "Advances in our understanding of the role of stress attenuation in the newborn."

1989

Annual conference, The Philadelphia Perinatal Society, January, 1989, Philadelphia, PA. Keynote Address: "Pain and its effects in the Human Neonate and Fetus."

Annual Conference, The New England Perinatal Society, February, 1989, Manchester, VT. Keynote Address: "Pain in the newborn baby."

The 1989 "Trends in NICU Nursing" Conference, April, 1989, Boston, MA. "Pain Management in the NICU".

First European Conference on Pediatric Pain, IASP & European Chapters for the Study of Pain, June, 1989, Maastricht, The Netherlands. Keynote Address: "Pain in the neonate: Myths and realities."

International symposium on "Opioids in Anesthesia II", September, 1989, Cleveland, OH. "Opioids and Outcome in Pediatric Surgery."

Fifth Annual Neonatal Symposium "Persistent Perinatal Problems", St. Elizabeth Hospital Medical Center, October, 1989, Youngstown, OH. "Ontogeny of pain perception in the human fetus and neonate".

Fifth Annual Neonatal Symposium "Persistent Perinatal Problems", St. Elizabeth Hospital Medical Center, October, 1989, Youngstown, OH. "Stress responses and their clinical implications in the fetus, preterm and term newborn".

Pediatric Grand Rounds, Department of Pediatrics, The Children's Hospital of Philadelphia, Philadelphia, March, 1989. "Can the newborn infant feel pain?"

Anesthesia Grand Rounds, Department of Anesthesia and Critical Care Medicine, The Children's Hospital of Philadelphia, Philadelphia, March, 1989. "anesthetic implications from neonatal stress responses."

Symposium on Pain, Harvard Anesthesia Center, Harvard Medical School, Boston, May, 1989. "Pain in the human neonate."

Neonatal Symposium, St. Joseph's Health Center and Lawson Research Institute, London, Ont., Canada, September, 1989. "Metabolic and endocrine accompaniments of pain in the newborn."

Pediatric Grand Rounds, Children's Hospital of Western Ontario, London, Ont., Canada) September, 1989. "Pain in the neonate: myths and realities."

Advances in Pharmacology Seminar, Department of Pharmacology and Robert's Research Institute, University of Western Ontario, London Ont., Canada, September, 1989. "Strategies for the management of pain in the human neonate."

CME Seminars, Department of Pediatrics and Adolescent Medicine, The Lahey Clinic, Burlington (USA), November, 1989. "Pain and its management in newborns and infants."

1990

Conference on "Shaping the Future of Children's Health Care", 25th Annual Conference, Association for the Care of Children's Health, Washington DC, May, 1990. "Assessing and managing pain in infants".

Fourth Annual John Lind Symposium on "Pain in Children", Trollhatan, Sweden, September, 1990. Keynote Address: "The neuroanatomy, neurophysiology, and neurochemistry of pain, stress and analgesia in newborns and children."

44th Annual congress, Svensk Forening Fro Anestesi och Intensivvard, Huddinge, Sweden, September, 1990. Keynote Address: "The neuroanatomy, neurophysiology, and neurochemistry of pain, stress and analgesia in newborns and children."

Contemporary Forums Annual Conference on 'Developmental Interventions in Neonatal Care', Washington DC (USA), November, 1990. "Assessment and management of pain in the neonate."

Nursing Grand Rounds, Department of Nursing, The Children's Hospital, Boston, MA, February, 1990. "Pain in neonates: common myths and current scientific facts."

Critical Care Medicine Seminars, Department of Anesthesiology and Critical Care Medicine, The Johns Hopkins Hospital, Baltimore, July, 1990. "Management of pain in the ICU."

Clinical Symposium, Department of Anesthesiology and Intensive Care, Children's Hospital, University of Goteberg, Goteberg, Sweden, September, 1990. "Recent findings from studies on surgical metabolism in neonates."

Pediatric Grand Rounds, Department of Pediatrics, Children's Hospital, University of Goteberg, Goteberg, Sweden, September, 1990. "Neuroanatomy, Neurophysiology, and Neurochemistry of Pain in Newborns and Children."
Joint Perinatal Symposium, Nobel Institute for Neurophysiology, Karolinska Institute, and Department of Pediatrics, Karolinska Hospital, Stockholm, Sweden, September, 1990. "Pain and

its Effects in the Human Neonate."

Perinatal Grand Rounds, Berkshire Medical Center, Pittsfield, MA, October, 1990. "Assessing and Managing Pain in Neonates."

Topics in Pediatrics, Berkshire Area Health Education Center, Pittsfield, MA, October, 1990. "Do newborns feel pain?"

1991

11th Myron B. Laver International Postgraduate Course, Department of Anaesthesia, University of Basel, Basel, Switzerland, March, 1991. "Developmental aspects of Pain."

10th Annual Meeting, American Pain Society, New Orleans, LA, November, 1991. Keynote Address: "Pain in the Newborn."

Junior Resident Rounds, Department of Medicine, Children's Medical Center, Fort Worth, TX, February, 1991. "Pain and stress responses in neonates."

Medicine Grand Rounds, Cook-Forth Worth Children's Medical Center, Fort Worth, TX, February, 1991. "Assessing and managing pain in infants."

Anesthesia Grand Rounds, University of Washington Department of Anesthesiology, Seattle, WA, March, 1991. "Pain and stress responses in neonates: Anesthetic effects."

Pediatric Grand Rounds, University of Washington Department of Pediatrics, Children's Hospital and Medical Center, Seattle, WA, March, 1991. "Developmental biology and clinical aspects of pain in infancy."

Neonatology Seminars, Division of Neonatal and Respiratory Diseases, University of Washington Medical Center, Seattle, WA, March, 1991. "Management of pain and stress in the Neonatal Intensive Care Unit."
Junior Resident Rounds, Department of Medicine, Children's Hospital, Boston, MA, April, 1991. "Philosophical basis for facing the issues of death and dying in pediatric patients."

Core Curriculum Lectures, Department of Medicine, Children's Hospital, Boston, MA, May, 1991. "Cardiovascular monitoring parameters: Pitfalls and usefulness in clinical medicine."

Anesthesia Grand Rounds, Department of Anesthesia, Children's Hospital, Boston, MA, October, 1991. "Metabolic changes during newborn surgery."

1992

Greater Boston Chapter, American Association of Critical Care Nursing, Boston, MA, January,

1992. "Pain in the neonate: basic sciences, assessment and management."

International Pain Symposium, Medical College of Georgia, Atlanta, GA, April, 1992. "Development of pain pathways."

International Pain Symposium, Medical College of Georgia, Atlanta, GA, April, 1992. Panel discussion on "Basic mechanisms of pain."

Annual Perinatal Symposium, University of Michigan, Ann Arbor, MI. May, 1992. "Pain and its clinical management in neonates."

21st Educational and Scientific Symposium, Society of Critical Care Medicine, San Antonio, TX, May, 1992. Panel discussion on "Endocrine response in the critically ill."

10th World Congress of Anesthesiologists, The Hague, The Netherlands, June, 1992. Refresher Course on "Surgical stress and metabolism in neonates."

1st World Congress of Pediatric Intensive Care, Baltimore, MD, June, 1992. "Stress responses and clinical outcome in newborn infants and children."

Special Ross Conference on "Hot Topics in Neonatology 1992", Washington, DC, December, 1992. "Analgesia and sedation in the Neonatal Intensive Care Unit."

Anesthesia Journal Club, Department of Anesthesia, Massachusetts General Hospital, Boston, MA, January, 1992. "Stress responses in neonatal cardiac surgery."

Neonatology Grand Rounds, The Medical Center of Central Massachusetts - Memorial, Worcester, MA, March, 1992. "Pain control in the neonate."

Anesthesia Grand Rounds, University of Michigan Medical Center, C.S. Mott Children's Hospital, Ann Arbor, MI, May, 1992. "Anesthesia and stress responses in neonates."
Pediatric Grand Rounds, University of Michigan Medical Center, C.S. Mott Children's Hospital, Ann Arbor, MI, May, 1992. "Pain in the neonate: scientific background and clinical approaches."

Respiratory Intensive Care Unit Seminars, Departments of Medicine, Surgery, & Anesthesia, Massachusetts General Hospital, Boston, MA, July, 1992. "Stress responses and clinical outcome in critical illness."

Fellows Conference, Division of Pediatric Intensive Care, Massachusetts General Hospital and Harvard Medical School, Boston, MA, September, 1992. "Newer agents for analgesia and sedation."

Pediatric Grand Rounds, Joint CME Program, Lawrence General Hospital and Holy Family Hospital, Lawrence, MA, October, 1992. "Analgesia and sedation in pediatric patients."

CME Seminars, Departments of Obstetrics and Neonatology, Georgetown University and The

Arlington Hospital, Arlington, VA, October, 1992. "Pain in the neonate: Myths and Realities."

CME Seminars, Departments of Obstetrics and Neonatology, Georgetown University and The Arlington Hospital, Arlington, VA, October, 1992. "Neonatal stress and responses."

CME Seminars, Departments of Obstetrics and Neonatology, Georgetown University and The Arlington Hospital, Arlington, VA, October, 1992. "Assessment and management of pain in the neonate."

CME Seminars, Departments of Obstetrics and Neonatology, Georgetown University and The Arlington Hospital, Arlington, VA, October ,1992. "Case discussions: Pediatric and neonatal pain management."

Research Seminars, Division of Critical Care Medicine, Children's Hospital of Dallas, University of Texas, Southwestern Medical School, Dallas, TX, October, 1992. "Pain and stress responses in neonates."

Pediatric Grand Rounds, Department of Pediatrics, The Rhode Island Hospital, Brown University, Providence, RI, October, 1992. "Pain in the neonate: myths and realities."

Research-in-Progress Seminars, Department of Pediatrics, Yale University, Yale-New Haven Hospital, New Haven, CT, November, 1992. "Pain and memory in the neonate."

1993

3rd International Meeting on Pediatric Intensive Care, Padova, Italy, June, 1993. "Role of analgesia in the clinical outcome of critically ill pediatric patients."

11th Annual Panhandle Regional Perinatal Symposium: "Challenges and Issues in Perinatal Care," Amarillo TX, October, 1993. "Development of Pain Perception in Fetal and Neonatal Life."

11th Annual Panhandle Regional Perinatal Symposium: "Challenges and Issues in Perinatal Care", Amarillo TX, October, 1993. "Clinical Assessment and Management of Pain in the Neonate."

Pediatric Grand Rounds, Department of Pediatrics, I.W. Killam Children's Hospital, Dalhousie University, Halifax, Nova Scotia, Canada, February, 1993. "Pain in neonatal and pediatric intensive care."

Psychology Grand Rounds, Department of Psychology, Dalhousie University, Halifax, Nova Scotia, Canada, February, 1993. "Developmental neurobiology of pain in humans."

Pediatric Grand Rounds, Department of Pediatrics, Cambridge Hospital and Mount Auburn Hospital, Harvard Medical School, Boston, MA, February, 1993. "Clinical importance of pain in neonates."

Pediatric Grand Rounds, Department of Pediatrics, Emory University and Egleston Children's

Hospital, Atlanta GA, December, 1993. "Assessment and management of pain in infants and children."

1994

23rd Educational and Scientific Symposium, Society of Critical Care Medicine, "Thinking About Tomorrow", February 1994, Orlando, FL "Metabolic Response to Stress in the Critically Ill Infant."

NICHD Symposium on "Neonatal Pain: Physiology and Management", Philadelphia PA, June, 1994. "Long-term clinical outcomes of repetitive neonatal pain: behavioral changes in rats".

3rd International Symposium on Pediatric Pain, International Association for the Study of Pain, Special Interest Group on Pain in Children, Philadelphia, PA, June, 1994. "Research in neonatal pain/stress: A personal journey."

3rd International Symposium on Pediatric Pain, International Association for the Study of Pain, Special Interest Group on Pain in Children, Philadelphia PA, June, 1994. "Current practices for analgesia and sedation in neonates."

Symposium on 'Strategies to Evaluate and Reduce Stress in Babies', Institute of Obstetrics and Gynecology, London, U.K., October, 1994. "The importance of pain and stress in critically ill newborn infants".

International Symposium on "Pain in Infants: Assessment and Management", Emory University School of Medicine, October, 1994. "Management of Acute Pain: an Overview".

Pediatric Grand Rounds, Department of Pediatrics, Emory University and Grady Memorial Hospital, Atlanta GA, January, 1994. "Brain death: definition and evaluation in children."

Pediatric Grand Rounds, Alfred I. duPont Institute and Jefferson Medical College, Wilmington DE, February, 1994. "Pain and Clinical Outcomes in Neonatal Intensive Care."

Neonatal Physiology Symposium, Department of Pediatrics, University of Illinois, Chicago IL, May, 1994. "Developmental neurobiology of pain in neonates."

Pediatric Grand Rounds, Mercy Hospital and Medical Center and University of Chicago, May, 1994. "Assessment and Management of Pain in Neonates".

Anesthesiology Seminars, Egleston Children's Hospital at Emory University, Atlanta, GA, July, 1994. "The stress response to anesthesia and surgery and its clinical implications".

1995

Symposium on "Practical Neonatal Pharmacology" University of North Carolina, Area Health Education Centers Program, January, 1995, Raleigh, NC. "Pharmacologic treatment of pain and

discomfort in the NICU."

Symposium on "Practical Neonatal Pharmacology" University of North Carolina, Area Health Education Centers Program, January, 1995, Raleigh, NC. "The physiology of pain in neonates."

5th Annual Southeast ECMO Conference, May, 1995, Atlanta, GA. "Analgesia and sedation in pediatric ECMO patients."

Nordic Congress on Children and Pain, September, 1995, Stockholm, Sweden. Keynote Address: "Of needles, tubes, and prematurity: What happens to the baby?".

2nd World Congress & Exposition on "Child Health 2000", Global Child Health Society, Health Canada, WHO, UNICEF, American Academy of Pediatrics, International Pediatric Association, and University of British Columbia, Vancouver, B.C., May, 1995. "Impact of pain in critically ill newborn infants and children".

2nd World Congress & Exposition on "Child Health 2000", Global Child Health Society, Health Canada, WHO, UNICEF, American Academy of Pediatrics, International Pediatric Association, and University of British Columbia, Vancouver, B.C., May, 1995. "Pain and stress in NICU care: Has actual therapy changed?"

72nd Annual Conference of the Canadian Pediatric Society, Symposium on "Pain in the Neonate", Montreal (PQ), Canada, June, 1995. "Physiology and management of pain in the neonate."

National Conference on "Practical Neonatal Pharmacology" University of North Carolina, Area Health Education Centers Program, September, 1995, Atlanta, GA. "Sedatives and Non-Opioid Analgesics"

National Conference on "Practical Neonatal Pharmacology" University of North Carolina, Area Health Education Centers Program, September, 1995, Atlanta, GA. "Conscious Sedation: working through the issues"

Pediatric Critical Care Colloquium, Panel Discussion on "Pediatric Pain: Measurement and Therapy", Sea Island, GA, October, 1995.

Symposium on "Changes, Challenges and Controversies in Neonatal Care", Regional Conference for Neonatal Nursing and Egleston Children's Health Care System, Atlanta, GA, October, 1995. "Clinical Indications and Problems in the Use of Sedatives and Analgesics in the Neonatal ICU".

Symposium on "Pediatric Pain Research in The Netherlands", Sophia Children's Hospital, Rotterdam, The Netherlands, October, 1995. "Differentiation between pain and stress in neonates".

XVII Annual Congress, Dutch Pediatric Association, Veldhoven, The Netherlands, November, 1995. Keynote Address: "Physiology and long-term effects of pain in neonates."

Conference on "Pediatric Pain: Challenges, Innovations, and Costs", Emory University School of Medicine and Egleston Children's Hospital, Atlanta GA, November, 1995. "A clinical primer in the use of opioids".

Conference on "Pediatric Pain: Challenges, Innovations, and Costs", Emory University School of Medicine and Egleston Children's Hospital, Atlanta GA, November, 1995. "Neonatal pain: current issues and future directions".

Contemporary Forums Annual Conference on 'Developmental Interventions in Neonatal Care', Chicago IL, (USA), November 1995. "Immediate and long-term effects of pain on neonatal brain development."

Pediatric Pain Symposium, Hilleroed Sygehus, Denmark, December, 1995. "Physiology of pain during fetal and neonatal development."

Pediatric Pain Symposium, Hilleroed Sygehus, Denmark, December, 1995. "Changes in adult behavior correlated with repetitive neonatal pain: experimental studies".

International Conference, The World Foundation for Pain Relief and Research, 'Current Concepts in Acute, Chronic, and Cancer Pain Management', December, 1995, New York NY. "Development and Assessment of Pain in Neonates and the Pediatric Population".

Multidisciplinary Seminars, Marcus Developmental Center and Emory University School of Medicine, Atlanta GA, February 1995. "The long-term sequelae of early pain and stress in ex-premature neonates."

Pediatric Grand Rounds, Department of Pediatrics, Emory University and Egleston Children's Hospital, Atlanta GA, March 1995. "A practical approach to acid-base homeostasis in pediatric patients."

Basic Science Fellows Conference, Department of Pediatrics, Emory University School of Medicine, Atlanta GA, March 1995. "Long-term effects of neonatal pain and stress".

Psychiatry Research Seminars, Department of Psychiatry and Behavioral Sciences, Emory University School of Medicine, Atlanta GA, March 1995. "Behavioral and neurobiologic studies on the long-term effects of neonatal pain and stress".

Teaching Seminars, Neonatal Nurse Practitioner Course, Emory University School of Nursing, Atlanta GA, March 1995. "Physiological basis for development of the pain system", "Assessment and management of pain and stress in critically ill neonates".

Panel discussion on "Does pain have a thermometer?", on the "Hurt Alert Day", Child Life Department, Egleston Children's Hospital at Emory University, Atlanta GA, March 1995.

Research Presentations, Georgia Biomedical Partnership, Inc.; April 1995; "Clinical and socio-economic importance of pain in the newborn infant".

Pediatric Grand Rounds, Parkway Medical Center, Columbia-HCA Health Care System, Lithia Springs GA, June 1995; "Assessment and management of pain in newborn infants".

Anesthesiology Seminars, Department of Anesthesia, Emory University School of Medicine and Egleston Children's Hospital, Atlanta GA, July 1995; "Physiology and assessment of pain in pediatric patients".

CCM Research Seminars, Department of Pediatrics, University of Florida Health Sciences Center, Jacksonville FL, July 1995. "Recent and ongoing research on neonatal pain".

Acute Care Symposium, Department of Pediatrics, Emory University School of Medicine, Atlanta GA, July 1995; "Pediatric C.P.R. or How to run a "Code" in pediatric patients".

Fellows Research Introductory Course, Department of Pediatrics, Emory University School of Medicine, Atlanta GA, July 1995; Panel discussion on "How to Establish an Academic Career".

Emergency Medicine Lecture Series, Emory University School of Medicine, Atlanta GA, August 1995; "Analgesia and Sedation in Pediatric Patients".

Anesthesia Grand Rounds, Department of Anesthesiology and Critical Care Medicine, Medical College of Wisconsin, Milwaukee WI, November 9, 1995. "Effects of anesthesia on surgical stress and clinical outcome".

Pediatric Grand Rounds, Department of Pediatrics, Medical College and Children's Hospital of Wisconsin, Milwaukee WI, November 10, 1995. "Pain and its effects in the neonate".

1996

International Symposium on Fetal Pain, University of Toronto, Toronto (Ont.) Canada, April, 1996. "Development of the Pain System".

21st Annual Symposium on Care of the Sick Newborn, University of California at Irvine and Long Beach Memorial Medical Center, Long Beach CA, April, 1996. Plenary Lecture: "Developmental Neurobiology of the Perception of Pain"

Symposium on Pediatric Pain, Texas A & M University Health Science Center and Scott & White Hospital, Austin TX, May, 1996. "Consequences of injury: does pain management make a difference?"

Symposium on Pediatric Pain, Texas A & M University Health Science Center and Scott & White Hospital, Austin, May, 1996. "Assessment and management of pain in the critically ill infant and child."

Symposium on Pediatric Pain, Texas A & M University Health Science Center and Scott & White Hospital, Austin TX, May, 1996. "Pain in the NICU: assessing and managing pain in critical

illness".

Symposium on Pediatric Pain, Texas A & M University Health Science Center and Scott & White Hospital, Austin, May, 1996. "Establishing a children's pain service".

4th Annual Neonatal Conference, University of Teesside, Middlesborough, U.K., June, 1996. "The international NOPAIN study".

4th Annual Neonatal Conference, University of Teesside, Middlesborough, U.K., June, 1996. "Metabolic consequences of operative and postoperative care in newborns".

Postgraduate Course on Pediatric Intensive Care, 2nd World Congress on Pediatric Intensive Care, Rotterdam, The Netherlands, June, 1996. "The evolution of a clinical problem towards a sound research question."

Postgraduate Course on Pediatric Intensive Care, 2nd World Congress on Pediatric Intensive Care, Rotterdam, The Netherlands, June, 1996. "Neuronal pathways and maturational aspects of pain."

2nd World Congress on Pediatric Intensive Care, Rotterdam, The Netherlands, June, 1996. "Developmental physiology and neurobiology of the pain system."

2nd World Congress on Pediatric Intensive Care, Rotterdam, The Netherlands, June, 1996. "Analgesia and sedation in the critically ill neonate and child."

8th World Congress on Pain, International Association for the Study of Pain, August, 1996, Vancouver (B.C.), Canada. Pediatric Plenary Lecture: "Long-term effects of pain in neonates and infants".

8th World Congress on Pain, International Association for the Study of Pain, August, 1996, Vancouver (B.C.), Canada. Topical Workshop: "Challenges and opportunities in postoperative and critical care pain management of children."

International Forum on Pediatric Pain, 'Measurement of Children's Pain', Halifax, Nova Scotia, Canada, October, 1996. "Biochemical and biophysical methods correlated with the assessment of pain at supraspinal levels of the brain."

16th Annual Convention, National Neonatology Forum, Chandigarh, India, November, 1996. "Clinical importance of pain and stress in the Neonatal Intensive Care Unit."

Neonatal Symposium, Georgia Nurses Association, Dekalb Medical Center, Atlanta GA, December , 1996. "Effects of repetitive neonatal pain on immediate and long-term clinical outcomes of prematurity."

Fellows Research Conference, Department of Pediatrics, Emory University School of Medicine, March, 1996. "Current analgesic practices in the NICU: national and international studies".

Teaching Seminars, Neonatal Nurse Practitioner Training Program, Nell R. Hodgson School of Nursing, Emory University, March, 1996. "Assessment and management of pain in preterm neonates".

Teaching Seminars, Clinical Chaplain Internship Program, Emory University and Egleston Children's Hospital, March, 1996. "The scientific philosophy of death and dying: applications for patient care".

Pediatric Grand Rounds, Department of Pediatrics, Emory University School of Medicine and Egleston Children's Hospital, May, 1996. "Presentations at the Pediatric Academic Societies Meetings' in 1996".

2nd Annual Fellows Research Introductory Course, Department of Pediatrics, Emory University School of Medicine, Atlanta GA, August 1996; Clinical Research Methods Workshop: "Measurement and sampling, sources of error and bias in clinical studies."

2nd Annual Fellows Research Introductory Course, Department of Pediatrics, Emory University School of Medicine, Atlanta GA, August 1996; Evaluation of Clinical Research Protocols.

Pediatric Grand Rounds, Case Western Reserve University, Rainbow Babies and Children's Hospital, Cleveland OH, November, 1996. "Assessment and Management of Acute Pain in Pediatric Patients".

Research Seminar, Division of Pharmacology and Critical Care, Department of Pediatrics, Case Western Reserve University, Rainbow Babies and Children's Hospital, Cleveland OH, November, 1996. "Long-term effects of pain in neonates: Clinical and neurobiological aspects."

1997

International Conference, The Physical and Developmental Environment of the High-Risk Infant, University of South Florida College of Medicine, January 30-February 1, 1997. "Pain and pain management in newborn infants."

Annual Winter Meeting, Society of Pediatric Anesthesia, February, 1997, San Antonio TX. "Physiologic rationale for pain management in neonates."
Fifth Annual Conference on Advanced Practice in Neonatal Care, Emory Regional Perinatal Center, April, 1997, Atlanta GA. "Scientific evaluation of pain and analgesia in preterm neonates: The NOPAIN Multicenter Trial".

Panel discussant, Satellite News Conference from the White House on "Early Childhood Development and Learning: What the newest research on the brain tells us about our youngest children", April, 1997, Egleston Children's Hospital, Atlanta, GA.

Fourth International Pediatric Pain Symposium, Special Interest Group on Pediatric Pain, International Association for the Study of Pain, July, 1997, Helsinki, Finland. Debate "The treatment of pain in children should not be based on self-report of pain".

Fourth International Pediatric Pain Symposium, Special Interest Group on Pediatric Pain, International Association for the Study of Pain, July, 1997, Helsinki, Finland. "Mechanisms, clinical assessment, and management of opioid tolerance in children."

International Symposium on Analgesia, Sedation, and Neuromuscular Blockade in Children, Federal University of Medicine, Sao Paulo, Brazil, September, 1997. "Hormonal and metabolic stress responses to pain and injury in the neonate."

International Symposium on Analgesia, Sedation, and Neuromuscular Blockade in Children, Federal University of Medicine, Sao Paulo, Brazil, September, 1997. "Treatment of pain in the neonate."

International Symposium on Analgesia, Sedation, and Neuromuscular Blockade in Children, Federal University of Medicine, Sao Paulo, Brazil, September, 1997. "Long-term effects of pain in the neonate."

Annual Meeting of the Perinatal Section, American Academy of Pediatrics, Chicago IL, September, 1997. "Clinical management of neonatal pain."

48th Annual Meeting, American Association for Laboratory Animal Science, Anaheim CA, November, 1997. "Neonatal pain perception: Where do we draw the line?"

International Conference, The World Foundation for Pain Relief and Research, 'Current Concepts in Acute, Chronic, and Cancer Pain Management', December, 1997, New York NY. "Development and assessment of pain in newborn infants and children".

Teaching Seminars, Neonatal Nurse Practitioner Training Program, Nell R. Hodgson School of Nursing, Emory University, March, 1997. "Assessment and management of pain in preterm neonates".

Pediatric Grand Rounds, Department of Pediatrics, McGill University and Montreal Children's Hospital, April, 1997. "Benefits and drawbacks of analgesia/sedation in critically ill pediatric patients".
Nursing Grand Rounds, Faculty of Nursing, McGill University and Montreal Children's Hospital, April, 1997. "Long-term effects of pain and stress in newborn infants and older children".

Pediatric Grand Rounds, Department of Pediatrics, University of Montreal and Hospital Saint Justine, April, 1997. "Benefits and drawbacks of analgesia/sedation in critically ill pediatric patients".

Pediatric Grand Rounds, Department of Pediatrics,, Medical College of Georgia, April, 1997, Augusta GA. "Of needles, tubes, and prematurity: What happens to the baby?".

Anesthesiology Seminars, Department of Anesthesia, Medical College of Georgia, April, 1997. "Assessment and management of analgesia/sedation in newborn infants".

Guest Lecturer, The Institute of Hospice, Hospice Atlanta Center, May, 1997. "Pain management in children: are we negligent?"

Pediatric Grand Rounds, Department of Pediatrics, Emory University School of Medicine, and Egleston Children's Hospital, May, 1997. "Does routine analgesia alter the clinical outcomes of ventilated preterm neonates?"

Research Seminars, Arkansas Children's Hospital Research Institute, University of Arkansas for Medical Sciences, Little Rock AR, October, 1997. "Neonatal Pain: Effects on the brain and behavior."

Anesthesiology Grand Rounds, Department of Anesthesiology, UCLA School of Medicine, Los Angeles Children's Hospital, November, 1997. "Long-term effects of pain in neonates: animal & human data."

1998

27th Educational and Scientific Symposium, Society for Critical Care Medicine, 'Current Concepts in Pediatric Critical Care 1998', February, 1998, San Antonio TX. "Overview of pain and analgesia in pediatric patients: biochemistry, physiology, and pharmacology".

Interdisciplinary Workshop on "The Science and Practice of Mind/Body Interactions", March, 1998, Sedona AZ, "Short- and long-term effects of pain in the neonate".

12th Annual Symposium on Critical Care and Emergency Medicine, April, 1998, Hot Springs AR. "Analgesia and sedation in the ICU".

International Consensus Conference on "Pain and Pain Management during Infancy", April, 1998, Nice, France. "Epidemiology of pain in neonates".

International Consensus Conference on "Pain and Pain Management during Infancy", April, 1998, Nice, France. "New alternatives for pain management in the future".

9th Annual Congress, European Society of Pediatric Intensive Care, September, 1998, Stockholm, Sweden. "Future impact of repeated neonatal procedural pain".

9th Annual Congress, European Society of Pediatric Intensive Care, September, 1998, Stockholm, Sweden. "Analgesics for neonatal intensive care".

2nd Biennial Pediatric Pain Forum, University of Dalhousie, September, 1998, Halifax, Nova Scotia, Canada. "Persistent effects of early pain experience (the animal literature)".

11th Western Extracorporeal Membrane Oxygenation Conference 'Back to the Future', October, 1998, Little Rock AR. "Recognition and management of pain during ECMO".

17th Annual Scientific Meeting, American Pain Society, San Diego, CA, November, 1998.

"Scientific Bases for the Definition of Pain", Moderator.

Annual Conference, Dutch Pain Society, Rotterdam, The Netherlands, November, 1998. Keynote Address: "Long-term effects of pain in neonates."

NICU Research Conferences, Department of Pediatrics, University of Chicago Children's Hospital, Chicago IL, February, 1998. "Current controversies in the management of pain in neonates."

Pediatric Grand Rounds, Department of Pediatrics, University of Chicago Children's Hospital, Chicago IL, February, 1998. "Of needles, tubes, and prematurity: what happens to the baby?"

Anesthesiology and Critical Care Grand Rounds, Department of Anesthesiology, Children's Memorial Hospital, University of Illinois, Chicago IL, February, 1998. "Long-term effects of neonatal pain and stress."

Grand Rounds, Department of Pediatrics, University of Arkansas for Medical Sciences, Arkansas Children's Hospital, February, 1998. "Does routine analgesia alter the clinical outcomes of preterm neonates?"

Anesthesia Research Seminars, Department of Anesthesia, University of Arkansas for Medical Sciences, Arkansas Children's Hospital, April, 1998. "Effects of pain in the neonate."

Research & Teaching conference, Department of Surgery, University of Arkansas for Medical Sciences, Arkansas Children's Hospital, April, 1998. "Prediction of resource utilization in pediatric surgical patients."

Lectures for Junior Medical Student Clerkship, University of Arkansas for Medical Sciences, August 7, September 4, October, 1998. "Overview of pain in children".

NICU Research Seminars, Hospital for Sick Children and University of Toronto, Toronto, Canada. August, 1998. "Recent advances in neonatal pain & pain management".
Semi-Annual Medical Staff Meeting, Arkansas Children's Hospital, Little Rock, Arkansas, September, 1998. "Analgesia and sedation in terminally ill children".

Advanced Pediatric Life Support Course, Arkansas Children's Hospital, Little Rock, September, 1998. "Status epilepticus."

Neonatology Seminars, Department of Pediatrics, U.A.M.S. and Arkansas Children's Hospital, September, 1998. "Data and design of the NOPAIN trial."

Pediatric Outreach Seminars, Area Health Education Center, Pine Bluff, Arkansas, October, 1998. "Clinical approach to pain in children."

Neonatal Grand Rounds, Sharp Mary Birch Hospital for Women, San Diego, November, 1998. "Management of pain in the NICU."

Sharp Health Care Educational Conference on "Responding to Neonatal Pain", November, 1998. "Neonatal pain anatomy and physiology."

Research Seminars, UAMS Department of Anesthesiology, November, 1998. "Prediction of resource utilization in pediatric surgical patients."

Sharp Health Care Educational Conference on "Responding to Neonatal Pain", November, 1998. "Systemic analgesia in the neonate."

Sharp Health Care Educational Conference on "Responding to Neonatal Pain", November, 1998. "Local, regional and topical analgesia in the neonate."

Community Neonatology Meeting, San Diego Area hospitals and University of California, November, 1998. "Recent research in neonatal pain management."

1999

Neonatal Pain Management Symposium, Department of Pediatrics, University of Washington and Swedish Medical Center, Seattle, WA, March, 1999. "Management of pain in neonates."

6th International Congress of Pediatric Emergency & Intensive Care, Padova, Italy, June, 1999. "Pain in critically ill infant and child: What we know, what we fear, what we can do?"

Pediatric Pain Meeting, International Planning Group for Clinical Studies, G. D. Searle Company, Chicago, IL. July, 1999. "Evaluation of COX-II inhibitors for analgesia in children."

2nd International Consensus Conference on Guidelines for the Prevention and Management of Procedural Pain in Infancy, Baden, Austria, August, 1999. "Neonatal pain management using systemic analgesics."
Fifth Greater Tulsa Area Pain Conference, University of Oklahoma and Greater Tulsa Nursing College, Tulsa, OK. October, 1999. Keynote Address: "Of needles, tubes, and prematurity: What happens to the baby?"

Pediatric Trauma/Critical Care Symposium, Departments of Nursing, Critical Care Medicine, and Emergency Medicine, Arkansas Children' s Hospital, Little Rock, AR. October, 1999. "Pain Management in Critically Ill Children"

52nd Annual Meeting, American Academy of Pediatrics, Washington DC, October, 1999. Plenary Podium Presentation: "Neonatal pain and clinical outcomes."

International Symposium on "Basic Mechanisms and Recent Advances in Pediatric Pain", German Pediatric Association and University of Erlangen, Kloster Weltenberg, Bavaria, Germany, October, 1999. "Long-term effects of pain in neonates: Clinical and neurobiological investigations."

IIIrd Congreso Internacional De Clinica Del Dolor Y Cuidados Paliativos, Asociacion Mexicana De Algologia A.C., Ciudad y Puerto de Veracruz, Veracruz, México, October, 1999. “Long-term effects of neonatal pain”.

IIIrd Congreso Internacional De Clinica Del Dolor Y Cuidados Paliativos, Asociacion Mexicana De Algologia A.C., Ciudad y Puerto de Veracruz, Veracruz, México, October, 1999. “Of needles, tubes, and prematurity: What happens to the baby?”

IIIrd Congreso Internacional De Clinica Del Dolor Y Cuidados Paliativos, Asociacion Mexicana De Algologia A.C., Ciudad y Puerto de Veracruz, Veracruz, México, October, 1999. “Management of neonatal pain: current therapies and novel options.”

“Sedation, Analgesia, and Neuromuscular Blockade”, UAMS Residents PICU Lecture Series; monthly lecture, January through December, 1999.

“Pain in Children”, UAMS Junior Medical Students Pediatric Clerkship Series; July 7, August, 30, 1999.

Journal Club Discussant, Department of Anesthesiology, University of North Carolina at Chapel Hill & UNC Hospitals, Chapel Hill, NC, February, 1999. “Do perinatal events lead to adult self-destructive behavior?”

Anesthesia Grand Rounds, University of North Carolina at Chapel Hill, Department of Anesthesiology, Chapel Hill, NC, February, 1999. “Of needles, tubes, and prematurity: What happens to the baby?”

Research Seminars, Department of Pediatrics, University of North Carolina at Chapel Hill, Chapel Hill, NC, February, 1999. “Management of pain in neonates.”

Seminars in Psychobiology, New York Psychiatric Institute, Columbia University College of Physicians and Surgeons, New York NY, March, 1999. "Mechanisms underlying the long-term effects of pain in neonates."

Department of Neonatology, Columbia-Presbyterian Hospital for Women and Children, New York NY, March, 1999. "Clinical outcomes resulting from repetitive pain during NICU care."

Grand Rounds, Department of Family Practice, University of Connecticut and Hartford Medical Center, Hartford, March, 1999. "Clinical approach to pain management in your practice."

Grand Rounds, Department of Pediatrics, University of Connecticut and Connecticut Children's Medical Center, Hartford, CT, March, 1999. "Effects of neonatal pain: mechanisms and clinical outcomes."

University of Arkansas for Medical Sciences, Neuroscience Course, Pre-clinical Medical Students, Department of Anatomy, Little Rock, AR; April, 1999. “Anatomy and physiology of the pain system.”

Grand Rounds, Department of Pediatrics and Arkansas Children's Hospital, University of Arkansas for Medical Sciences, Little Rock, AR. July, 1999. "Can perinatal stimulation alter brain development and subsequent behavior?"

Research Presentations, Medical Research Endowment Board, University of Arkansas for Medical Sciences, Little Rock, AR. October, 1999. "Does isolation increase apoptosis in the neonatal rat brain?"

2000

Annual Meeting, Danish Pediatric Society and University Hospital, Copenhagen, Denmark, January, 2000. Keynote Speaker: "Repetitive pain in neonates: clinical and laboratory studies."

International Symposium on Infant Pain, Astrid Lindgren's Children's Hospital and the Karolinska Institute, Stockholm, Sweden, January, 2000. Keynote Address: "Repetitive pain in neonates: windows from the laboratory bench."

International Symposium on Infant Pain, Astrid Lindgren's Children's Hospital and the Karolinska Institute, Stockholm, Sweden, January, 2000. "Repetitive pain in neonates: windows from the hospital bedside."

"Pediatric Anesthesiology 2000", Joint Annual Meeting of the Society for Pediatric Anesthesia & Section of Anesthesiology, American Academy of Pediatrics, Sanibel Island, Sanibel, FL, February, 2000. Baxter Visiting Professor, Plenary Session: "Prevention of opioid and benzodiazepine withdrawal syndromes."

27th Neonatal & Infant Symposium, University of California at Irvine, College of Medicine, Vail, Colorado, March, 2000. " Mechanisms of pain in the fetus and neonate"

27th Neonatal & Infant Symposium, University of California at Irvine, College of Medicine, Vail, Colorado, March, 2000. "Do ventilated premature infants require analgesia?"

27th Neonatal & Infant Symposium, University of California at Irvine, College of Medicine, Vail, Colorado, March, 2000. "Pain in the neonate: Current practice & options."

27th Neonatal & Infant Symposium, University of California at Irvine, College of Medicine, Vail, Colorado, March, 2000. "Long-term effects of neonatal pain & stress"

27th Neonatal & Infant Symposium, University of California at Irvine, College of Medicine, Vail, Colorado, March, 2000. "Prediction clinical outcomes in pediatric surgical patients"

Symposium on "Pain in Children: Conquering the Hurt", Pain Awareness Week, The Hospital for Sick Children & University of Toronto, Toronto, Canada, March, 2000. Keynote Speaker: "Long-term effects of pain in neonates: Clinical and molecular aspects."

5th Annual Symposium on Pediatric Pain, Texas A & M University, Department of Anesthesiology, Scott & White Hospital, San Antonio, TX , April, 2000, "Long-term effects of neonatal pain"

5th Annual Symposium on Pediatric Pain, Texas A & M University, Department of Anesthesiology, Scott & White Hospital, San Antonio, TX, April, 2000. "Pain management of the critically ill infant and child"

5th International Symposium on Pediatric Pain, Special Interest Group for Pain in Children, International Association for the Study of Pain, London, England, June, 2000. Workshop Presentation: "Effects of repetitive pain on neurologic outcome and behavior."

3rd World Congress on Pediatric Intensive Care, Montreal Canada, Co-Chairman of the Pharmacology, Pain & Sedation Track, June, 2000.

3rd World Congress on Pediatric Intensive Care, Montreal Canada, Nursing Program, June, 2000. Plenary Presentation: "The physiology of pain."

3rd World Congress on Pediatric Intensive Care, Montreal Canada, Pharmacology, Pain & Sedation Track, June, 2000. Plenary Presentation: "Analgesia and sedation in neonates."

3rd World Congress on Pediatric Intensive Care, Montreal Canada, Pharmacology, Pain & Sedation Track, June, 2000. Symposium Session: "Drug dose modification in prematurity."

3rd World Congress on Pediatric Intensive Care, Montreal Canada, Chairman of the Pharmacology, Pain & Sedation Track, June, 2000. Joint Plenary: "Future Directions". Annual Meeting, American Society of Anesthesiologists, San Francisco, CA; Panel Discussion: Pain Management in Children: Biology and Clinical Applications, October, 2000. "The neuroplasticity of pain in the newborn".

Annual Meeting, American College of Surgeons, Chicago IL; Workshop on Metabolic Support of the Pediatric Surgical Patient, October, 2000. "Alterations of the acute metabolic stress response related to painful stimuli in children".

19th Annual Scientific Meeting, American Pain Society, Atlanta GA; November, 2000. Problem-based, Case-oriented, Active discussion on Chronic Pain Management: "Opioid tolerance in the I.C.U."

Research & Teaching Seminars, Department of Paediatrics, All-India Institute for Medical Sciences, New Delhi, India. January, 2000. "Can perinatal stimulation alter brain development and future behavior?"

CME Conference, Indian Association of Paediatrics (NOIDA Branch), Noida Medical Center, New Delhi, India. January, 2000. "Management of pain and sedation in pediatric patients."

Neuroscience Research Seminars, Astrid Lindgren's Children's Hospital and the Karolinska

Institute, Stockholm, Sweden, January, 2000. "Ontogeny of supraspinal pain processing in infant rats."

Grand Rounds, Department of Pediatrics, University of Tennessee and Le Bonheur Children's Hospital, Memphis, TN, May, 2000. "Abnormal perinatal stimulation and long-term behavioral effects."

Grand Rounds, Department of Surgery, University of Tennessee and Le Bonheur Children's Hospital, Memphis, TN, May, 2000. "Analgesia and sedation in the newborn: Physiology and Pharmacology."

Grand Rounds Presentation, Department of Pediatrics, Lutheran General Hospital, Park Ridge, IL, May, 2000. "Long-term effects of pain in neonates".

I.C.U. Fellows Seminar, Department of Pediatrics, Lutheran General Children's Hospital, Park Ridge, IL, May, 2000. "Issues related to analgesia and sedation in critically ill children."

Residents' Seminar, Departments of Pediatrics and Emergency Medicine, Lutheran General Children's Hospital, Park Ridge, IL, May, 2000. "Analgesia and sedation in neonates."

Arkansas Caduceus Club Scientific Session; 32nd Annual Alumni Weekend, University of Arkansas for Medical Sciences, Little Rock AR, June, 2000. "Do Perinatal Events Affect Subsequent Behavior?"

St. Peter's Hospital Chertsey, and The European Institute of Health and Medical Sciences at the University of Surrey, Chertsey, Surrey, U.K., June, 2000. Public Lecture: "Of needles, tubes, and prematurity: What happens to the baby?"

Regional Meeting, Committee for the Future, ACH Foundation, Little Rock, AR, August, 2000. "Recent research in the Pain Neurobiology Laboratory".

Neonatology Seminar Series, Department of Pediatrics, University of Kentucky Children's Hospital, Lexington, KY, October, 2000. "Of needles, tubes, and prematurity: What happens to the baby?"

Neonatal-Perinatal Medicine Seminars, Department of Pediatrics and Department of Obstetrics & Gynecology, University of North Carolina at Chapel Hill and Wake Medical Center, Raleigh NC, October, 2000. "Of needles, tubes, and prematurity: What happens to the baby?"

Fall Seminar Series, Department of Pharmacology, University of Arkansas for Medical Sciences, Little Rock, AR, November, 2000. "Pain mechanisms during development".

2001

30th International Scientific Symposium, Society for Critical Care Medicine, Current Concepts of Pediatric Critical Care Course, San Francisco CA, February, 2001. "Mechanisms and therapies for opioid tolerance and withdrawal".

10th Annual Symposium on Neonatal-Perinatal Medicine, University of Michigan, Ann Arbor, MI, April, 2001. Keynote Address: "Long-term effects of pain in neonates, infants, and children."

10th Annual Symposium on Neonatal-Perinatal Medicine, University of Michigan, Ann Arbor, MI, April, 2001. "Guidelines for the management of neonatal pain."

10th Annual Symposium on Neonatal-Perinatal Medicine, University of Michigan, Ann Arbor, MI, April, 2001. Pro-Con Debate: "This house believes that exposure to pain causes detrimental effects on the clinical outcomes of preterm neonates."

Joint Annual Meeting of the Pediatric Academic Societies, Special Interest Group for Pain in Children, Baltimore, MD, April, 2001. "Neonatal pain and acute clinical outcomes."

Joint Annual Meeting of the Pediatric Academic Societies, Special Interest Group for Pain in Children, Baltimore, MD, April, 2001. "Evidence-based guidelines for neonatal pain management."

14th Annual Meeting of the Canadian Pain Society, Education Day Workshop, Montreal, Canada, May, 2001. "Pain, plasticity, and preterm birth: a prescription for permanent suffering?"

14th Annual Meeting of the Canadian Pain Society, Symposium on Pediatric Pain, Montreal, Canada, May, 2001. "Update on Pediatric Pain."

8th Annual Neonatology Symposium, University of Wisconsin and North Central Neonatology Group, Lake Geneva, Wisconsin, June, 2001. "Development of Neonatal Pain Processing"

8th Annual Neonatology Symposium, University of Wisconsin and North Central Neonatology Group, Lake Geneva, Wisconsin, June, 2001. "Management of pain in the neonate: Current practices & novel options"

Swedish Neonatal/Perinatal Medicine Seminars, Karolinska Hospital and Astrid Lindgren's Children's Hospital, Stockholm, Sweden, June, 2001. "Neuronal effects of Repetitive Pain in Neonates: Why do ex-preterm children have poor cognitive outcomes?"

2nd Nordic Congress on Pain in Children, Stockholm, Sweden. Plenary lecture, September, 2001. "Does repetitive pain damage the developing brain?"

2nd Nordic Congress on Pain in Children, Stockholm, Sweden. Mini-symposium on Pediatric Pharmacology, September, 2001. "Clinical Pharmacology of Opioids."

2nd Nordic Congress on Pain in Children, Stockholm, Sweden, September, 2001. Symposium on Management of Neonatal Pain, "Pharmacological approaches to pain management."

NIMH-Sponsored Network, Annual Symposium, Early Experience and Stress: Before and After the First Breath, University of Michigan, Ann Arbor, MI, October, 2001."Early repetitive pain: is there evidence for global neurodevelopmental effects?"

2001 National Conference and Exhibition, American Academy of Pediatrics, San Francisco CA, October, 2001."Evidence-based Guidelines for Pain Management in the Newborn" (2hr seminar) 9:30am and again at 1:30pm.

XVII Brazilian Congress of Perinatology, Brazilian Association of Pediatrics, Florianopolis, Brazil, November, 2001. "Update in neonatal sedation."

XVII Brazilian Congress of Perinatology, Brazilian Association of Pediatrics, Florianopolis, Brazil, November, 2001. "Long-term effects of pain in the neonate".

XVII Brazilian Congress of Perinatology, Brazilian Association of Pediatrics, Florianopolis, Brazil, November, 2001. "Importance of Pain in the Neonatal Period "

XVII Brazilian Congress of Perinatology, Brazilian Association of Pediatrics, Florianopolis, Brazil, November, 2001. "Pharmacological Treatment of Pain in the Neonatal Period ".

Investiture Ceremony, Morris & Hettie Oakley Endowed Chair of Pediatric Critical Care, Department of Pediatrics, University of Arkansas for Medical Sciences, Little Rock, AR; April, 2001. "Love, Pain and Care: as the Golden Age of Pediatrics dawns…."

Department of Anatomy and Neurobiology, University of Arkansas for Medical Sciences, Faculty Interactive Seminars, August, 2001. "Repetitive pain and neuronal cell death: evidence for global neurodevelopmental effects."

Anesthesiology Research Seminars, Department of Anesthesiology and Critical Care Medicine, Children's Hospital and Harvard Medical School, Boston, MA, August, 2001. "Why do ex-preterm children have poor cognitive outcomes?"

Faculty Research Conference, Department of Pediatrics, University of Arkansas for Medical Sciences, Arkansas Children's Hospital Research Institute, November, 2001. "Does repetitive neonatal pain cause brain damage?"

Neuropharmacology Graduate Course, Department of Pharmacology and Toxicology, University of Arkansas for Medical Sciences, December, 2001. "Pain management."

PICU Residents Lecture, Department of Pediatrics, University of Arkansas for Medical Sciences, Arkansas Children's Hospital (January through December, 2001 monthly lecture series). "Sedation and analgesia in critically ill patients."

2002

21st Annual Scientific Meeting of the American Pain Society, Symposium on "Changing the Face of Pediatric Pain", Workshop Session: Present State and Future Directions of Pediatric Pain Research, March, 2002, Baltimore MD. "Experimental models for neonatal pain research."

NIC/Q 2002, Annual Meeting of the Vermont-Oxford Neonatal Network, New Orleans, LA, April, 2002. Keynote Address: "Neurobiology of neonatal pain as a foundation for clinical practice."

PAS Annual Meeting 2002, State-of-the-Art Plenary Session on Pediatric Pain, Baltimore MD, May, 2002. "Pain, Plasticity, and preterm birth: Findings form the bench & bedside".

18th European Congress of Perinatal Medicine, June, 2002; Plenary Session on Neonatal Pain, Oslo, Norway. "Prevention and management of pain in the newborn."

28Th Annual Congress, German Society of Neonatology and Pediatric Intensive Care, June, 2002; Plenary Session on Neurology and Neurointensive Care, Mainz, Germany. "Long-term effects of repetitive pain or prolonged analgesia in preterm neonates."

28Th Annual Congress, German Society of Neonatology and Pediatric Intensive Care, June, 2002; Plenary Session of the Nursing Track, Mainz, Germany. "Neonatal pain and acute clinical outcomes."

4th International Forum on Pediatric Pain, September, 2002, White Point Beach, Nova Scotia. Keynote Speaker: "Experimental models of pain and early adverse experience".

NIC/Q 2002, Fall Meeting of the Vermont-Oxford Network, September, 2002, Chicago, IL. "Potentially better practices for neonatal analgesia".

NIC/Q 2002, Fall Meeting of the Vermont-Oxford Network, September, 2002, Chicago, IL. "Role of sucrose in neonatal pain management".

International IPOKRaTES Seminar on "Neonatal Comfort and Care" October, 2002, Gmunden, Austria. "Mechanisms of pain in the fetus and neonate"

International IPOKRaTES Seminar on "Neonatal Comfort and Care" October, 2002, Gmunden, Austria. "Long-term effects of repetitive pain in the neonate"

International IPOKRaTES Seminar on "Neonatal Comfort and Care" October , 2002, Gmunden, Austria. "Does the ventilated premature infant require routine analgesia?"

International IPOKRaTES Seminar on "Neonatal Comfort and Care" October , 2002, Gmunden, Austria. "Management of pain in the neonate: Current practice and novel approaches".

Dean's Research Forum, University of Arkansas for Medical Sciences, October, 2002, Little Rock, AR. "Pain, plasticity, prematurity: findings from the bench and the bedside".

8th Biennial Congress, European Society for Developmental Pharmacology, October, 2002. Liège, Belgium. Plenary Lecture: "Effects of perinatal pain and stress: a pharmacological approach."

8th Biennial Congress, European Society for Developmental Pharmacology, October 2002. Liège, Belgium. Moderator: "Pain in children: where are we in terms of assessment and management?"

12th Jackson Rees International Symposium on *Pain in Children: The Next Step*, Academisch Ziekenhuis Rotterdam, Erasmus University and Sophia Children's Hospital, October, 2002, Rotterdam, The Netherlands. "Pain in Neonates: Where are we going?"

20th Neonatal Course for Senior Paediatricians, Imperial College of Medicine, November, 2002, London, England. The Lesley Cooper Memorial Lecture: "Neonatal pain."

Arkansas Children's Hospital Auxiliary Officers Meeting, Little Rock, January, 2002. "Research directions on pain in children at ACHRI".

Invited Lecturer, Saturday Open Forum, Unitarian Universalist Church of Little Rock, January, 2002. "Universal principles from Sikhism and other religions".

Students Forum, Hendrix College, Conway, AR. January, 2002. "Death and Dying: Before and After".

Grand Rounds, Department of Anesthesiology, Wayne State University, Children's Hospital of Michigan, Detroit, MI. June, 2002. "Opioid analgesia in the neonate: bench research and clinical trials."

PICU Fellows Research Conference, Departments of Pediatrics and Pharmacology, Wayne State University, Children's Hospital of Michigan, Detroit, MI. June, 2002. "The anatomy and physiology of a research project".

Grand Rounds, College of Pharmacy and Pharmaceutical Sciences, Wayne State University, Detroit, MI. June, 2002. "Neonatal pain management: physiological effects and clinical outcomes".

Neonatal ICU Seminars, , Department of Pediatrics, Wayne State University, Children's Hospital of Michigan, Detroit, MI. June, 2002. "Does routine analgesia alter clinical outcomes?"

Case Discussion Seminar, Pediatric Pain Interest Group, Departments of Pediatrics, Anesthesiology, and Pharmacy, Wayne State University, Children's Hospital of Michigan, Detroit, MI. June, 2002. "Systematic approach for the management of chromic pain patients".

Grand Rounds, Department of Pharmacology, Wayne State University, Children's Hospital of Michigan, Detroit, MI. June, 2002. "Opioid Tolerance and Withdrawal: mechanisms and novel therapies".

Grand Rounds, Department of Pediatrics, Wayne State University, Children's Hospital of Michigan, Detroit, MI. June, 2002. "Pain, plasticity, and prematurity: What happens to the baby?"

Arkansas Colleges and University Representatives, Rhodes Scholarships Selection Committee, Arkansas Children's Hospital, August, 2002, Little Rock, AR. "Selection criteria and preparation for the Rhodes Scholarship Interviews".

Pediatric Grand Rounds, Children's Medical Center, University of Texas Southwestern Medical School, September, 2002, Dallas, TX. "Management of pain and distress caused by invasive procedures in neonates and children"

Clinical Grand Rounds, Children's Medical Center, University of Texas Southwestern Medical School, September, 2002, Dallas, TX. "Long-term effects of repetitive pain in neonates".

Division of Neonatology Research Conference, Parkland Memorial Hospital, University of Texas Southwestern Medical School, September, 2002, Dallas, TX. "Does the ventilated preterm neonate require analgesia routinely? Results from the NOPAIN and NEOPAIN Trials".

Dinner Speaker, Department of Pediatrics, Children's Medical Center, University of Texas Southwestern Medical School, September, 2002, Dallas, TX. "Outcomes of premature birth: What's happening in school?".

Pediatric Grand Rounds, Medical City Dallas-North Texas Hospital for Children, September, 2002, Dallas, TX. "Management of procedural and postoperative pain in neonates".

Neonatal ICU Seminars, Medical City Dallas-North Texas Hospital for Children, September, 2002, Dallas, TX. "Opioid tolerance and strategies for preventing opioid withdrawal".

Medical Staff Meeting, Medical City Dallas-North Texas Hospital for Children, September, 2002, Dallas, TX. "Long-term effects of pain in the neonatal period".

Pediatric Grand Rounds, Departments of Pediatrics, Obstetrics and Gynecology, Presbyterian Hospital of Dallas, September, 2002, Dallas, TX. "Neonatal and infant pain: Current therapies and novel options".

Neonatal ICU Seminars, Department of Pediatrics, Presbyterian Hospital of Dallas, September, 2002, Dallas, TX. "Long-term effects of neonatal pain".

Medical Staff Monthly Conference, Presbyterian Hospital of Dallas, September, 2002, Dallas, TX. "Does the ventilated preterm neonate require analgesia routinely?"

Resident's Seminar Series, UAMS Department of Pediatrics, September, 2002, Little Rock, AR. "Death and Dying: Management of Terminal Illness"

Faculty Research Conference, Arkansas Children's Hospital Research Institute, September, 2002, Little Rock, AR. "Does gastric suctioning at birth increase long-term risk for functional intestinal disorders in adulthood?"

College of Medicine, Dean's Research Forum, University of Arkansas for Medical Sciences, October, 2002, Little Rock, AR. "Pain, plasticity, prematurity: findings from the bench and the bedside".

Neurotoxicology Grand Rounds, National Center for Toxicological Research, December, 2002, Jefferson, AR. "The Science of Neonatal Pain: Short-term and Long-term Neurodevelopmental effects".

2003

25th Annual "Management of the Tiny Baby" Conference, January, 2003, Orlando, Florida. "The Science of Neonatal Pain: Short-term and Long-term Neurodevelopmental Effects"

25th Annual "Management of the Tiny Baby" Conference, January, 2003, Orlando, Florida. "Neonatal Pain Management: The Art and the Medicine".

NICHD/FDA Planning Meeting, Newborn Drug Development Initiative, Best Pharmaceuticals for Children Act, February, 2003; Baltimore, MD. "Goals for the Anesthesia/Analgesia Task Force".

Annual Meeting, Child Health Accountability Initiative (CHAI), March, 2003, St. Louis, MO. "State-of-the-Art and Science of Neonatal Pain Management".

The Diamond Conference, May, 2003, Little Rock, AR. "What happens in the premature baby's brain when invasive medical procedures are performed without any pain relief?"

International IPOKRaTES Seminar on "Neonatal Comfort and Care" June, 2003, Padova, Italy. "Mechanisms of pain in the fetus and neonate"

International IPOKRaTES Seminar on "Neonatal Comfort and Care" June, 2003, Padova, Italy. "Long-term effects of repetitive pain in the neonate"

International IPOKRaTES Seminar on "Neonatal Comfort and Care" June, 2003, Padova, Italy. "Does the ventilated premature infant require routine analgesia?"

International IPOKRaTES Seminar on "Neonatal Comfort and Care" June, 2003, Padova, Italy. "Management of pain in the neonate: Current practice and novel approaches".

2nd International EURAIBI (Europe Against Infant Brain Injury) Workshop, June, 2003, Siena, Italy. Honorary Keynote Address: "Long-term effects of pain in the developing brain" (live broadcast of opening ceremony to 125 countries by Reuters International).

4th World Congress on Pediatric Intensive Care, World Federation of Pediatric Intensive and Critical Care Societies, June, 2003, Boston, MA. "Mechanisms of Pain: Immediate & long-term effects in critical illness".

4th World Congress on Pediatric Intensive Care, World Federation of Pediatric Intensive and Critical Care Societies, June, 2003, Boston, MA. "Opioid tolerance and withdrawal: Novel strategies for prevention".

4th World Congress on Pediatric Intensive Care, World Federation of Pediatric Intensive and Critical Care Societies, June, 2003, Boston, MA. Pro/Con Debate: "Sedation is not required for mechanically ventilated children".

4th World Congress on Pediatric Intensive Care, World Federation of Pediatric Intensive and Critical Care Societies, June, 2003, Boston, MA. "Management of pain and stress in neonates".
34th Annual Meeting of the Perinatal Research Society, September, 2003, Charleston, South Carolina. Keynote Address: "Long-term Effects of Repetitive Pain and Analgesia in Neonates".

9th Annual Vanderbilt Neonatology Symposium, Neonatal/Perinatal Section, Vanderbilt University, October, 2003, Nashville, TN. "Repetitive pain or prolonged analgesia: Who is the greater enemy?"

9th Annual Vanderbilt Neonatology Symposium, Neonatal/Perinatal Section, Vanderbilt University, October, 2003, Nashville, TN. "Of needles, tubes, and prematurity: What happens to the baby?"

National Conference & Exhibition 2003, American Academy of Pediatrics, Sections of Critical Care, Home Health and Perinatal Pediatrics, American Academy of Pediatrics, October, 2003, New Orleans, LA. "Pain Palliation and the Long Term Effects of Early Pain Experience in Infants and Young Children"

National Conference & Exhibition 2003, American Academy of Pediatrics, October, 2003, New Orleans, LA. Plenary Lecture, Section of Perinatal Pediatrics: "Repetitive Pain or Neonatal Analgesia: Who is the greater enemy?"

FDA and NIH Joint Working Group, Newborn Drug Development Initiative, February, 2003, Baltimore, MD. "Future directions for neonatal analgesia and sedations".

Neonatology Research Conference, Baylor University and Texas Children's Hospital, February, 2003, Houston, TX. "Does the Newborn Brain Process Pain at the Supraspinal Levels?

Physiology Conference, Departments of Pediatrics, Anesthesiology, and Neonatal/Pediatric Nursing, Baylor University and Texas Children's Hospital, February, 2003, Houston, TX. "Analgesia and Sedation in the Critically Ill Neonate".

Newborn Center Pain Committee, Department of Pediatrics and Anesthesiology, Baylor University and Texas Children's Hospital, February, 2003, Houston, TX. "Review of Pain Pocket Guidelines for Procedural Pain in Neonates".

Division of Neonatology, Department of Pediatrics, Baylor University and Texas Children's Hospital, February, 2003, Houston, TX. "Case studies in neonatal pain management".

Nursing Research Scholars & Fellows, Baylor University School of Nursing and Texas Children's Hospital, February, 2003, Houston, TX. "Developing a Program of Research"

Pain Quality Improvement Committee, Department of Pediatrics, Nursing and Pharmacy, Texas Children's Hospital, February, 2003, Houston, TX. "Assessing Quality Improvement Outcomes in Pain Management: Past, Present, & Future"

Residents' Noon Lecture Series, Department of Pediatrics, Nursing and Pharmacy, Texas Children's Hospital, February, 2003, Houston, TX. "Opioid Tolerance and Dependence in Neonates: Mechanisms, Diagnosis, Assessment & Management".

Newborn Center Pain Committee, Department of Pediatrics, Baylor University and Texas Children's Hospital, February, 2003, Houston, TX. "Guidelines for opioid weaning".

Pediatric Pain Workshop, Department of Pediatrics and Anesthesiology, Baylor University and Texas Children's Hospital, February, 2003, Houston, TX. "Local, Regional and Topical Analgesia Techniques for Procedural Pain in the Neonate".

Neonatology Fellows Conference, Department of Pediatrics, Baylor University and Texas Children's Hospital, February, 2003, Houston, TX. "Managing chronic pain in neonates requiring prolonged hospitalization".

Arnold J. Rudolph Memorial Grand Rounds, Department of Pediatrics, Baylor University and Texas Children's Hospital, February, 2003, Houston, TX. "Long-term effects of repetitive pain in preterm neonates".

Neonatology Fellows Conference, Department of Pediatrics, Baylor University and Texas Children's Hospital, February, 2003, Houston, TX. "Neurologic Outcomes & Pre-emptive Analgesia in Neonates: The NEOPAIN Multicenter Trial".

Residents Noon Conference, Department of Pediatrics, Baylor University and Texas Children's Hospital, February, 2003, Houston, TX. "End-of-Life Decisions in the NICU: Medical Infanticide or Palliative Terminal Care?"

Introduction to Clinical Medicine, UAMS College of Medicine, March, 2003, Little Rock, AR. "Cultural diversity and ethical challenges in medical decision-making".

Fellows Research Conference, CCM Section, UAMS Department of Pediatrics and Arkansas Children's Hospital, March, 2003, Little Rock, AR. "Neonatal pain research: an update".

Fellows Teaching Conference, CCM Section, UAMS Department of Pediatrics and Arkansas Children's Hospital, March, 2003, Little Rock, AR. "Fluid and electrolyte problems in the Pediatric ICU."

Pediatric Grand Rounds, St. Jude's Children's Hospital and Research Center, May, 2003, Memphis, TN. "Long-term effects of repetitive neonatal pain".

Course Director, ***"The Cutting Edge of Pediatric Intensive Care"***, Arkansas Children's Hospital and UAMS Department of Pediatrics, March, 2003, Little Rock, AR.

Pediatric Grand Rounds, UAMS Department of Pediatrics and Arkansas Children's Hospital, August, 2003, Little Rock, AR. "Final results from the NEOPAIN Multicenter Trial".
Mid-Central Region Mini-Conference, Sri Sathya Sai Baba Center of Kansas City, October, 2003, Kansas City, MO. "Pathways to Self-Realization."

Critical Care Medicine Research Conference, University of Pittsburgh and Children's Hospital of Pittsburgh. October, 2003. "Repetitive Pain and Ketamine Analgesia: Neurotoxic or Neuroprotective?"

Meet the Professor Session, Department of Critical Care Medicine, University of Pittsburgh, October, 2003. "A research career in academic medicine."

Pediatric Anesthesia Grand Rounds, University of Pittsburgh and Children's Hospital of Pittsburgh. October, 2003. "Opioid Tolerance and Withdrawal: Mechanisms and Novel Therapies"

Critical Care Medicine Grand Rounds, Department of Critical Care Medicine, University of Pittsburgh, October, 2003. "Of needles, tubes and prematurity: What happens when babies grow up?"

ACHRI President Recruitment Seminar, Arkansas Children's Hospital, November, 2003, Little Rock, AR. "Repetitive pain or prolonged analgesia in neonates: Who is the greater enemy?"

Grand Rounds, Departments of Pediatrics and Anesthesiology, Children's Hospital of New Jersey (Newark Beth Israel Medical Center), December, 2003, Newark, NJ. "Long-term Effects of Repetitive Pain in Neonates."

Neonatology Seminars for Residents, Department of Pediatrics, Children's Hospital of New Jersey (Newark Beth Israel Medical Center), December, 2003, Newark, NJ. "Practical management of pain and sedation in neonates."

2004

10th Annual Conference of the Indian Society of Critical Care Medicine, Indian Society of Critical Care Medicine, February, 2004, Mumbai, India. "Pain management in the Pediatric ICU."

Keynote Address at UNESCO 2004 Congress, "La douleur de l'enfant: Quelles réponses?", February, 2004, Paris, France. "Morphine for ventilated preterm neonates: Results of the NEOPAIN Study"

10th Annual Conference, "Current Topics and Controversies in Perinatal & Neonatal Medicine", California Association of Neonatology, San Diego CA, February, 2004. "Pharmacology and pain management in neonates."

10th Annual Conference Current Topics and Controversies in Perinatal and Neonatal Medicine, California Association of Neonatology, February, 2004, Coronado, CA.
" Pain management in the neonate and the care of the terminally ill infant".

3rd Meeting, Maternal-Fetal NIMH Network: Development of Interdisciplinary Approaches to Study the Impact of Adverse Fetal and Neonatal Experience on Child and Adolescent Mental Health, University of Michigan, March, 2004, Ann Arbor, MI. "Pain and stress in the newborn rat: A model for long-term cognitive outcomes?"

FDA/NICHD Newborn Drug Development Initiative Workshop, March, 2004; Baltimore, MD. Plenary lecture: "Overview of the progress by the Neonatal Pain Task Force".

FDA/NICHD Newborn Drug Development Initiative Workshop, March, 2004; Baltimore, MD. Plenary lecture: "Potential Trial Designs for Neonatal Pain studies".

FDA/NICHD Newborn Drug Development Initiative Workshop, March, 2004; Baltimore, MD. "Sample trial designs for procedural pain studies in neonates."

8th Spring Meeting, Royal College of Paediatrics and Child Health, University of York, York (UK), March, 2004. Windermere Honorary Lecture: "Love, Pain and Neonatal Care".

3rd Nordic Congress on Children and Pain, The Swedish Paediatric Pain Society, May, 2004, Linkoping, Sweden. Keynote Address: "Love, Pain and Care: Effects on brain development and clinical outcomes".

4th Annual Neonatal Pharmacology Conference sponsored by Contemporary Forums, May, 2004, Chicago, IL. "Evidence-Based Management of Pain in Neonates".

Xth International Postgraduate Course in Neonatal Intensive Care, May, 2004, Buenos Aires, Argentina. " Management of Pain in the Neonate: Current Practice Recommendations".

Xth International Postgraduate Course in Neonatal Intensive Care, May, 2004, Buenos Aires, Argentina. "Of needles, tubes, and prematurity: What happens to the baby?"

Xth International Postgraduate Course in Neonatal Intensive Care, May, 2004, Buenos Aires, Argentina. "Does the Ventilated Premature Infant Require Routine Analgesia?"

Neonatal Update 2004, University of Massachusetts Medical Center, June, 2004, Marlboro, MA. "Of Needles, Tubes and Prematurity – What happens to the baby?"

Maternal-Fetal Network Meeting, The British Columbia Research Institute for Children's and Women's Health, University of British Columbia, September, 2004, Vancouver, British Columbia. "Update on neonatal pain research."

21st Annual NOGAN Lecture, Association of Georgia Neonatologists, Atlanta, GA; December, 2004. "Management of pain in preterm neonates: lessons from the NEOPAIN Trial".

Presentation to the Chief Minister, Health Minister and Administrative Secretaries of Delhi State, January, 2004. "Proposal for a specialized Pediatric health care system".

Visiting Professor Rounds, Department of Pediatrics, All-India Institute of Medical Sciences, New Delhi, February, 2004. "Neonatal pain and stress"

Neonatology Seminars, Department of Paediatrics and the Simpson Maternity Pavilion, University of Edinburgh, Edinburgh, April, 2004. "Research design and interpretation of preliminary data."

Neuroscience Course (M1 Medical Students; Course Director – Dr. Robert D. Skinner), The Department of Neurobiology and Developmental Sciences, University of Arkansas for Medical Sciences, April, 2004. "The Anatomy and Physiology of Pain".

NIH Grant Review for Dr. Pao-Feng Tsai (Education Building III (COPH building) Room # 5231), UAMS School of Nursing, August, 2004.

Research Seminars, Departments of Pediatrics and Pharmacology, University of California at San Diego, College of Medicine and College of Pharmacy, San Diego, November, 2004. "Repetitive pain or prolonged analgesia in neonates: Which is the lesser evil?"

Monthly Lecture Series, Pain Arkansas! Club at University of Arkansas for Medical Sciences, October, 2004. "Novel approaches to the blockade of opioid tolerance".

Grand Rounds, Departments of Pediatrics and Pharmacology, University of California at San Diego, November, 2004. "Long-term effects of pain in neonates".

Pediatric Resident Mock Codes, Department of Pediatrics, University of Arkansas for Medical Sciences, November, 2004. "CPR in pediatric patients".

CME Lecture for Advanced Pediatric Nurses, Pediatric Intensive Care Unit, Arkansas Children's Hospital, December, 2004. "Analgesia and sedation in PICU patients".

Neuropharmacology Course (PCOL 5133; Course Director – Dr. Galen R. Wenger), Department of Pharmacology & Toxicology, University of Arkansas for Medical Sciences, December, 2004. "The Pharmacological Control of Pain".

Grand Rounds, Department of Pediatrics, Emory University School of Medicine and Children's Health Care of Atlanta at Egleston, December, 2004. "Effects of repetitive pain in the development of preterm neonates".

Neonatology Noon Lectures, Department of Pediatrics, Emory University School of Medicine and Grady Memorial Hospital, Atlanta, GA; December, 2004. "Novel research on neonatal pain."

Emergency Medicine Seminars, Department of Pediatrics and Emergency Medicine, Children's HealthCare of Atlanta, Atlanta, GA; December, 2004. "Acute Pain Management for Invasive Procedures in the Emergency Room."

2005

Plenary Speaker, 25th Anniversary of IPOKRaTES Seminars, New Frontiers in Neonatology: A Global Forum for Research and Science; March, 2005; Innsbruck, Austria. "The impact of repetitive pain on the developing brain".

Plenary Speaker, 2nd International IDNIC Conference "Infant Development in Neonatal Intensive Care", March, 2005; London, U.K. "Consequences of painful experiences during neonatal intensive care".

24th Annual Scientific Meeting of the American Pain Society, March, 2005; Boston, MA; Pediatric Pain Forum on "Pediatric Drug Development – A Regulatory Perspective", invited lecture: "Neonatal Pain Management: Current research and Future directions"

24th Annual Scientific Meeting of the American Pain Society, March, 2005; Boston, MA; Workshop on "Infant Pain: Sharpening our understanding within critical stages of Infant Development", invited lecture: "Acute Pain in Preterm Neonates".

Annual Meeting of the Pediatric Academic Societies', May, 2005; San Francisco, CA. Moderator for the Brain Injury Poster Symposium Session.

11th World Congress on Pain, Workshop on "Nationwide guidelines on pain in children: Development and implementation in different countries", August, 2005, Sydney, Australia. "Evidence Based Guidelines: Report from the NIH-FDA Neonatal Pain Control Group".

11th World Congress on Pain, Chairman, Workshop on "Impact of Neonatal Pain on Subsequent Pain Processing, Pain Thresholds and Responses to Analgesia", August, 2005, Sydney, Australia.

International Medical Conference on Sai Ideal Health Care, September, 2005, Prasanthi Nilayam, Puttaparthi (India). "Purity, Prema, and Prevention: The Pillars of Pediatric Care".

5th National Neonatal Nurses Meeting, sponsored by Neonatal Network and The Academy of Neonatal Nursing, September, 2005; Chicago, IL. "Neonatal Pain: Clinical and Biological Relevance"
5th National Neonatal Nurses Meeting, sponsored by Neonatal Network and The Academy of Neonatal Nursing, September, 2005; Chicago, IL. "Ventilated Preterm Neonates: Analgesia, Sedation, or What?"

International Symposium on "The Neonatal Brain", to celebrate 90 years of Kinderklinik Glanzing on October, 2005 in Vienna, Austria. "Repetitive Pain alters the Developing Brain".

Symposium on "Developmental Neuroscience: Imaging the Fetal and Newborn Brain", University of Arkansas for Medical Sciences, October, 2005. "Pain in the Fetus and Newborn: Cortical and subcortical processing?"

House Judiciary Subcommittee on the Constitution, Congress of the United States House of Representatives, November, 2005, Washington, DC. Presenting "Expert Testimony on Pain of the Unborn".

Keynote Speaker, Dr. Martin Luther King, Jr. Commemoration Day, University of Arkansas for Medical Sciences, University Chancellor's Diversity Committee, January, 2005. "Dr. Martin Luther King, Mahatma Gandhi and a Theory of Human Relativity".

Monthly Lecture Series, Pain Arkansas! Club at University of Arkansas for Medical Sciences, January, 2005. "Neuroimaging and neonatal pain".

Physician ECMO Training and Refresher Course, UAMS Department of Pediatrics, UAMS Office of Continuing Education, and Arkansas Children's Hospital; February, 2005; Little Rock, AR. "Sedation and Analgesia in ECLS Support".

Research Competition Judge, 11th Annual Residents' Day, Department of Anesthesiology, University of Arkansas for Medical Sciences, February, 2005; Little Rock, AR.

Anesthesiology Grand Rounds, Department of Anesthesiology, Baylor University School of Medicine and Texas Children's Hospital, March, 2005; Houston, TX. "Neurodevelopmental effects of sedative, analgesic, and anesthetic drugs".

Neonatology/Critical Care Medicine Joint Seminars, Department of Pediatrics, Baylor University School of Medicine and Texas Children's Hospital, March, 2005; Houston, TX. "Management of Pain in the neonate: Current practice and novel options".

Anesthesiology Fellows Conference, Department of Anesthesiology, Baylor University School of Medicine and Texas Children's Hospital, March, 2005; Houston, TX. "Prediction of clinical outcomes in pediatric surgical patients".

John S. Liebeskind Visiting Professorship, Grand Rounds, UCLA Department of Pediatrics, Harbour-UCLA Medical Center, April, 2005. "Repetitive pain vs. prolonged analgesia: Which is the lesser evil?"

John S. Liebeskind Visiting Professorship, UCLA Faculty Club, Departments of Pediatrics, Medicine, Psychology, History, Sociology, Anthropology, University of California at Los Angelis, April, 2005. "Pain and the Brain: unifying roles in Evolution and Human Development".

Fellows Conference, Critical Care Medicine Section, Department of Pediatrics, University of Arkansas for Medical Sciences, September, 2005; Little Rock, AR. "Future models of health care delivery: report from the International Sai Medical Conference".

Gregory Mark Taubin Distinguished Lecturer, Department of Pediatrics, Children's National Medical Center, GW University School of Medicine, December, 2005; Washington DC. "Pain and stress in critically ill pediatric patients".

Grand Rounds, Department of Pediatrics, New York University School of Medicine & NYU Medical Center, December, 2005; New York, NY. "Prematurity, pain management, and brain plasticity: Developmental origins of adult behavior?"

2006

NICU-PICU Specialty Conference, Pediatric Pharmacy Advocacy Group, March, 2006, Baltimore, MD. ***Keynote Address:*** "Pain Management in Neonatal and Pediatric Patients."

Pediatric Academic Societies' Annual Meeting, San Francisco, CA, April, 2006. Workshop on CPCCRN: The NICHD Collaborative Pediatric Critical Care Research Network: "Towards Evidence-Based Management of Sedation in Pediatric Critical Care".

12th Annual Ruth Rappaport Seminar on Pediatric Pain Management: "Facing The Future". The Technion: Israel Institute of Technology, Haifa, Israel, June, 2006. ***Honorary Guest Lecture***: "Consciousness, behavior, and clinical impact of the definition of pain".

12th Annual Ruth Rappaport Seminar on Pediatric Pain Management: "Facing The Future". The Technion: Israel Institute of Technology, Haifa, Israel, June, 2006. "Evidence based treatment of neonatal pain".

Annenberg Center for Health Sciences, 3rd Annual Meeting, Evidence vs. Experience in Neonatal Practices, Boston MA, June, 2006. "Pharmacological Management of Pain and Sedation in the NICU"

CIHR Pain in Child Health Summer 2006 Institute, Rockwater Cove, B.C., Canada, June, 2006. "The Stress of Early Surgery and its long term effects."

7th International Symposium on Pediatric Pain, IASP Special Interest Group on Pain in Children, Vancouver, B.C., Canada, June, 2006. Workshop on Analgesic Drugs: Safety and Efficacy in Children; "Efficacy of Pharmacological Analgesia in Newborn Infants."

CIHR Pain in Child Health Summer 2006 Institute, Rockwater Cove, B.C., Canada, June, 2006. "The most important challenges in pediatric pain".

7th International Symposium on Pediatric Pain, IASP Special Interest Group on Pain in Children, Vancouver, B.C., Canada, June, 2006. Workshop on Pharmacogenomics of Analgesic Drugs: Sense or Nonsense? "Pharmacogenomics: The Bioethics Challenge of the 21st Century."

7th International Symposium on Pediatric Pain, IASP Special Interest Group on Pain in Children, Vancouver, B.C., Canada, June, 2006. Chaired the Expert Panel Discussion on "Role of Drug Regulatory Agencies in the use and approval of analgesics in children".

7th International Symposium on Pediatric Pain, IASP Special Interest Group on Pain in Children, Vancouver, B.C., Canada, June, 2006. Workshop on Development and Implementation of Evidence Based Guidelines on Pain in Children. "Evidence Based Guidelines: Report from the NIH-FDA Neonatal Pain Control Group".

7th International Symposium on Pediatric Pain, IASP Special Interest Group on Pain in Children, Vancouver, B.C., Canada, June, 2006. ***Plenary Podium Presentation***: "Childhood Analgesia: Getting off-label drugs on-label".

International Symposium on "Emerging Trends in Biological and Chemical Sciences", Department of Biosciences and Chemistry, Sri Sathya Sai Institute of Higher Learning (Deemed University) Prasanthi Nilayam (AP), India, August, 2006. ***Plenary Podium Presentation***: "*Primum non dolore*: First, Cause No Pain".

23rd International Neurotoxicology Conference, "Neurotoxicity in Development & Aging", Little Rock, AR, September, 2006. B. Clancy, B. Kersh, K.J.S. Anand, et al. "What is that in rat days? A Web-Based Approach to the Translation of Neurodevelopmental Time across Mammalian Species".

2006 Annual Meeting, Society for Pediatric Anesthesia, Chicago, IL, October, 2006. ***Plenary Inaugural Address:*** "Neurobiology of Acute Pain in Infants and Children".

NIMH-funded Maternal-Fetal Network (Impact of Adverse Fetal and Neonatal Experience on Child and Adolescent Mental Health), University of Minneapolis, Center for Human Development, November, 2006. "A novel bioinformatics approach for translating developmental time across mammalian species".

Annual BPCA Drug Prioritization Meeting, National Institute of Child Health and Human Development, National Institutes of Health, Bethesda, MD, December, 2006. "Update on BPCA-related Activities: Research Agenda for Neonatal Pain".

Pfizer Visiting Professorship in Pain Medicine, University of Utah School of Medicine and School of Pharmacy, Salt Lake City, UT, January, 2006. Pediatric Grand Rounds: "Pain, plasticity and Prematurity: neonatal shadows on development".
Pfizer Visiting Professorship in Pain Medicine, University of Utah School of Medicine and School of Pharmacy, Salt Lake City, UT, January, 2006. Pharmacology & Pharmaceutics Grand Rounds: "Opioid tolerance and withdrawal: Mechanisms and novel therapies".

Pfizer Visiting Professorship in Pain Medicine, University of Utah School of Medicine and School of Pharmacy, Salt Lake City, UT, January, 2006. Neonatal Fellowship Program Seminars. "Management of analgesia and sedation in neonates".

Pfizer Visiting Professorship in Pain Medicine, University of Utah School of Medicine and School of Pharmacy, Salt Lake City UT, January, 2006. Pain Center Workshop, Department of Anesthesiology: "Role of the cortex in human consciousness and pain perception".

Nursing Grand Rounds, Nursing Education Department, Arkansas Children's Hospital, February 28th, 2006, Little Rock, AR. "Consent, Assent and Clinical Research in Children"

Grand Rounds, Department of Geriatrics, University of Arkansas for Medical Sciences, March 1st, 2006, Little Rock, AR. "Pain Management at the Two Ends of Life: Lessons from the Newborn".

Visiting Scientist Seminars, National Center for Toxicological Research, Jefferson, AR; March, 2006. "Pain and stress in Laboratory Animals: Prevention, Assessment, and Management".

Medical Students Block 10 Electives, UAMS College of Medicine, Reynolds Center for Aging, Little Rock, AR; March, 2006. "Inter-faith and cross-cultural issues for geriatric patients".

Complementary and Alternative Medicine Course, Reynolds Center on Aging, Little Rock, AR, March, 2006. "Role of Spirituality in the Interpretation of Death and Dying".

Clinton School of Public Service and University of Arkansas, Public Meeting at the William J. Clinton Presidential Center & Library, March, 2006. "Bridge to the Future: Role of Religion and Ethnicity in Building a Caring Community & Nation".

Faculty Seminar Series, Department of Neurobiology & Developmental Sciences, UAMS College of Medicine, Little Rock, AR; April, 2006. "Consciousness without the Cortex: Neuroscience, Clinical Medicine, or Voodoo?"

Executive Presentation, Child Health Corporation of America, Kansas City, KS; April, 2006. "Participation in the NIH-funded CPCCRN Network studies for CHCA-affiliated hospitals".

UAMS College of Medicine, M2 Medical Students, September, 2006. Faculty for Patient Beliefs Panel Discussion (Moderated by Dr. James Graham).

NICU Grand Rounds, University of Western Ontario and St. Joseph's Hospital, London, Ontario, Canada; Tuesday, October, 2006. "Pain Management in the Neonate".

NICU Nursing Seminars, University of Western Ontario and St. Joseph's Hospital, London, Ontario, Canada; Tuesday, October, 2006. "Pain Assessment in the Neonate: New findings and their clinical application".

Visiting Scientist Program, Children's Hospital Research Institute, University of Western Ontario, London, Ontario, Canada, October, 2006. "Long-term Effects of Pain in Preterm Neonates".

Paediatric Grand Rounds, Children's Hospital of Western Ontario, University of Western Ontario, London, Ontario, Canada, October, 2006 "Mechanisms and Management of Opioid Tolerance in Children".

Pediatric Grand Rounds, Department of Pediatrics, Eastern Virginia Medical School and Children's Hospital of The King's Daughters, Norfolk, VA, October , 2006: "Management of pain in neonates: Current state-of-the-art".

Resident Noon Conference, Department of Pediatrics, Eastern Virginia Medical School and Children's Hospital of The King's Daughters, Norfolk, VA, October, 2006: "Long-term effects of medical and surgical procedures in preterm neonates".

Patient Care Seminars, Department of Surgery, Children's Hospital of The King's Daughters, Norfolk, VA, October, 2006: "Developing a practical neonatal pain management protocol".

NICU Nursing Professional Development Day, Children's Hospital of The King's Daughters, Norfolk, VA, October, 2006: "Pain Assessment in the Neonate: New findings and their clinical application".

Guest Speaker, Fortis Lt. Rajan Dhall Specialty Hospital, Vasant Kunj, New Delhi, India, November, 2006. "The advancement of Pediatric Care in India: Barriers and Solutions".

2007

4th International Conference on Children's Pain and Palliative Care, Vodafone Foundation Institute for Paediatric Pain Therapy and Paediatric Palliative Care and Dattel Children's Hospital, Recklinghausen, Germany, February, 2007. "Pain in Neonates: Assessment, management, long-term effects".

4th International Conference on Children's Pain and Palliative Care, Vodafone Foundation Institute for Paediatric Pain Therapy and Paediatric Palliative Care and Dattel Children's

Hospital, Recklinghausen, Germany. February, 2007. "Meet the Expert session on Neonatal Pain".

22nd Congress of the Indian Society of Study of Pain "ISSPCON 2007" at Sanjay Gandhi Postgraduate Institute of Medical Sciences, Lucknow, India. Video conference on February, 2007. "Basic and neonatal science in relation to paediatric pain with implications of early pain experience on long term consequences".

The Medical Home Model for Children after Life-Threatening Illness or Injury: A National Experts' Conference, National Center for Medical Rehabilitation Research (NCMRR) at NICHD, American Academy of Pediatrics (AAP) and the Health Resources and Services Agency (HRSA), March, 2007 in Bethesda, MD. "Transition from PICU to the Home & Community: presentation of a new conceptual model".

Open Public Hearing, Anesthesia and Life Support Drugs Advisory Committee, Division of Anesthesia, Analgesia and Rheumatology Products, Center for Drug Evaluation and Research, FDA, March, 2007, Baltimore MD. "Ketamine neurotoxicity in animal models should not alter its use in humans".

17th Annual Neonatology Update, American Academy of Pediatrics (Chapter VII) and Northwestern University School of Medicine, June, 2007; Chicago IL. "Management of Pain in Neonates: an evidence-based approach".

International Congress to commemorate the 50th Anniversary of the Rome Treaties: "The Human Being and the Problem of Pain" University of Tor Vergata, Rome, Italy, June, 2007. "Love, pain, and conscious perception in premature neonates".

5th World Congress on Pediatric Critical Care, World Federation of Pediatric Intensive Care Societies, June, 2007, Geneva, Switzerland. Poster presentations: (a) Acupuncture reduces inflammatory hyperalgesia in newborn rats. (b) Neonatal pain alters adult cognitive performance & brain cytokine expression.

5th World Congress on Pediatric Critical Care, World Federation of Pediatric Intensive Care Societies, June, 2007, Geneva, Switzerland. Oral presentation: "Acupuncture reduces brain cell death following neonatal inflammatory pain."

18th Annual NIDCAP Trainers Meeting, International Foundation for Developmental Care, September, 2007, Combrit, France. "Consciousness, Pain and Development in the Newborn."

18th Annual NIDCAP Trainers Meeting, International Foundation for Developmental Care, September, 2007, Combrit, France. "Pain management and Development Care: Two sides of the same coin".

14th Annual Father Joseph Biltz Awards Ceremony, Just Communities of Central Arkansas (formerly the NCCJ of Arkansas), October, 2007, Little Rock, AR. "Acceptance speech: Translating the message of love into our life".

Master of Pain Management, Module 8, Universitat Autonoma de Barcelona, October, 2007, Barcelona, Spain. "Conscious perception of Neonatal Pain and its Clinical Management."

9th National Pediatric Critical Care Congress, Indian Society for Critical Care Medicine, New Delhi, India, November, 2007. Plenary Lecture: "Pain in Early Life: Science, Assessment, Management".

Grant Review Sessions, Department of Neurobiology and Developmental Sciences, University of Arkansas for Medical Sciences, January, 2007. "Use of Acupuncture to Reduce Inflammatory Pain in Infants: A translational approach".

Visiting Professor at Stanford University, Lucille Packard Children's Hospital, Pediatric Pain Management & Pediatric Intensive Care Meeting, Thursday, February, 2007. "Novel therapies for management of opioid tolerance".

Visiting Professor at Stanford University, Lucille Packard Children's Hospital, Department of Anesthesiology Research Seminars, February, 2007. "Use of acupuncture in infancy: Results from an animal model".

Visiting Professor at Stanford University, Lucille Packard Children's Hospital, Pediatric Grand Rounds, February, 2007. "The Evidence for Fetal Pain: Clinical Medicine, Neuroscience, or Voodoo?

Panel Discussion on "Spirituality in Medicine", Course on Complementary and Alternative Medicine (CAM) for Senior Medical Students, University of Arkansas for Medical Sciences, March, 2007. "How does spirituality relate to religion? Answers from the Sikh Gurus and Sri Sathya Sai Baba".

Core Curriculum Lectures, Pediatric Critical Care Medicine Fellowship Program, Department of Pediatrics, University of Arkansas for Medical Sciences, March, 2007. "Culturally Driven Management of Death and Dying".

Fellow's Research Conference, Pediatric Critical Care Medicine Fellowship Program, Department of Pediatrics, University of Arkansas for Medical Sciences, April, 2007. "The CRISIS Prevention Trial: rationale and training".

Department of Pediatrics, University of Utah and CPCCRN Steering Committee Meeting, Park City, Utah, May, 2007. "The PROTAW Trial: Mini-protocol presentation".

Department of Pediatrics, University of Utah and CPCCRN Steering Committee Meeting, Park City, Utah, May, 2007. "Psychological Outcomes of Critically Ill Children following PICU Admission".

Neonatology Research Seminars, Karolinska Institute and Astrid Lindgren's Children's Hospital, Stockholm, Sweden, June, 2007. "Pain and its effects in the newborn: 20 years later".

Pediatric Grand Rounds, Escorts Heart Institute and Research Center, Fortis Healthcare Institute, New Delhi, India, August, 2007. "Pain in infancy: science, assessment, management."

Pediatric Grand Rounds, Department of Pediatrics, All-India Institute of Medical Sciences, New Delhi, India, August, 2007. "Emerging approaches for neonatal pain management."

Fellow's Conference, Department of Pediatrics, Critical Care Medicine Section, University of Arkansas for Medical Sciences, August, 2007: "Current Management of PICU Sedation/Analgesia".

Anesthesiology Grant Rounds, Department of Anesthesiology & Critical Care Medicine, Harvard Medical School and Children's Hospital, Boston MA, October, 2007. "Pain in the Neonate and Fetus: 20 years later".

Pediatric Grant Rounds, Department of Medicine, Harvard Medical School and Children's Hospital, Boston MA, October, 2007; "Pain in the Neonate and Fetus: current developments and future directions".

Senior Resident Clinical Rounds, Department of Medicine, Children's Hospital, Boston MA, October, 2007; "Case discussion: Periodic fevers in Children".

CCM Fellows Conference, Department of Anesthesiology & Critical Care Medicine, Children's Hospital, Boston MA, October, 2007. "Case discussion: Sedation/analgesia during ECMO".

CCM Fellows Conference, Department of Pediatrics, Critical Care Medicine Division, Massachusetts General Hospital, Boston MA, October, 2007. "Pain in the Neonate and Fetus: 20 years later".

Neurosurgical Grand Rounds, Department of Neurosurgery, University of Arkansas for Medical Sciences, October, 2007. "Pain during early life: Neuroscience and Development".

Graduate Student Seminars, Department of Neurobiology & Developmental Sciences, University of Arkansas for Medical Sciences, October, 2007. Mentor for Chaoxuan Dong: "Ketamine Neurotoxicity is Age-Dependent and Dose-Dependent".

Mayday Foundation site visit, Research Seminar, Arkansas Children's Hospital Research Institute, December, 2007. "The safety and efficacy of acupuncture for relieving acute pain in newborn infants".

2008

1st Interdisciplinary Swiss Conference on ***Pain Management in Neonates: Investing in the future,*** Institute of Nursing Science of the University of Basel, Switzerland (INS); Bern, Switzerland, January, 2008. Keynote Address: "The clinical importance of pain in term and preterm neonates: Focus on the vulnerability of the developing brain".

Institute of Nursing Science, University of Basel & the University Children‘s Hospital, Basel, Switzerland, January, 2008. Special Lecture: “Neonatal Analgesia in the post-NEOPAIN era”.

Invited Speaker, House of Commons of the British Parliament, Special Meeting on Term Limits, MP Nadine Dorries, London, U.K., January, 2008. “Emerging Scientific Evidence for Fetal Pain”.

Pain Through the Ages-Common Themes, Canadian Pain Society, Victoria, British Columbia, May, 2008. “Pain in Neonates: Long-Term Changes in Brain Function and Behavior.”

Neonatal Advanced Practice Nursing Forum, Dartmouth-Hitchcock Medical Center, Washington, D.C., June, 2008. “The Evidence For and Importance of Fetal Pain”.

NIDCAP International Conference, HELSE SUNNMØRE HF, Aalesund, Norway, June, 2008. “Conscious Pain Perception in the Newborn”.

IPOKRaTES Seminar, IPOKRaTES, Madrid, Spain, June, 2008. “Neonatal Comfort: analgesia, sedation and individualized loving care”.

IPOKRaTES Seminar, IPOKRaTES, Madrid, Spain, June, 2008. “Management of Pain in Premature Infants: Lessons from the NEOPAIN Trial”.

12th World Congress on Pain, International Association for the Study of Pain, Glasgow, Scotland, August, 2008. “Neonatal pain management: Current controversies and new data”.

PedsPLACE, UAMS Center for Distance Health, Little Rock, Arkansas, September, 2008. “The Collaborative Critical Care Research Network-access to a national resource”.

Arkansas Biosciences Institute Fall Research Symposium, Little Rock, Arkansas, October, 2008. Posters presented “Acupuncture reduces inflammatory hyperalgesia in newborn rats” and “Repetitive neonatal pain alters adult cognitive performance and brain cytokine expression”.

1st International Congress of UENPS Union of European National and Perinatal Societies, Rome, Italy, November, 2008. “Pain at the Dawn of Human Consciousness”.

Faculty Facilitator, Mock Code on Septic Shock, Arkansas Children's Hospital’s PULSE center, Little Rock, AR, February, 2008.

Grand Rounds, Department of Pediatrics, University of Arkansas of Medical Sciences, February, 2008. “Once a Pediatrician, always a Pediatrician? - Views from the American Board of Pediatrics”.

Panel Discussion, Complementary & Alternative Medicine Spirituality Panel, University of Arkansas of Medical Sciences, March, 2008. “Religion and spirituality in the practice of medicine: what, when, and why?”

Research Seminars, Department of Pediatrics, M.D. Anderson Cancer Center, Houston, Texas, March, 2008. "New frontiers in neonatal pain research".

Grand Rounds, Department of Pediatrics, University of Texas at Houston and Hermann Memorial Children's Hospital, Houston, Texas, March, 2008. "Neonatal pain management: current state-of-the-art and novel directions".

CPCCRN Steering Committee meeting, Bethesda, MD; March, 2008. Full Protocol presentation for the PROTAW randomized trial.

2009

22nd Annual Graven's Conference o the Physical and Developmental Environment of the High Risk Infant, Clearwater Beach, Florida, January, 2009. "Neonatal Pain Management".

22nd Annual Graven's Conference on the Physical and Developmental Environment of the High Risk Infant, Clearwater Beach, Florida, January, 2009. ***Keynote Address:*** "Pain at the dawn of human consciousness".

1st NeoOpioid Project Workshop, Stockholm, Sweden, January, 2009. "Opioid Tolerance in the PICU/NICU; mechanisms, assessment, and management".

Pediatric Grand Rounds, Cooper Regional Children's Hospital, Camden, New Jersey, February, 2009. "Pain Management of the Pediatric Trauma Patient".

Special Residents lecture, Cooper Regional Children's Hospital, Camden, New Jersey, February, 2009. "Pain Management in the NICU".

54th Annual Meeting; Swedish Paediatric Society, **Nils Rosén von Rosenstein Award lecture**, University of Uppsala and the Swedish Society of Medicine, April, 2009. "Love, Pain & Intensive Care".

27th Neonatal Conference, Nationwide Children's Hospital, Columbus, OH, May, 2009. "Physiology of Fetal & Neonatal Pain & Stress"

27th Neonatal Conference, Nationwide Children's Hospital, Columbus, OH, May, 2009. "Love, Pain & Neonatal Intensive Care: How to Make a Difference"

Fellows Research Seminar, University of Ohio, Nationwide Children's Hospital, Columbus, OH, May, 2009. "Ketamine analgesia for neonates: Friend or foe?"

32nd Annual Neonatal Advanced Practice Nursing Forum; Washington, D.C., June, 2009. "Developing Brain & Pain: Apply Developmental Pharmacology to Pain Management".

32nd Annual Neonatal Advanced Practice Nursing Forum; Washington, D.C., June, 2009. "Management of Acute Procedural Pain"

32nd Annual Neonatal Advanced Practice Nursing Forum; Washington, D.C., June, 2009. "Case Studies in the Management of Prolonged Pain"

Second Annual Pediatric Pain Master Class, Children's Hospitals & Clinics of Minnesota, Minneapolis, MN, June, 2009. "Pain Management in Infants"

Development Neurobiology Colloquium presentation, Center for Study Behavior and Development, University of Minnesota, Minneapolis, MN, June, 2009. "Love, Pain & Neonatal Intensive Care: How to Make a Difference"

2nd Neonatal & Pediatric Palliative Care Conference, University Hospital, University of Medicine and Dentistry of New Jersey, Newark, NJ, October, 2009; Keynote Address: "Love, Pain & Neonatal Intensive Care".

The **Sixth Annual Josephine Templeton Honorary Lecture**, The Children's Hospital of Philadelphia, Department of Anesthesiology & Critical Care Medicine, Philadelphia, PA, September, 2009. "Love, Pain & Intensive Care: Efforts in the clinic and community"

The Pediatric Critical Care Sub-Board Meeting, October, 2009, The American Board of Pediatrics, Chapel Hill. "Establishing a Simulation-Based Curriculum"

2nd Regional Neonatology Conference "A New Era: Advances in Palliative Care for Infants and Children in Pain", New Jersey Medical School, New Jersey, October, 2009. "Neonatal Pain Management: From Dosage to Withdrawal."

The Steering Committee Meeting, October, 2009, Collaborative Pediatric Critical Care Research Network (CPCCRN), Washington, D.C., "Planning for the H1N1Epidemic and a Novel Triage Strategy."

Pediatric Analgesic Clinical Trials Workshop, Division of Analgesia, Anesthesia, and Rheumatology Products, Center for Drug Evaluation and Research, Food and Drug Administration, Baltimore, MD; December 3, 2009. "Dose finding studies in neonatal analgesia".

2010

Mid-South Seminar on the Care of the Complex Newborn, Le Bonheur Children's Hospital and University of Tennessee Health Science Center, Memphis, TN, January, 2010. "Love, Pain and Intensive Care."

1st Annual Conference on Pediatric Psychological Trauma in Infants and Young Children from Illness, Injury and Medical Intervention, The University of Southern California, Los Angeles,

CA, February, 2010. "Consciousness, Cortical Function, and Pain Perception in Non-Verbal Humans."

8th International Symposium on Pediatric Pain, International Association for the Study of Pain, in Acapulco, Mexico, March 7th, 2010 ."Use of Ketamine for Neonatal Pain Management."

8th International Symposium on Pediatric Pain, International Association for the Study of Pain, in Acapulco, Mexico, March 7th, 2010 ."Fetal Pain and Consciousness."

Pediatric Grand Rounds, Department of Pediatrics, University of Michigan and C.S. Mott Children's Hospital, Ann Arbor, MI, March, 2010. "Ketamine for Infants: Poison or Panacea?"

Pediatric Scientific Seminar Series, Department of Pediatrics, University of Michigan and C.S. Mott Children's Hospital, Ann Arbor, MI, March, 2010. "Analgesia and Sedation in the PICU: Evidence-based management for special cases".

24th Annual Pediatric Anesthesiology Meeting, Society for Pediatric Anesthesiology, Symposium on *Pain and the Pediatric Patient*, San Antonio, TX, April, 2010."Prolonged opioids, pediatric patients, and problems."

36th Annual Pediatric Critical Care Colloquium, University of Pittsburg School of Medicine, Pennsylvania, May, 2010. "Crises in Haiti: the Critical Needs of Children."

3rd Annual Pediatric Pain Master Class, Children's Hospitals and Clinics of Minnesota, Minneapolis, MN, June, 2010. "When Opioids Don't Work Anymore – Biology and Management."

3rd Annual Pediatric Pain Master Class, Children's Hospitals and Clinics of Minnesota, Minneapolis, MN, June, 2010. "Pain Management in Infants."

Invited Speaker, Consecration Ceremony for the opening of Le Bonheur Children's Hospital, June 2010.

2010 Perinatal Medicine Conference, *Perinatal Health & Healing: Partnerships for Success,* St. Dominic Hospital, Mississippi Perinatal Association, Jackson, MS, July, 2010. "Pain Control in the NICU."

Ron Lemire Symposium on Contemporary Pediatric Critical Care Medicine, Seattle Children's Hospital, Seattle, WA, August, 2010. ***Keynote Address***: "The Pathobiology of Pain & Stress in PCIU/NICU Patients."

"Open Hearts, Open Minds and Fair Minded Words", A Conference on Life and Choice in the Abortion Debate, Princeton University, New Jersey, Newark, NJ, October, 2010. "When Might a Fetus Feel Pain and What Should We Do About It?"

Frontiers-In-Pain-Research Lecture Series, Montreal General Hospital, Quebec, Canada, November, 2010. "Use of Ketamine in Neonates: Toxic or Therapeutic?"

3rd International Conference on **Excellence in Pediatrics**, London, UK, December, 2010. Expert Round Table on "Pain Management" "Management of Acute Pain in Neonates."

8th International Conference, Pediatric Cardiac Intensive Care Society, Miami Beach, Miami, FL, December, 2010. "Post-operative Analgesia/Sedation and Modulation of the Stress Response."

Children's Foundation Research Center Seminar, The University of Tennessee Health Science Center, Le Bonheur Children's Hospital, Memphis, TN, December, 2010. "Use of Ketamine for Neonates: Toxic or Therapeutic?"

2011

FDA Anesthetic and Life Support Drugs Advisory Committee (ALSDAC), Center for Drug Evaluation and Research, Silver Springs, MD, March 10, 2011. *"Ketamine and the Neonatal Brain: Rat Pups vs. Babies."*

Brain Awareness Week Symposium and Public Lecture, UT Neuroscience Institute, University of Tennessee Health Science Center and The Urban Child Institute, Memphis, TN., March, 2011. "*Consciousness, Pain and Stress in Early Life: How it shapes who we are and what we become."*

Pediatric Academic Societies and Asian Society for Pediatric Research Joint Meeting, PAS Topic Symposium: "**Impact of Surgery, Anesthesia and Analgesia on the Newborn Brain**", Denver, CO., April 30 - May 3, 2011. *"Pain Therapy and the Brain - A Scientific Rationale."*

The Urban Child Institute and Children's Foundation Research Center, Le Bonheur Children's Hospital, Memphis; May 16, 2011. *"Use of the MEG for research on early brain development"*.

Pain Management and Developmental Care in Premature Newborns Symposium, Mayanei HaYeshua Medical Center, Bnei Brak, Tel Aviv, Israel, May 19, 2011. *"Consciousness and Pain in Early Life."*

Pain Management and Developmental Care in Premature Newborns Symposium, Mayanei HaYeshua Medical Center, Bnei Brak, Tel Aviv, Israel, May 19, 2011. *"Love, Pain, and Intensive Care."*

5th Annual NeoOpioid Meeting, Karolinska Institute and Astrid Lindgren's Children's Hospital, Stockholm, Sweden, June 1, 2011. *"Advantages and disadvantages of Morphine vs. Fentanyl in a historical, present and future perspective".*

Quarterly Meeting, American Association of Physicians from India, Memphis Chapter, Germantown TN, June 9, 2011. *"Summer Youth Conference on UNITY and HOPE: a program for youth development in Memphis"*.

4th Annual Pediatric Pain Master Class, Children's Hospitals and Clinics of Minnesota, Minneapolis, MN, June 16, 2011. *"Pain Management in Infants."*

4th Annual Pediatric Pain Master Class, Children's Hospitals and Clinics of Minnesota, Minneapolis, MN, June 16, 2011. *"When Opioids Don't Work Anymore - Biology and Management."*

Pediatric Critical Care Medicine, Fellow's Didactic Lectures, Le Bonheur Children's Hospital, Memphis TN; July 19, 2011. *"Analgesia and Sedation in Critically Ill Children"*.

Hospital Ethics Committee, Le Bonheur Children's Hospital, Memphis TN; July 20, 2011. *"Increased mortality in Latino/Hispanic patients at Le Bonheur"*.

Quality Council, Le Bonheur Children's Hospital, Memphis TN; July 29, 2011. *"Increased mortality in Latino/Hispanic patients at Le Bonheur"*; *"Selected Outcomes and Medical Errors monitored in PICU patients"*.

Pediatric Critical Care Medicine, Fellow's Lectures, Le Bonheur Children's Hospital, Memphis TN; August 30, 2011. *"When Opioids Don't Work Anymore - Biology and Management."*

Pediatric Intensive Care Unit, Multi-Disciplinary Staff Training Courses, Le Bonheur Children's Hospital, Memphis TN; August 24, 25 & 31, September 1 & 9, 2011. *"Brief Introduction to TeamSTEPPS Training"*.

System Ethics Committee Meeting, Methodist Le Bonheur Healthcare System, Center of Excellence in Faith & Health, Innovation Studio, Methodist University Hospital, Memphis; September 13, 2011. *"Increased mortality in Latino/Hispanic patients at Le Bonheur"*.

Department of Pediatrics, Grand Rounds Presentation, Le Bonheur Children's Hospital, Memphis, TN; September 14, 2011. *"Faculty, Funds, and the Fourth Leg of Academia"*

Monthly Fellows Seminar for Neonatal-Perinatal Medicine, Pediatric Surgery, and Pediatric Critical Care Medicine Fellows, Le Bonheur Children's Hospital, Memphis, TN; September 14, 2011. *"Mechanical Ventilation"*.

City of Memphis, Mayor's Office, Multi-Cultural Coalition Meeting, Memphis, TN. September 22, 2011. *"Race/Ethnicity and Clinical Outcomes in Children: Are we doing the best we can?"*

2nd International Conference, Trauma in Infancy on "Do Babies Remember Trauma: The Psychology and Neurobiology of Early Trauma", Columbia Center for Psychoanalytic Training & Research and the Margaret Mahler Foundation; October 1, 2011. Keynote Speaker: *"Consciousness and Pain in Early Development"*.

Anesthesia Grand Rounds, Department of Anesthesia, Harvard Medical School and Children's Hospital, Boston, MA; October 5, 2011. *" Ketamine in neonates: toxic or therapeutic?"*

Acute and Emergency Care Pediatric Conference, Emergency Medical Services for Children and American Academy of Pediatrics (Tennessee Chapter), Le Bonheur Children's Hospital, October 22, 2011; Memphis, TN. *"Children Caught in a Disaster: Special Considerations for Assessment, Management and Triage."*

63rd Annual Scientific Assembly, Tennessee Academy of Family Physicians'' (TNAFP), Convention Center in Gatlinburg, TN; October 25-28, 2011. *"Pediatric Pain Assessment and Management"*.

5th Annual Neonatology Conference at Scott & White *Current Concepts and Footsteps for the Future,* Department of Pediatrics, Scott & White Healthcare and Medical Education Center, Scott & White Hospital, Temple, Texas; November 1-2, 2011. Keynote Lecture: "*Pain and its Management in Neonates"*.

Annual Retreat, Division of Critical Care Medicine, Department of Pediatrics and Pediatric Intensive Care Unit Staff, Le Bonheur Children's Hospital, Memphis; November 9, 2011. *"Balancing the Paradox of Time, Outputs, and Measures: the three roles we all play"*.

Annual Retreat, Department of Pediatrics and Le Bonheur Children's Hospital, Fogelman Business Center, University of Memphis, Memphis; November 12, 2011. *"Steps to becoming a top-tier Children's Hospital"*.

Pediatric Critical Care Medicine, Fellow's Didactic Lectures, Le Bonheur Children's Hospital, Memphis TN; November 15, 2011. *"Extubation Preparedness"*.

4th Annual Pediatric Research Day, "Current Research in Neurodevelopment and Neurological Disorders in Children at the University of Tennessee Health Science Center and Le Bonheur Children's Hospital", Morning Session Chair and Master of Ceremonies, November 16, 2011. *"Neurodevelopmental Research and Introduction of Speakers"*.

National Center for Toxicological Research, Center for Neurotoxicology and Neurodevelopment Research Seminars, Jefferson, AR; November 30, 2011. *"Anesthetic Neurotoxicity associated with Ketamine: Current Results and Future Directions"*.

International Pediatric Cardiac Surgery Conference, Fortis Escorts Heart Institute & Research Center, New Delhi, India; December 28, 2011. Keynote Lecture: *"Pain Management and Brain Protection in Cardiac Surgery: is there any connection?"*

2012

International Trauma Meeting, Danish National Conference*, Consensus Conference on Pediatric Trauma* in Odense, Denmark; January 16-17, 2012. Keynote Address:*"Pain, plasticity, prematurity: What are the long-term consequences of severe pain stimulation in infants?"*

International Trauma Meeting, Danish National Conference*, Consensus Conference on Pediatric Trauma* in Odense, Denmark; January 16-17, 2012. *"Assessment and Treatment of Pain in Infants".*

Society for Pediatric Anesthesia Meeting, *Pediatric Anesthesiology 2012* in Tampa Florida; February 23 – 26, 2012. *"Pain, Analgesics, and the Developing Brain: How much and for how long?"*

2nd International Obstetrie & Neonatologie Congres, Máxima Medisch Centrum Hospital, Veldhoven, The Netherlands, March 6-9, 2012. Inaugural Address:*"Pain, Consciousness, and the Making of a Human"*.

2nd International Obstetrie & Neonatologie Congres, Máxima Medisch Centrum Hospital, Veldhoven, The Netherlands, March 6-9, 2012. Workshop on Pharmacology of the Newborn:*"Pharmacologic aspects of Morphine use in Neonates".*

Pediatric Critical Care Medicine, Fellow's Lectures, Le Bonheur Children's Hospital, Memphis, TN; March 19, 2012. "*Regulatory Considerations in Clinical Research and Data & Safety Monitoring Board*".

Pediatric Critical Care Medicine, Fellow's Didactic Lectures, Le Bonheur Children's Hospital, Memphis TN; March 20, 2012. *"Pressors, Inotropes, Vasodilators and Inodilators"*.

Annual Brain Awareness Week, University of Tennessee Neuroscience Institute and The Urban Child Institute, Memphis, TN; March 22, 2012. *"Long-term Effects of Neonatal Pain/Stress".*

Sujit and Uma Pandit Lectureship in Anesthesiology, University of Michigan Health Systems, Ann Arbor, MI; March 28, 2012. Anesthesia Lunch & Learn:*"Opioid/Sedative Withdrawal: Case Presentation and Novel Strategies".*

Sujit & Uma Pandit Lectureship in Anesthesiology, University of Michigan Health Systems, Ann Arbor, MI; March 29, 2012. M&M Conference. *"Ketamine Neurotoxicity in Newborns: New Findings".*

Pediatric Critical Care Medicine, Fellow's Didactic Lectures, Le Bonheur Children's Hospital, Memphis TN; April 10, 2012. *"Poisoning"*.

Invited Guest Speaker, ***Teach for America*** Induction Ceremony, Minglewood Hall, Memphis, TN; June 8, 2012. *"Ending the vertical transmission of poverty and social disadvantage in Memphis"*.

5th Annual Pediatric Pain Master Class, Children's Hospitals and Clinics of Minnesota, Minneapolis, MN, June 14, 2012. *"Evidence-Based Pain Management in Neonates & Infants."*

5th Annual Pediatric Pain Master Class, Children's Hospitals and Clinics of Minnesota, Minneapolis, MN, June 14, 2012. *"When Opioids Don't Work Anymore - Biology and Management."*

48th Annual Meeting of the Japanese Society of Perinatal & Neonatal Medicine; Saitama, Japan on July 8 - 10, 2012. Special Lecture: *"Development of the pain in the fetus and neonate"*.

48th Annual Meeting of the Japanese Society of Perinatal & Neonatal Medicine; Saitama, Japan on July 8 - 10, 2012. Keynote Lecture: *"Management of pain in the neonate: current practice and novel options"*.

48th Annual Meeting of the Japanese Society of Perinatal & Neonatal Medicine; Saitama, Japan on July 8 - 10, 2012. Workshop on *"Love, Pain, and Intensive Care"*.

Pediatric Critical Care Medicine, Fellow's Didactic Lectures, Le Bonheur Children's Hospital, Memphis TN; July 24, 2012. *"Analgesia and Sedation"*.

Quality Council Presentation, Le Bonheur Children's Hospital, Memphis, TN; July 27, 2012. *"Annual Report for PICU Patient Outcomes: Benchmarking with other Academic Children's Hospitals"*.

Lectures at Summer Course, International Youth Conference, Guyana University, Georgetown; August 3, 2012. *"Developing Career Pathways and Training Programs for Pediatricians"*.

Lectures at Summer Course, International Youth Conference, Guyana University, Georgetown; August 4, 2012. *"Science, Spirituality, & Service: The Role of the Youth"*.

Sophia Children's Hospital, Rotterdam, The Netherlands; September 11, 2012. "*Long Term effects of opioid analgesia in neonates"*.

UT RocKs at University of Tennessee Health Science Center, Department of Pediatrics, Memphis, TN; September 18, 2012. *"Writing the K-Award Career Development Plan"*.

Keynote Speaker, International Conference on ***"Do Babies Remember Trauma? The Psychology and Neurobiology of Early Trauma"*** sponsored by The Margaret Mahler Foundation & The Columbia Center for Psychoanalytic Training and Research, Columbia University, New York, NY; October 1, 2012. *"The Long-term Effects of Pain and Stress in Early Life"*.

CANDLE Investigators Meeting, The Urban Child Institute, Memphis, TN; October 10, 2012. *"Hair cortisol as a measure of chronic stress"*.

Pediatric Critical Care Medicine, Fellow's Didactic Lectures, Le Bonheur Children's Hospital, Memphis TN; October 16, 2012. *"Mechanical Ventilation"*.

National Conference & Exhibition (NCE), American Academy of Pediatrics, October 20-23, 2012; New Orleans, LA. Joint Program: Section on Perinatal Pediatrics and Section on Anesthesiology & Pain Medicine. *"Opioid & Benzodiazepine Tolerance and Withdrawal"*.

National Conference & Exhibition (NCE), American Academy of Pediatrics, October 20-23, 2012; New Orleans, LA. Joint Program: Section on Perinatal Pediatrics and Section on Anesthesiology & Pain Medicine. *"Long-term effects of Neonatal Pain & Analgesia"*.

Pediatric Critical Care Fellow's Lecture Series, Department of Pediatrics, Le Bonheur Children's Hospital, Memphis, TN; October 23, 2012. "*Extubation Preparedness."*

81st Perinatal & Developmental Medicine Symposium, American Academy of Pediatrics, Perinatal Section, "Neonatal Pain, Stress and Sedation in the 21st Century" Marco Island, Florida; November 15-18, 2012. *"Fetal and Neonatal Pain: Development, Physiology, Assessment"*.

81st Perinatal & Developmental Medicine Symposium, American Academy of Pediatrics, Perinatal Section, "Neonatal Pain, Stress and Sedation in the 21st Century" Marco Island, Florida; November 15-18, 2012. *"Opioids in Neonates: Early Studies and Current Research"*.

Quality Council Presentation, Le Bonheur Children's Hospital, Memphis, TN; December 14, 2012. *VPS Annual Report.*

2013

Pediatric Critical Care Fellow's Lecture Series, Le Bonheur Children's Hospital, Memphis, TN; January 10, 2013. *"Pressors, Inotropes, Vasodilators and Inodilators"*.

Invited Speaker & Panel Discussant, ACTTION Pediatric Pain Research Consortium Meeting, January 24-25, 2013 St. Regis Hotel, Washington, DC. *"Clinical Trials for Neonates and Infants: Challenges in Study Design and Execution"*.

51st Clinical Conference in Pediatric Anesthesia, University of Southern California and Children's Hospital Los Angeles, Anaheim, CA; February 8-10 2013. *The Dr. Digby Leigh Distinguished Speaker. "Anesthetic Neurotoxicity: Lessons from Ketamine"*.

Child Development Conference, Kinnaret College, Tzubeh, Israel; April 9, 2013. *Keynote Speaker: "Long-term implications of pain/stress in infancy"*.

CANDLE Investigators Meeting, The Urban Child Institute, Memphis, TN; April 10, 2013. *"Summary of NIH Workshop: Nature and Nurture: Genetic and environmental Influences on Children's Responses to Adversity"*.

Visiting Professorship, Albert Einstein School of Medicine, Montefiore Medical Center Department of Anesthesiology, New York, New York; April 21, 2013. *"Ketamine for Neonates: Toxic or Therapeutic?"*

Invited Speaker, research seminar, Department of Anesthesiology, Columbia University Medical Center, New York, NY; April 24, 2013. *"Opioid tolerance & withdrawal: scientific opportunity or wasteland ahead?"*

Invited Grand Rounds Speaker, Department of Anesthesiology, Columbia University Medical Center, New York, NY; April 25, 2013. *"Ketamine, Neurotoxicity, and Rats! Where do we go from here?"*

CANDLE Investigators Meeting, The Urban Child Institute, Memphis, TN; May 1, 2013. "*Methods for hair cortisol measurements".*

Pediatric Academic Societies Annual Meeting, Washington, D.C.; May 6, 2013. Community, Family, Health and Genetics: Risk Factors for Socio-emotional Development in Urban Children. Conditions Affecting Neurocognitive Development and Learning in Early Childhood. " *What, Why, & How: Does early stress shape child development?".*

Visiting Professorship, Chicago Children's Research Center, Lurie Children's Hospital, Chicago, IL; May 8-10, 2013. *"Transforming Clinical Research at Lurie Children's: funded, futuristic, family-centered".*

6th Annual Pediatric Pain Master Class, Children's Institute for Pain and Palliative Care, Minneapolis, MN; June 1-7, 2013. *"Pain Management in Infants."*

6th Annual Pediatric Pain Master Class, Children's Institute for Pain and Palliative Care, Minneapolis, MN; June 1-7, 2013. *"When Opioids Don't Work Anymore – Biology & Management."*

9th International Symposium on Pediatric Pain, International Association for the Study of Pain (IASP), Special Interest Group on Pediatric Pain, Stockholm, Sweden; July 15-21, 2013. Workshop Chair: *Opioid Therapy in Neonates: Long-term Effects & Functional Outcomes*.

PCCM Fellows' Conferences, Department of Pediatrics, University of Tennessee Health Science Center and Le Bonheur Children's Hospital, Memphis, TN; July 23rd, 2013. *"Mechanical Ventilation 101"*

PCCM Fellows' Conferences, Department of Pediatrics, University of Tennessee Health Science Center and Le Bonheur Children's Hospital, Memphis, TN; August 1st, 2013. *"Professionalism in Academic Medicine"*

UT RocKs – K-club, Department of Pediatrics, University of Tennessee Health Science Center and Le Bonheur Children's Hospital, Memphis, TN; August 13th, 2013. *"Grantsmanship"*

Faculty Seminars, Universal Business School and the Strive India Educational Foundation, Karjat/Mumbai, India; August 27th, 2013. *"Can Faulty Afford not to Fund Raise?"*

Honorary Visiting Professor Lecture & Workshop, Universal Business School and the Strive India Educational Foundation, Karjat/Mumbai, India; August 28th, 2013. *"Professionalism: A Critical Element for Developing Business Leaders"*.

Pediatrix Medical Group, Annual Conference "Innovations in the Care of the Surgical Neonate", San Antonio, TX; September 18 - 20, 2013. *"Neonatal Anesthesia: Adverse effects, Tolerance and Neurotoxicity"*

Pediatrix Medical Group, Annual Conference "Innovations in the Care of the Surgical Neonate", San Antonio, TX; September 18 - 20, 2013. *"Postoperative Pain Management in Neonates"*

International Conference, Society for Longitudinal and Life Course Studies (SLLS), "Growing Up and Growing Old: Health Transitions throughout the Lifecourse", Amsterdam, The Netherlands; September 23-25, 2013. CANDLE Study Symposium: *"Hair Cortisol Levels in Early Childhood suggest HPA Axis Dysregulation"*

10th Annual **Masterclass for Honors Medical Students**, 100th Anniversary Celebrations of the Erasmus University Medical Center, Faculty of Medicine, Rotterdam, The Netherlands; October 3rd, 2013. *"Professionalism, Creativity, and Serendipity in Developing an Academic Career"*

9th Annual **"In Praise of Medicine" Public Meeting**, 100th Anniversary Celebrations of the Erasmus University Medical Center, Faculty of Medicine, 150th Anniversary of Sophia Children's Hospital, Rotterdam, The Netherlands; October 4, 2013. ***Keynote Public Address***: *"Pain in infancy: from stress to society"*

14th Jackson Rees Symposium, Sophia Children's Hospital, Rotterdam, The Netherlands; October 5, 2013. ***Dr. Jackson Rees Distinguished Lecturer***: *"Neurotoxic vs. Neuroprotective Effects of Neonatal Ketamine"*

NIH/NIDA Webinar on "Measuring Risk & Resilience for Developing Drug Abuse in Adolescents", The Urban Child Institute, Memphis, TN; November 20th, 2013. *"Biomarkers for Chronic Stress during Early Childhood"*.

AstraZeneca and Quintiles Consulting Group, Mock FDA Session for approval of Nalextoxigol, Doubletree Hotel, Wilmington, DE; December 20th, 2013. *"Opioid Tolerance in Children"*.

2014

Harmony Health Clinic, Governor Mike Beebe Annual Volunteer Recognition Day, Governor's Mansion, Little Rock, Arkansas. January 22, 2014. *"Providing compassionate health care for the uninsured"*.

Mid-South Seminar on the Care of the Complex Newborn, Department of Pediatrics, Le Bonheur Children's Hospital and University of Tennessee Health Science Center, Memphis, TN; January 24-25, 2014. *"Pain, Consciousness, and the Personification of Newborns"*.

Mid-South Seminar on the Care of the Complex Newborn, Department of Pediatrics, Le Bonheur Children's Hospital and University of Tennessee Health Science Center, Memphis, TN; January 24-25, 2014. *"Pain Management in Newborns: Identifying best practices."*

Annual Neonatology Keynote Lecture, Pediatrics Section, Combined Sections Meeting of the American Physical Therapy Association (APTA), Las Vegas, Nevada; February 4-6, 2014. *"Needles, tubes, and intensive care: What happens to the baby?"*

3rd Annual Neonatal & Pediatric Pearls (NAPP) Conference, UCLA Department of Pediatrics and Mattel Children's Hospital, Mumbai, India; February 8-9, 2014. Keynote Address: *"Development of nociception in the fetus and the newborn."*

3rd Annual Neonatal & Pediatric Pearls (NAPP) Conference, UCLA Department of Pediatrics and Mattel Children's Hospital, Mumbai, India; February 8-9, 2014. Debate: *"Pain medications should / should not be used in the NICU"*

Le Bonheur 101 Science Presentation, Le Bonheur Children's Foundation and Children's Foundation Research Institute, Memphis, TN; March 20th, 2014. *"Research on Pain in Infancy: from stress to society"*

Post-Norfleet Symposium Debriefing Meeting, The Urban Child Institute, Memphis, TN; March 21st, 2014. *"Future Directions for the CANDLE Study"*

Integrated Biomedical Science Seminar, School of Graduate Studies, Loma Linda University, Loma Linda, CA; April 17th, 2014. *"Ketamine for neonates: toxic or therapeutic?"*

Pediatric Academic Societies' Annual Meeting, American Pediatric Society/Society for Pediatric Research, Workshop on **"Neonatal Pain: Lost in Translation"**, Vancouver, British Columbia, Canada; May 1-6, 2014. *"Battle of the bedside and bench: Is your data clinically relevant or scientifically sound?"*

Pediatric Academic Societies' Annual Meeting, American Pediatric Society/Society for Pediatric Research, Platform presentations, Chairman of the session on **"Neonatal Pain Management"**, Vancouver, British Columbia, Canada; May 1-6, 2014.

Pediatric Academic Societies' Annual Meeting, American Pediatric Society/Society for Pediatric Research, Platform presentations, **"Neonatal Pain Management"**, Vancouver, British Columbia, Canada; May 1-6, 2014. *"Number of procedures and analgesic therapy in neonates admitted to NICUs: EPIPAIN-2 Study"*

Executive Dean's Invited Lecture, University of Miami Miller School of Medicine, Miami, FL; May 19th, 2014. *"Love, Pain, & Intensive Care: Building Pediatrics for the 21st Century"*.

5th Annual ***Professor I. David Todres, MD Grand Rounds***, Department of Pediatrics, Harvard Medical School and Massachusetts General Hospital, Boston, MA; June 2-3, 2014. *"Pain in infancy: from stress to society"*

7th Annual Pediatric Pain Master Class, Children's Institute for Pain and Palliative Care, Minneapolis, MN; June 13, 2014. *"Pain Management in Infants."*

7th Annual Pediatric Pain Master Class, Children's Institute for Pain and Palliative Care, Minneapolis, MN; June 13, 2014. *"When Opioids Don't Work Anymore – Biology & Management."*

Grand Rounds Presentation, Department of Pediatrics, University of Southern California, Children's Hospital Los Angeles, Los Angeles, CA: August 1, 2014. "*Pain in Infancy: From stress to society."*

Fellows' Conference, Department of Anesthesiology & Critical Care Medicine, University of Southern California, Children's Hospital Los Angeles, Los Angeles, CA: August 1, 2014. *"Ketamine for Neonates: Toxic or Therapeutic?"*

Department of Pediatrics Research Seminars, University of Maryland School of Medicine, Baltimore, MD: August 7, 2014. "*Positive and Negative inputs into early development: A search for non-invasive biomarkers."*

Grand Rounds Presentation, Department of Pediatrics, University of Maryland School of Medicine, Baltimore, MD: August 7, 2014. *"Pain in infancy: From Stress to society."*

Keynote Speaker, Health Beliefs and Practices Forum, Health Ministry Network of the Mid-South, Catholic Center, Memphis, TN. August 14th, 2014.

33rd Annual Neonatal & Perinatal Conference, Pan-American Association of Pediatrics, Santiago, Chile; August 21-23, 2014. Keynote Address: *"The development of pain processes in the fetus and newborn"*

33rd Annual Neonatal & Perinatal Conference, Pan-American Association of Pediatrics, Santiago, Chile; August 21-23, 2014. *"Long term consequences of pain in newborn babies"*

33rd Annual Neonatal & Perinatal Conference, Pan-American Association of Pediatrics, Santiago, Chile; August 21-23, 2014. *"Post-surgery management of pain in newborn babies"*

Research Seminars, Department of Pediatrics, Stanford University School of Medicine and Lucille Packard Children's Hospital, Palo Alto, CA; October 14th, 2014. *"Pain in infancy: from stress to society"*.

12th Annual ***Dr. John J. Fangman Distinguished Professorship,*** Minnesota Association of Neonatologists, Children's Hospital and Clinics – Minneapolis, MN; October 27, 2014. *"Ketamine for Neonates: Toxic or Therapeutic?"*

Grand Rounds, Department of Pediatrics, Children's Hospital and Clinics – Minneapolis, MN; October 28, 2014. *"Current evidence for pain management in the NICU".*

Invited Speaker, International Hindi Day Celebrations, Indian Cultural Society Conference, Houston, TX; December 5th, 2014. Recitations of Hindi/Urdu Poetry.

2015

Senior Faculty Forum, Department of Pediatrics, Stanford University School of Medicine and Lucille Packard Children's Hospital, Palo Alto, CA; February 2nd, 2015. *"Building Critical Care Pediatrics for the 21st Century".*

International Advisory Group, Leading Causes of Life Initiative, Wake Forest School of Medicine, Division of Public Health Sciences, Department of Social Sciences and Health Policy, Winston-Salem, NC; February 25th, 2015. *"Clinical experiences and Leading Causes of Life".*

44th Annual Journees Nationales de Neonatologie, Institut Pasteur, Paris (France); March 26th and 27th, 2015. *Neurotoxicity vs. neuroprotection from analgesic agents in newborns*.

44th Annual Journees Nationales de Neonatologie, Institut Pasteur, Paris (France); March 26th and 27th, 2015. *Sedation and analgesia in European NICUs: Preliminary results from the EuroPAIN survey*.

Pediatric Academic Societies' Annual Meeting, San Diego, CA, April 25th, 2015. Platform presentation: *"Neonatal Electrical Stimulation of Acupuncture Points: Can Alternative Therapy Relieve Heelstick Pain in Neonates?"*

XIV International Congress of Intensive Care Medicine of Minas Gerais, Belo Horizonte, Brazil, May 21-23 2015. *"The Importance of Pain Relief in the Intensive Care Unit".*

XIV International Congress of Intensive Care Medicine of Minas Gerais, Belo Horizonte, Brazil, May 21-23 2015. *"Options for sedation and analgesic in newborns: Is there any safe drug?"*

10th International Symposium on Pediatric Pain, International Association for the Study of Pain, Special Interest Group on Pain in Childhood, Seattle, WA; June 1-3, 2015. Plenary session: *"Selection of the Distinguished Career Award for Pediatric Pain 2015".*

Annual Investigators Meeting, Pediatric Pain Research Consortium (PPRC), ACTTION Partnership (Analgesic, Anesthetic, & Addiction Clinical Trial Translations, Innovations, Opportunities, and Networks), June 1st, 2015. *"Protocol to delay or prevent opioid tolerance".*

8th Annual Pediatric Pain Master Class, Children's Institute for Pain and Palliative Care, Minneapolis, MN; June 13, 2015. *"Assessment and Management of Pain in Infants."*

8th Annual Pediatric Pain Master Class, Children's Institute for Pain and Palliative Care, Minneapolis, MN; June 13, 2015. *"Paying the price for opioid therapy: Tolerance and withdrawal."*

PCCM Fellows' Conferences, Department of Pediatrics, University of Tennessee Health Science Center and Le Bonheur Children's Hospital, Memphis, TN; July 23rd, 2015. *"Mechanical Ventilation 101".*

PCCM Fellows' Conferences, Department of Pediatrics, University of Tennessee Health Science Center and Le Bonheur Children's Hospital, Memphis, TN; August 1st, 2015. *"Professionalism in Academic Medicine".*

PCCM Fellows' Conferences, Department of Pediatrics, University of Tennessee Health Science Center and Le Bonheur Children's Hospital, Memphis, TN; August 18th, 2015. *"Clinical use of Steroids in Children with Sepsis".*

Invited Speaker, WELL Faculty Brainstorming Session, Stanford Prevention Research Center, Department of Medicine, Stanford University School of Medicine; November 3rd, 2015. *"Biomarkers for Stress and Resilience: Lessons from Pre-School Children".*

Invited Speaker and Panel Member, 5th Annual leadership Summit, **"Shaping Tomorrow's Global Leaders",** Thursday, November 12th, 2015 at One World Trade Center, New York, NY. "*Lessons learned from personal leadership*".

2016

3rd Annual Meeting, Society for Pediatric Pain Medicine (SPPM), The Broadmoor, Colorado Springs, CO; March 31st, 2016. *"Neonatal Pain: Assessment and Management".*

7th Annual Pediatric Research Retreat, Department of Pediatrics, Berg Hall, Li Ka Shing Center for Learning & Knowledge, Stanford University School of Medicine, April 8th, 2016. *"Opioid Tolerance and Withdrawal: Exploring newer therapeutic options".*

Nursing Shared Leadership Workshop, Pediatric ICU and Cardiac ICU Nursing Staff, Lucile Packard Children's Hospital, Palo Alto, CA; April 25th, 2016. *"Analgesia and sedation in critically ill children".*

Nursing Shared Leadership Workshop, Pediatric ICU and Cardiac ICU Nursing Staff, Lucile Packard Children's Hospital, Palo Alto, CA; April 25th, 2016. *"Opioid tolerance and withdrawal: Prevention and Management".*

Pediatric Critical Care Medicine Fellows Conference, Department of Pediatrics, Stanford University School of Medicine; June 16th, 2016. *"Steroids for ARDS: Evidence in Children".*

9th Annual Pediatric Pain Master Class, Children's Institute for Pain and Palliative Care, Minneapolis Children's Hospital & Clinics, Minneapolis, MN; June 15th, 2016. *"Assessment and Management of Pain in Infants."*

9th Annual Pediatric Pain Master Class, Children's Institute for Pain and Palliative Care, Minneapolis Children's Hospital & Clinics, Minneapolis, MN; June 14th, 2016. *"Paying the price for opioid therapy: Tolerance and withdrawal."*

Neonatology Clinical Consensus Conference, Division of Neonatal & Developmental Medicine, Department of Pediatrics, The Johnson Center for Pregnancy and Newborn Services, Stanford University School of Medicine, Palo Alto, CA; June 27th, 2016. *"Evidence-based pain management in the NICU"*.

Pediatric Critical Care Medicine Boot Camp, Washington University School of Medicine and Center for Simulation, Advanced Education and Innovation, Children's Hospital of Philadelphia, St. Louis, MO; July 16th, 2016. *"Guidelines for Traumatic Brain Injury"*.

Visiting Professor, Pain Awareness Week, Cincinnati Children's Hospital Medical Center, Department of Anesthesia, Pain Management Division, University of Cincinnati, Cincinnati OH. September 20-22, 2016.

Pediatric Grand Rounds, Cincinnati Children's Hospital Medical Center, Department of Pediatrics, University of Cincinnati, Cincinnati OH. September 20, 2016. *"Neonatal Pain Management: Integrating the science, the evidence, the art of therapeutics with early development"*.

Anesthesia Grand Rounds, Cincinnati Children's Hospital Medical Center, Department of Anesthesia, University of Cincinnati, Cincinnati OH. September 21, 2016. *"Paying the Price for Opioid Therapy: Avoid the credit cards of tolerance and withdrawal"*.

Nursing Grand Rounds, Cincinnati Children's Hospital Medical Center, Department of Pediatric Nursing, Cincinnati OH. September 21, 2016. *"Long-term Consequences of Repetitive Pain vs. Prolonged Analgesia in Neonates"*.

Advanced Pharmacy Lecture Series, Cincinnati Children's Hospital Medical Center, Department of Pediatric Pharmacy, Cincinnati OH. September 22, 2016. *"Use of Ketamine in Infants: Toxic or Therapeutic?"*.

Pediatric Grand Rounds, Department of Pediatrics, California Pacific Medical Center, San Francisco, CA; Oct. 14th, 2016. *"The Yin & Yang of Childhood: Can we measure it?"*.

Pediatric Critical Care Medicine Fellows Conference, Department of Pediatrics, Stanford University School of Medicine; Nov. 3rd, 2016. *"Assessment and Management of Infant Pain"*.

International Medical Conference, Sri Sathya Sai Sanjeevani International Centre for Child Heart Care & Research, Millenium Hotel & Conference Center, Baghola (Haryana), India; Nov. 26th, 2016. *"Love, Pain, & Intensive Care: Re-defining Pediatrics for the 21st Century"*.

2017

Republic Day Celebrations, Societal Action & Initiative Global Mission, CET Soto Theater, San Jose, CA; Jan. 21st, 2017. *"Why focus on Child Heart Care?"*.

Physician Speaker at the Weekly All Hands Safety Meeting, Lucile Packard Children's Hospital & Stanford Children's Healthcare; Feb. 6th, 2017. *"Your role in the future of child health care"*.

Pediatric Critical Care Medicine Fellows Conference, Department of Pediatrics, Stanford University School of Medicine; Feb. 9th, 2017. *"Summary of Advances in Neurocritical Care"*.

Research Seminar, *Eunice Kennedy Shriver* National Institute for Child Health & Human Development (NIH/NICHD), Pediatric Trauma and Critical Illness Branch (PTCIB); Feb. 14th, 2017. *"Summative measures for chronic stress and resilience in preschool children: Measuring the affective inputs in early development"*.

Invited presentation, Community Advisory Board, Stanford University School of Medicine, March 8th, 2017. *"Proposal to measure chronic stress and resilience in preschool children"*.

Presentation to the Critical Care Medicine Division, Department of Pediatrics at Fortis Medical Research Institute, Gurgaon (India); March 28th, 2017. *"Management of Analgesia and Sedation in the Pediatric ICU"*.

Public Health Nursing Seminar, Maternal, Child and Family Health Branch, Department of Health & Human Services, Santa Clara County, San Jose, CA; April 14th, 2017. *"Public health impact of chronic stress and resilience in preschool children"*.

Staff Training Seminar, First 5 Organization, Santa Clara County, San Jose, CA. *"The Yin and Tang of Early Child Development: How can we measure it?"*

Leadership Training Seminar, First 5 Organization, Santa Clara County, San Jose, CA. *"A Leading Causes of Life perspective applied to early child development in low SES families"*.

Meeting for prospective Rhodes Scholarship applicants, Bechtel International Center (Assembly Room), Stanford University, April 27th, 2017. *"How to increase the odds for winning a Rhodes Scholarship to Oxford University"*.

50th Anniversary Sikh Foundation International Conference on "Advancing Sikhs through education", Li Ka Shing Center, Stanford University, May 7th, 2017. *"Love, Pain, & Intensive Care: Re-defining Pediatrics for the 21st Century"*.

50th Anniversary Sikh Foundation International Conference on "Advancing Sikhs through education", Li Ka Shing Center, Stanford University, May 7th, 2017. Chaired the Health Care Panel: *"Sikh Contributions to Health Care"*.

Critical Care Medicine Specialty Conference, Department of Anesthesia, Perioperative & Pain Medicine, Stanford University School of Medicine, Stanford Hospital, May 16th, 2017. *"Assessment of Prolonged Pain in Early Development: Need for a new taxonomy?"*.

2nd Annual Ideal Village Conference on *"Collaborations for the Ideal Village"*, Tresidder Memorial Union, Stanford University School of Medicine, June 16th, 2017. *"Global Health and the Ideal Village"*.

10th Annual Pediatric Pain Master Class, Children's Institute for Pain and Palliative Care, Minneapolis Children's Hospital & Clinics, Minneapolis, MN; June 19th, 2016. *"Infant pain is no gain"*.

10th Annual Pediatric Pain Master Class, Children's Institute for Pain and Palliative Care, Minneapolis Children's Hospital & Clinics, Minneapolis, MN; June 20th, 2016. *"Opioids sans Tolerance"*.

PICU Nursing Shared Leadership and Joint Staff Meeting, Lucile Packard Children's Hospital Stanford, July 13th, 2017. *"Clinical Outcomes for PICU Patients in 2016: Results from the vPICU Database"*.

Pediatric Critical Care Medicine Fellows Conference, Department of Pediatrics, Stanford University School of Medicine; July 20th, 2017. *"Introduction to Mechanical Ventilation"*.

Pediatric Critical Care Medicine Fellows Conference, Department of Pediatrics, Stanford University School of Medicine; July 27th, 2017. *"Biomarkers in hair from critically ill children: Research Opportunities in the Pain/Stress Neurobiology Lab"*.

Keynote Address: 25th Annual Scientific Meeting, North American Sikh Medical & Dental Association (NASMDA), UB School of Medicine & Biomedical Sciences, State University of New York at Buffalo, Long Beach, CA; August 4th, 2017. *"Love, Pain, & Intensive Care: Re-defining Pediatrics for the 21st century"*.

Keynote Address: Children's Symposium, Rigshospitalet, University of Copenhagen Hospital, Copenhagen, Denmark; September 22nd, 2017. *"Pain perception, long-term effects and anesthesia-induced neurotoxicity in newborns"*.

APPENDIX:

Special Training Courses:

1992	"Pediatric Flexible Bronchoscopy" Course University of North Carolina at Chapel Hill, August 1992 (Course Director: Dr. Robert Wood)
1993	"Pediatric and Neonatal E.C.M.O." Course, Egleston Children's Hospital at Emory University, October 1993 (Course Director: Dr. Devn Cornish)
1993	"Seven Habits of Highly Effective People", Emory University Community Education Courses, Fall 1993
1994	"How to Manage Projects, Priorities, and Deadlines", National Seminars Group, Rockhurst College Continuing Education Center, February 1994 (Director: Mark R. Truitt)
1994	"Powerful Communication Skills" National Seminars Group, Rockhurst College Continuing Education Center, October 1994 (Director: Steven C. Powell)
1994	"*In Situ* Hybridization and Recombinant DNA Technology" Exon-Intron and Johns Hopkins University, November 1994 (Course Director: Robert E. Farrell, Ph.D.)
2001	"Senior Administrators for Pediatric Departments", Pediatric Academic Societies' Meeting, Baltimore, May 2001. (Course Director: Thomas Boat, M.D.)
2008	UAMS Leadership Institute, Selected for the Class of 2009, completed intensive course on leadership in academic medicine.
2010	Workshop on the *7 Habits of Highly Effective People*, University of Tennessee Health Science Center, Human Resources Division.
2011	AAMC Workshop on ***Strategies, Skills Building & Best Practices in Philanthropy*** for the Faculty Members at Academic Medical Centers, February 10th, 2011.
2011	Participated in the AAMC Training Course ***2011 Executive Development Seminar for Associate Deans and Department Chairs***, Sept 30-Oct 4, 2011.
2015	Participated in the **3rd Annual Pediatric Education Day**, Department of Pediatrics. Stanford University School of Medicine.
2015	Participated in "Advances in Pediatric Trauma and Critical Illness Research: Building the field – Advancing the field", Pediatric Trauma & Critical Illness Branch, *Eunice Kennedy Shriver* National Institute for Child Health & Human Development, Bethesda, MD, Dec. 11th, 2015.

Activities as Director, Office for Research Promotion, 1995-96
Department of Pediatrics, Emory University School of Medicine

1. Information on grant opportunities for Departmental Divisions and young investigators.
2. Editorial support for planned studies and grants, Departmental liaison with the Office for Sponsored Programs. Extramural grant support submitted July 1995 to August 1996:
   - Total number of grant applications = 94
   - Total grant dollars applied for = $ 9,655,658.00
     * direct expenses = $ 7,788,920.00
     * indirect expenses = $ 1,867,238.00
3. Editorial support for abstracts and manuscripts by fellows and young investigators.
4. Departmental review of oral and poster presentations presented at the Pediatric Academic Societies' Meeting, Washington, DC, May 6-10, 1996.
5. Supervision of Dr. Kevin Sullivan (statistician) for Departmental support activities.
6. Planning for an intramural Seed Grants Program with three cycles of funding.
7. Planned and executed the Fellows Introductory Course, August 1996, which included:
   - Clinical Methods Workshop
   - Computer Skills and Software Training
   - Statistical Methods Course
   - Grant Applications to the N.I.H.
   - Developing an Academic Career
8. Designed and installed the Departmental Research Database.
9. Formulated a long-term Departmental Research Strategy with senior faculty members.
10. Established the availability of MPH students from Department of Epidemiology, Rollins School of Public Health to work on clinical research projects in Pediatrics.
11. Developed procedures for the handling of controversial research data with the Risk Management Unit in Egleston Children's Hospital.
12. Chairman of a multidisciplinary task-force to define Research Administration at Egleston Children's Hospital. Designed structures to allow for:
    - accounting and billing for research services
    - central clearinghouse for tracking IRB approved protocols, examine consent forms
    - provide help in developing budgets for grant applications
13. Interviewed candidates for the position of Chairman, Department of Pediatrics, with a focus on research development for Chairman candidates.

Academic Activities During Residency Training and Fellowship:

1. Lectures in Elementary Statistics: - A complete course of statistics given in 6 weekly lectures to residents, fellows an staff members of the Department of Anesthesia, Children's Hospital, Boston; November & December 1986.

2. Fellows Lectures: - (Dept. of Anesthesia, The Children's Hospital, Boston).

(a) May, 1986: "Does the newborn infant really need anesthesia?"
(b) June, 1986: "Scoring methods in anesthesia, surgery, and trauma. I. Studies in adult patients."
(c) June, 1986: "Scoring methods in anesthesia, surgery and trauma. II. Studies in pediatric patients and prediction of postoperative outcome."
(d) September, 1986: "Randomized trials of halothane and fentanyl anesthesia in newborn infants."
(e) March, 1987: "Evidence for pain perception in the human fetus and neonate."
(f) June, 1987: "Results of the randomized trial of high-dose sufentanil anesthesia for neonates undergoing cardiac surgery."
(g) July, 1987: "Neuroendocrine stress responses in neonates: where do we go from here?"
(h) December, 1987: "The historical basis for current anesthetic practices in neonates."

3. Resident's Lectures: - (Dept. of Medicine, Children's Hospital, Boston.)

(a) October, 1988: "Assessment and management of pain in children."
(b) September, 1989: "Toilet training practices across different cultures: implications for pediatric practice."
(c) March, 1990: "Headache and recurrent abdominal pain in children."
(d) September, 1990 "School phobia in children: assessment and management."
(e) October, 1990: "Attention deficit hyperactivity disorder."
(f) April, 1991: "Assessment and management of constipation in our outpatient practice."
(g) May, 1991: "The many faces of child abuse."

4. Arranged Core Curriculum Lectures in Pediatrics for the year 1990-91, Department of Medicine, Children's Hospital, Boston.

5. Fellow's Lectures: - (Neonatal & Pediatric Intensive Care Units, M.G.H. Boston, MA
(a) July, 1991: "Pain and sedation in the ICU."
(b) August, 1991: "Transport of critically ill burn patients."
(c) August, 1991: "Management of status epilepticus. "
(d) September, 1991: "Neonatal stress responses: clinical implications."
(e) September, 1991: "How to write a research grant application."
(f) September, 1991: Hemodynamic monitoring and oxygen transport."
(g) September, 1991: "Use of Swan-Ganz catheters in pediatric patients."
(h) October, 1991: "Diagnosis and management of the cyanotic newborn."
(i) November, 1991: "Diabetic ketoacidosis."
(j) November, 1991: "Pain, sedation, and muscle relaxation in the ICU."
(k) December, 1991: "Drug therapy for IVH in premature neonates."

(l) December, 1992: "Practical Instructor for P.A.L.S. course."
(m) January, 1992: "Respiratory physiology and ventilator management."
(n) January, 1992: "Analgesia and sedation in the ICU."
(o) February, 1992: "Respiratory physiology in neonates and older children."
(p) July, 1992: "Update on analgesia and sedation in the Pediatric I.C.U."
(q) August, 1992: "Sedation and muscle relaxation in the Pediatric I.C.U."
(r) October, 1992: "Asthma in pediatric patients."
(s) November, 1992: "Analgesics, sedatives and muscle relaxants."
(t) November, 1992: "Approach to the cyanotic neonate."
(u) December, 1992: "RSV bronchiolitis in PICU patients."
(v) December, 1992: "Instructor of P.A.L.S. course."
(w) December, 1992: "Use of analgesics, sedatives, and muscle relaxants."
(x) December, 1992: "ARDS in pediatric patients."
(y) January, 1993: "Oxygen transport: physiology and pathology."
(z) February, 1993: "Septic shock."
(aa) March, 1993: "Intraventricular hemorrhage in neonates."
(bb) March, 1993: "Management of increased ICP."
(cc) April, 1993: "Update on ARDS."
(dd) April 1993: "Status Epilepticus."

DECLARATION OF DR. KANWALJEET S. ANAND

I am Dr. Kanwaljeet S. Anand, M.B.B.S., D.Phil., FAAP, FCCM, FRCPCH who files this declaration under penalty of perjury. I am a pediatrician specialized in the care of critically ill newborns and children. I serve as a fully tenured Professor of Pediatrics, Anesthesiology, Perioperative & Pain Medicine at Stanford University School of Medicine, and as Director of the Pain/Stress Neurobiology Laboratory at Children's Hospital Research Institute. For more than 30 years, I have conducted intensive research and study on the development of pain/stress in human newborns, their development during early childhood, and long-term outcomes. I have authored 311 scientific publications (125 in the last 10 years), edited 9 books, and received numerous professional awards. My true and correct Curriculum Vitae is attached. I am personally familiar with Opioid Use Disorder in adult females and Neonatal Abstinence Syndrome and have reviewed the materials referenced below.

The President of the United States had declared a national medical emergency caused by the Opioid Crisis in America[1]. The immediate effects of the Opioid Crisis, however, may be strikingly less consequential when compared to its effects on the individuals who were exposed to opioid drugs prenatally, many of whom were diagnosed with NAS. These children, through no fault of theirs, have been condemned to suffer from the short-term and long-term effects of opioid exposure from birth throughout their childhood, adolescence and into their adult lives. Though the current Opioid Crisis looms large on the thinking of social, medical, or government establishments, but its long-term impact is inestimable because of the pervasive and persistent effects of prenatal opioids on all aspects of an individual's development. Their cumulative burden of suffering, and the total impact of their exposures on all facets of our society is so huge and unparalleled in human history that this is truly the real emergency. Unless they are monitored/supported/treated NOW, the problems of these children will become intractable and unmanageable as they grow into adulthood, wiping away generations of human endeavor because of our short-sightedness. I offer the following statements for the Court's consideration:

Definitions

- Opioid Use Disorder (OUD) is defined in the DSM-5 as a problematic pattern of opioid use leading to clinically significant impairment or distress. OUD was previously classified as Opioid Abuse or Opioid Dependence in DSM-IV.
- OUD has also been referred to as "opioid addiction" in previous publications. Addiction is defined as a chronic, relapsing syndrome of psychological dependence and craving of a drug for its psychedelic, sedative, or euphoric effects; characterized by compulsion, loss of control, and continued use of a substance despite knowledge of its harmful effects[2].
- Infants and children are not "users" as defined under the DSM-5 criteria and are excluded from the class of persons suffering from OUD. Regardless, the birth mothers of children diagnosed with neonatal abstinence syndrome (NAS) would be included within the definition of OUD.
- Neonatal abstinence syndrome (NAS) or neonatal opioid withdrawal syndrome (NOWS) are terms used to denote a group of problems that occur in the children who were exposed to opioid or opiate drugs in the mother's womb. NAS is diagnosed clinically based on the clinical signs occurring in the 1 week after birth, characterized by neurologic hyperexcitability, gastrointestinal dysfunction, and autonomic instability. Most common neurologic signs include anxiety, agitation,

grimacing, insomnia, increased muscle tone/reflexes, exaggerated startle reflexes, high-pitched crying, tremors and abnormal movements, seizures; gastrointestinal symptoms include vomiting, diarrhea, poor sucking, dehydration; autonomic signs include elevated heart rate, respiratory rate, and blood pressure, fever, sweating, mottled skin, yawning, skin excoriation, cold extremities[2-5].

Notes: 1. Most clinicians diagnose NAS in children with modified Finnegan score of 8 or greater from two (2) consecutive assessments performed by a qualified healthcare practitioner with a minimum interval of 4 hours between the two consecutive NAS assessments[6-9]. Although the Finnegan NAS was criticized in various publications and alternatives were suggested, however, it is still the most widely used method for making a clinical diagnosis of NAS[10,11]. Simplified versions of the Finnegan NAS scale were developed and cross-validated against the original Finnegan score but did not show any significant improvement in psychometric properties[12-14]. Other methods for making the NAS diagnosis include the Rivers opiate withdrawal tool[15], the Lipsitz narcotic withdrawal score (cut-off score of 4 or more indicates NAS)[14], the neonatal narcotic withdrawal index (cut-off score of 5 or more indicates NAS)[16], and other less commonly used methods. Two recent studies have substantiated the validity of a clinical diagnosis for NAS coded within the patient's medical record at the time of hospital discharge[17,18]. A quality improvement (QI) initiative showed increases in the accuracy and consistency of Finnegan NAS scoring by nurses, but the effects of this training were short-lasting[19].

2. Although all children born to birth mothers suffering from OUD in pregnancy may or may not show signs/symptoms of NAS or NOWS, their brain development has been altered by repeated exposures to opioid drugs in the prenatal period. NAS signs/symptoms are the clinical manifestations resulting from sudden withdrawal of the prenatal opioid exposure, whereas the structural and functional alterations in their brain cells, connections, and architecture, as well as the brain damage from opioid-induced apoptosis (programmed cell death) occurs long before a child is born. These changes in brain development are permanent and will affect these children throughout their entire lifespan (see below). Therefore, we need to establish a class of individuals who were exposed to opioid drugs prenatally, particularly those who were diagnosed with NAS/NOWS after birth.

3. For the purposes of monitoring and surveillance, therefore, the following objective criteria will identify children with NAS and at risk for long-term neurodevelopmental consequences of prenatal opioid exposures:

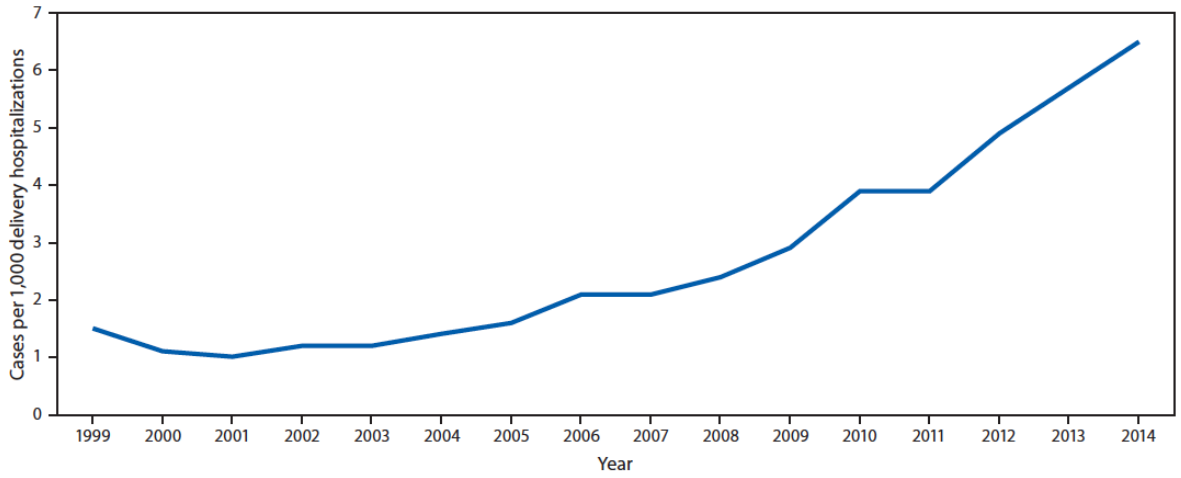
a) Diagnosis of NAS or NOWS documented in the child's medical record, for example, using the diagnostic codes of: P96.1/P04.49 (ICD-10 CM), 779.5/760.72 (ICD-9 CM)[18]; and/or
b) Monitoring of NAS/NOWS score(s) after birth, meeting the diagnostic criteria as defined above; and/or
c) Postnatal weaning of opioid drugs (morphine, methadone, buprenorphine, or other opioids); and/or
d) Children who are already listed in a national registry or other registries established for NAS[20]; and/or
e) Toxicology screen of (a) maternal blood, urine, or hair analysis, (b) umbilical cord blood, (c) baby's meconeum testing positive for opioids (excluding mothers who were prescribed opioids after the onset of, or for the purpose of treating labor pains, or for treating procedural pain).

The numbers of babies exposed to prenatal opioids annually

1) Based on trend analyses for birth mothers suffering from OUD in pregnancy, approximately 36,000 babies are likely to be born with prenatal opioid exposures in 2018[21] (projected using the CDC birth rate data)[22-24]. CDC data show that the documented rate for birth mother OUD was 6.5 per 1,000 delivery hospitalizations in 2014 (MMWR, August 2018[21]). This is a conservative estimate, since it does not include babies delivered at home, at maternity clinics, or birthing centers. Epidemiological studies show that rates of birth mother OUD may be higher among women who use non-hospital birthing centers or prefer delivering their baby at home[21,25-27].

2) Using data from 1999 to 2014[21], the National Average Annual increase in opioid exposed birth rates for mothers suffering from OUD was 0.39 per 1,000 delivery hospitalizations per year. This estimate averages the increases in birth mother OUD rates over 16 years of collected data, although the rate of increase was much greater in the last 5 years of data collection (Figure 1).

FIGURE 1. National prevalence of opioid use disorder per 1,000 delivery hospitalizations* — National Inpatient Sample (NIS),† Healthcare Cost and Utilization Project (HCUP), United States, 1999–2014



Even using this conservative yearly rate increase (3.9%) will give us prenatal opioid exposure rates increasing up to 8.45 per 1,000 delivery hospitalizations in 2019. However, if we project the prenatal opioid exposure rate increases from the past 5 years, National Average increases show an increased rate of 7.2% or 0.72 per 1,000 delivery hospitalizations per year. This will give us prenatal opioid exposure rates increasing to 10.1 per 1,000 delivery hospitalizations in 2019. These data are listed in **Table 1** on the next page. Table 1 also includes the "corrected" prenatal opioid exposure rates after adjusting for: (1) women undergoing detox before the baby's birth, whose babies may not show signs of NAS; and (2) those women who do not deliver in a hospital (previous studies have reported higher OUD rates among these women).

Annual growth rate of individuals at risk for NAS

3) More than half (60-75%) of the individuals born to birth mothers with OUD in pregnancy are expected to be diagnosed with NAS as defined above[21,28-36]. Those diagnosed with NAS are more likely than non-NAS individuals to have more significant exposures to prenatal opioids and to have developed subcellular and other physiological changes as a result of such exposures. CDC states that individuals at risk for NAS are **"clearly underestimated and under-reported"** but

the data available from 36 states in 2015 showed approximate increases of 7.2% occurring in each year between 2011 and 2015[21,26,27,37,38].

Table 1: Numbers of Individuals at risk for NAS: Trend analyses from 2014 to 2019

	National Average Increase 0.39/year (**1999-2014** data)			National Average Increase 0.72/year (**2011-2014** data)			Estimates including babies who detox *in utero* and those born in non-hospital settings		
	OUD rate/1000 hospital deliveries	Number of live-births: CDC data	Newborns with prenatal opioid exposures	OUD rate/1000 hospital deliveries	Number of live-births: CDC data	Newborns with prenatal opioid exposures	Corrected OUD rates/1000 live births	Number of live-births: CDC data	Newborns with prenatal opioid exposures
2014	6.5	3,988,076	25,922	6.5	3,988,076	25,922	7.5	3,988,076	29,911
2015	6.89	3,978,497	27,412	7.22	3,978,497	28,725	8.5	3,978,497	33,817
2016	7.28	3,945,875	28,726	7.94	3,945,875	31,330	9.4	3,945,875	37,091
2017	7.67	3,853,472	29,556	8.66	3,853,472	33,371	10.3	3,853,472	39,691
2018*	8.06	3,776,403	30,438	9.38	3,776,403	35,423	11.1	3,776,403	41,918
2019*	8.45	3,738,639	31,591	10.1	3,738,639	37,760	11.9	3,738,639	44,490

*2018 Number of Live-births estimated with a 2% decrease in births from 2017; *2019 Number of Live-births estimated with a 1% decrease in births from 2018

Constellation of clinical conditions associated with NAS

4) Opioids are proven hazardous substances for prenatal human development. Thus, NAS is associated with premature birth, low birth weight, intrauterine growth retardation (IUGR), perinatal or neonatal mortality, increased birth defects, delayed cognitive development, long-term behavioral problems, ADHD, auditory deficits, speech delay, swallowing difficulty, gastro-esophageal reflux disease (GERD), digestive or gastrointestinal motility disorders, delayed feeding, failure to thrive, congenital neurological defects, and congenital heart defects[39-45].

Time periods of interventions to achieve the best outcomes

5) For most of the conditions listed above, the best possible outcomes can only be achieved with proper management of NAS before hospital discharge, coupled with increased monitoring and surveillance, as well as active multi-disciplinary interventions that are initiated just after birth and continued for the child's entire childhood and adolescence (up to 18 years of age)[30,39,46-56].

Evidence suggesting that prenatal opioid exposure damages DNA

6) Huge amounts of published data substantiate the findings that prenatal opioid exposures alter genetic regulation and DNA structure, although many of these studies were performed in animal models[57]. Almost 40 years ago, however, leading researchers discovered that prenatal opioid

exposure damages human DNA and/or prevents DNA repair occurring from other causes of DNA damage (e.g. UV light)[58]. Since then, accumulating data have shown the progressive and persistent effects of repetitive prenatal opioid exposure on DNA fragmentation occurring in the developing human brain and in peripheral blood cells[58-71]. More recently, several studies also documented the epigenetic effects of opioid addiction, capable of intergenerational and transgenerational transmission to the offspring of opioid addicts[72-80]. Although pregnant women were excluded from some of these studies, the underlying mechanisms are the same and will have extensive effects on the massive amounts of DNA synthesis occurring during prenatal human development[66,81].

Consequent to the opioid effects on human DNA cited above, a large number of studies have found a higher incidence of birth defects in the babies exposed to maternal opioids *in utero*[45]. Seventeen (17) studies found opioid exposure linked with facial/oral defects (e.g., cleft lip, cleft palate, or others), heart defects (e.g., ventricular septal defects, atrial septal defects, hypoplastic left heart syndrome, pulmonary valve stenosis, conoventricular septal defects), limb deformities (e.g., clubfoot), visceral organ defects (e.g., gastroschisis), or neural tube defects (e.g., spina bifida)[40,41,43-45]. Most of these conditions require multiple surgical operations and long-term medical care to support the optimal development of these severely affected children[43,82].

Long-term cognitive and behavioral outcomes of individuals diagnosed with NAS

7) Brain Development: Opioids have drastic and sustained effects on brain development in the fetal and postnatal periods, affecting the brain's size, architecture, networks and connections between brain cells, neurochemical and other functions of each cell, as well as the brain DNA's structure, its expression and regulation. Thus, prenatal opioid exposures have robust and long-term effects on the cognitive and behavioral outcomes of the individuals diagnosed with NAS[82]. Opioids affect brain development by disrupting oligodendrocyte development, altering the temporal sequencing and quality of nerve fiber myelination[83], decreasing the growth of nerve cell dendrites[84,85] and their branching pattern complexity of pyramidal neurons in the cerebral cortex[40], and by suppressing cell proliferation and neuronal migration to the cortical plate[86]. These effects may reduce regional brain volumes in the basal ganglia[87] and other brain areas[87-90], with lower developmental potential.

8) Brain Growth: A large number of studies have reported lower birth weights and smaller head circumferences in opioid-exposed babies with relatively increased risks in those exposed [20,36,87,91-99]. A controlled comparison showed that reduced fetal head and body growth in infants of opioid-dependent mothers were not explained by gestational age, cigarette smoking, area deprivation, infant gender, maternal age or parity[100]. Given the limited maternal/environmental effects on head circumference, it is likely that the robust effects of opioid exposure on head circumference occur by reducing brain growth[82,101]. This was confirmed in a pilot study of 16 infants, where volumetric MRI scans showed smaller whole brain volumes and basal ganglia volumes compared to age-matched population means[87]. In another follow-up MRI study that included 38 youths in the opioid-exposed group and 44 youths in the non-exposed group (aged 17 to 22 years), the drug-exposed group displayed smaller brain volumes, smaller surface areas of the cerebral cortex, and thinner cortical mantles than unexposed youth[88].

9) Functional Effects: The consequences of this impaired brain growth are also pervasive, with altered dyadic interactions between mothers and infants[102], impaired early development in all domains of the Griffith's Mental Development Scales[103], impaired visual acuity and visuomotor

functions (eye-hand coordination)[101,103,104], impaired language-related cognitive skills and executive functions[105,106], with inattention, hyperactivity, impulsivity, aggression, ADHD, other social and behavioral problems persisting into adolescence and even adulthood in those born to opioid-dependent mothers during pregnancy[88,91,107-109]. Baldacchino et al. identified 200 follow-up studies of opioid exposures during pregnancy, but only 8 studies met inclusion criteria with 4 studies in infancy, 3 assessing preschool children, and 1 on school children[110,111]. All these were case-control studies conducted within urbanized, low socioeconomic communities, with mothers exposed to either heroin or methadone. Five studies had data usable for meta-analysis, with a total of 218 opioid-exposed and 205 non-exposed children. In all outcomes opioid-exposed children had lower scores as compared to controls[110].

10) Neurodevelopmental Consequences: Differences in neurodevelopment between children with and without exposure to prenatal opioids are related to the age at which they were assessed, with milder differences occurring at birth, greater differences during infancy and early childhood but widening gaps noted during school age and adolescence. Individuals with NAS at birth had impaired behavioral regulation, greater excitability and arousal, and poorer quality of their movements[112-121]. Among infants and toddlers, NAS was associated with impaired mental and language development as well as poorer neuromotor and psychomotor development before 24 months of age[122]. Because of the very limited roles for cognitive or executive functions in early childhood, studies performed in the younger age groups showed minimal differences in cognitive or executive functions with and without NAS[123,124] (e.g., every infant is likely to fail an algebra test). In contrast, the Bayley Scales of Infant Development revealed more prominent neurodevelopment deficits, with greater vulnerability among boys than in girls[125-127]. Assessment in later childhood revealed differences in IQ, motor performance[128-131], language performance[132], lower IQ scores, behavior and attention problems compared with unexposed children at 8.5 years of age[107,108]. Children exposed to methadone prenatally also had elevated levels of aggression, fear, and anxiety[91,130,133]. Even after controlling for their sociodemographic factors and birth mother's medical history, elevated symptoms of ADHD occurred in children who were exposed to prenatal opioids compared with children not exposed to opioids *in utero* [91,130,134].

A recent systematic review and meta-analysis of cohort studies of 1,455 children from birth to 18 years found that prenatal opioid exposures negatively impacted neurocognitive outcomes and physical/motor development from age 6 months onwards, and this association persisted until adolescence[135]. The study could not differentiate between the contributions of prenatal opioid exposure vs. opioid treatment for NAS after birth and recommended that all NAS children should receive long-term monitoring, with social, emotional and educational support or intervention[135]. The long-term effects of prenatal opioids on cognition tended to increase over time, even in those children who were adopted or placed in foster care, thus being exposed to minimal postnatal risk factors[107]. NAS children discharged home with their birth mother, despite a longer hospital stay, had a higher likelihood of being referred for early intervention services (81%) compared to those placed in foster care (66%)[136].

11) Executive Functions: Executive functions are thinking skills that help us with the information processing, reasoning, planning, problem-solving, for coping with stress, regulating our emotions and managing our lives. As a child progresses through school, the executive functions assume greater importance in their academic success, goal setting, and employability[137]. Children exposed to prenatal opioids have difficulties with information processing[138], poorer performance on a

vigilance task[139], lower overall executive functioning[105], significantly lower visual acuity[101], impaired visual-motor and perceptual performances, and fewer goal-directed eye movements[140-142]. Children with NAS were far more likely to have developmental delays and lower IQ[143], 2.3 times more likely to be hospitalized for neuropsychiatric disorders[144], 4.5 times more likely to be hospitalized for child abuse[144] and die during hospitalization[144], perform poorly on educational testing[145], and show cognitive disabilities requiring extra classroom therapies and services[146]. CDC compared 1815 children with NAS and 5441 children without NAS (age 3-8 years). Children with NAS were more likely referred for disability evaluation (19.3% vs. 13.7%), have a learning disability (15.6% vs. 11.7%) and require classroom therapies (15.3% vs. 11.4%). These differences remained significant even after controlling for maternal smoking, maternal education, birth weight, gestational age, and/or NICU admission[146]. Children with NAS had lower scores on standardized testing in grade 3; by grade 7, children with NAS were scoring lower than other children in grade 5 and showing progressively greater deficits[145]. The increasingly complex cognitive processing and executive functioning required within a competitive high school environment place these children with NAS at progressively greater disadvantage and much higher likelihood of adverse outcomes, thus widening the gap between those with and without NAS.

12) Neuropsychiatric outcomes: Although Uebel et al. (2015) had found that more children with NAS were hospitalized with neuropsychiatric disorders (adjustment, conduct, anxiety, emotional, or speech disorders), three recent studies have highlighted the very high prevalence and distribution of mental health conditions among individuals with prenatal opioids. Using a Medicaid database, Sherman et al. (2019) found that half of all children with NAS were diagnosed with mental disorder before age 5, compared with 30% of all other births. Children with NAS were more likely to have conduct disturbances (2.7-fold), hyperkinetic syndromes (2.6-fold), adjustment difficulties (2.5-fold), stress/anxiety disorders (1.5-fold), emotional problems (1.9-fold), childhood-onset psychoses (1.7-fold), intellectual disabilities (2.3-fold), specific developmental delays (1.7-fold)[147]. Mental health conditions were 1.6-fold more prevalent in children with a history of NAS than the opioid-exposed children without a history of NAS, and 1.4-fold higher among children with Medicaid vs. commercial health insurance (Table 2 from Conner et al., 2019)[148]. From a longitudinally followed youth cohort (17-22 years) with prenatal opioid exposures (± other drugs) who were adopted/fostered before 1 year of age, Nygaard et al. (2019) found **2- to 8-fold higher lifetime risk of mental disorders** compared to matched controls[149]. These risks mainly included

TABLE 2 Diagnoses of mental health conditions in children with and children without neonatal abstinence syndrome (NAS), by Medicaid or commercial insurance coverage

	Commercial insurance (N=1,405,712)				Medicaid[a] (N=270,772)			
	NAS (N=190)		No NAS (N=1,405,522)		NAS (N=1,046)		No NAS (N=269,726)	
Diagnosis (*ICD-9* code)	N	%	N	%	N	%	N	%
Any mental health condition/diagnosis	68	35.8	313,021	22.3	511	48.9	81,814	30.3
Specific delays in development (315)	48	25.3	115,785	8.2	327	31.3	49,591	18.4
Disturbance of conduct (312)	11	5.8	37,120	2.6	113	10.8	10,879	4.0
Hyperkinetic syndrome of childhood (314)	13	6.8	102,770	7.3	94	9.0	9,372	3.5
Adjustment reaction (309)	9	4.7	63,295	4.5	75	7.2	7,799	2.9
Acute reaction to stress (308)	2	1.1	6,995	.5	49	4.7	8,123	3.0
Neurotic disorders (300)	9	4.7	60,749	4.3	43	4.1	7,365	2.7
Special symptoms or syndromes (307)	11	5.8	58,585	4.2	41	3.9	9,672	3.6
Disturbance of emotion specific to childhood and adolescence (313)	2	1.1	23,686	1.7	39	3.7	5,350	2.0
Intellectual disabilities (317–319)	1	.5	2,596	.2	37	3.5	4,074	1.5
Psychoses with origin specific to childhood (299)	8	4.2	26,860	1.9	32	3.1	4,752	1.8

[a] Source: Sherman et al., 2019 (2). Adapted by permission from American Psychiatric Association Publishing.

major depression, alcohol abuse, ADHD, and **aggressive behaviors** even after controlling for age, gender, and caregivers' education. These children not only engaged in sex at younger ages and had **more sexual partners** compared to controls, but also experienced **suicidality** (28.8%), **psychoses** (17.7%), or **antisocial personality disorder** (15.6%) more often than their peers[149].

Such bleak outcomes portend a future tsunami of neurocognitive and neuropsychiatric disorders among the children and youth with NAS. The Opioid Crisis has increased over the past 20 years; therefore, multiple generations of such children and youth have been affected. While we continue to argue about priorities and preferences, these children are growing up – and every day that passes without the medical monitoring or supportive services being offered to these children, it makes their problems more and more intractable, imposing on them poorer outcomes and greater societal disadvantages.

Urgent need for more scientific investigations of individuals with NAS

Despite the recent flurry of scientific publications on this topic, there are numerous unanswered questions about the epidemiology, risk factors, diagnoses, management, and responses to therapy in the children with NAS. Therefore, there is an urgent need for a court-appointed Science Panel with the imperative to document the long-term outcomes of children exposed to prenatal opioids, through multiple, well-designed, large studies that prospectively enroll adult women with OUD and ensure good retention rates, to longitudinally follow their children with NAS at least until 18 years of age. All these children will require detailed neurocognitive and neuropsychiatric testing, as well as functional monitoring. Such tests are not available during routine doctor visits or other healthcare settings. To be explicit, these needs exist well-above and beyond the routine pediatric care and/or schooling required for non-opioid exposed children. These needs are not currently covered by Medicaid, or any private health insurance or any kind of Special-Ed funding. To obtain such data and to ensure that appropriate therapies and social services are offered, these children require detailed medical monitoring and surveillance through a well-coordinated, standardized, multidisciplinary, and nationally implemented protocol as described below. The results of such monitoring and surveillance must be regularly evaluated by the court-appointed Science Panel, so that accumulating data and scientific insights can be applied to the ongoing care of these children. To inform members of the Science Panel, they must be given access to all scientific and medical studies, data, experiments, white papers, research forms, or other materials related to the synthetic opioids, regardless of whether such materials had ever been provided to the FDA or whether they were protected assert trade secret protection.

Protocol for monitoring/surveillance of children diagnosed with NAS

1) Biological variability is based on genetic and epigenetic mechanisms, or factors related to the prenatal opioid exposure that manifested NAS (specific drugs, dosage, period(s) of pregnancy affected, detox or treatment effects, exposures to smoking, alcohol, or other drugs), as well as the postnatal treatments for NAS. All these will influence the child's long-term neurodevelopmental consequences resulting from NAS. Individual differences occurring between humans are difficult to determine specifically, but a common medical monitoring program is absolutely essential for all NAS victims because they are all at high-risk for common detrimental outcomes, associated with 'hidden' or latent conditions and disorders that can be ameliorated through medical monitoring, scheduled assessments, surveillance procedures and appropriate therapies. The proposed monitoring is different from that normally recommended in the absence of opioid exposures and

there is immense clinical value in the early detection and diagnosis of long-term opioid effects. If our societal goal is to achieve the maximal developmental outcomes for all children, then uniform and robust program will be necessary. Although some children might ultimately benefit more than others, however, that can be attributed to a biological variability in response to therapy, other psychosocial factors, or presently unknown factors that require further scientific investigation.

2) Children with NAS are at higher risk for a variety of adverse outcomes as noted above. Therefore, they are worthy of a more structured and specialized program of monitoring and surveillance with scheduled extra assessments, for at least two reasons. First, their families/caregivers want to know if their child is healthy and growing and developing normally, and they want to know about the health or other problems likely to be encountered in the future. Special concerns often arise at childhood or social transition points, such as entering childcare or changing school levels, thus requiring careful guidance and advice. Second, most of their developmental problems can be ameliorated or prevented if detected early – identification of high-risk groups for targeted interventions can be both cost-effective and efficient. Multidisciplinary advice from Doyle et al. (2014)[150] was used to design the monitoring protocol as outlined below.

3) If these periodic diagnostic medical exams identify a particular deficit or disability, the child's caregivers must be provided access to the specific resources and treatment(s) that they will need to overcome the long-term impacts of NAS. Additionally, caring for a victim of NAS is difficult, associated with increased risks for repeated hospitalizations of the child. An educational program aimed at increasing the understanding of NAS in parents and other caregivers is recommended, including access (or referral) to resources for both the caregiver and the child.

4) Barriers for implementing standardized monitoring protocols must be anticipated and addressed. These may include providing funding for transportation to scheduled assessments or making the transport arrangements, providing token compensation to participants, facilitating access by offering home visits or assessments at a location convenient for the parent/caregiver, consideration for living situation, and other barriers.

5) Most of these assessments are required annually, unless specified otherwise. Certain specialist assessments may be required only once (e.g., cardiology evaluation to rule-out congenital heart disease), or to be determined by the results of the previous testing – more frequent assessments will be required for the NAS children with abnormal/atypical results.

6) The data gained from these assessments must be deidentified, aggregated and securely stored in a state-level database, with query access available to researchers, practitioners, social or healthcare agencies, advocacy groups and others.

In conclusion, implementation of the studies referenced herein as well as the long-term care and treatment of these babies is essential to the resolution of the Opioid Crisis and its impact on our society. This report is based upon the information available at the time it was prepared. With the recent increase in NAS cases, the scientific understanding of NAS and the outcomes of NAS victims continues to evolve. And yet, much work remains to be done, which is the goal of implementing a long-term Court-appointed Science Panel – to study the results of the monitoring and surveillance and to recommend interventions as needs arise. With the Court's permission, I

would like to reserve the right to update this report in order to reflect the accumulating scientific and medical evidence as necessary.

I certify under penalty of perjury that the foregoing is true and correct.

Executed on December 8, 2019.

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Marc Dann Declaration in Support of Motion for Class Certification

Exhibit 6

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Home: 473 Devon Road, Morgantown, WV 26505 (304) 291-5820
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EDUCATION

West Virginia University, Morgantown, West Virginia
Masters of Public Health – May 2002
Concentration in Occupational and Environmental Health

Kirksville College of Osteopathic Medicine, Kirksville, Missouri.
Doctor of Osteopathic Medicine - June, 1996
Honors: Student Leadership Award Scholarship 1992-93
Student Ambassador Award 1996

Temple University, Philadelphia, Pennsylvania
January 1990 to May 1991. Pre-medical science courses.

Montgomery County Community College, Blue Bell, Pennsylvania
1987 to 1989. German courses for personal enrichment.

Drexel University, Philadelphia, Pennsylvania
B.S., Commerce and Engineering - June 1987
Fields of Concentration - Operations and Human Resources Management
Honors: Deans List 1985-86.

POST GRADUATE TRAINING

West Virginia University, Morgantown, West Virginia. July 2000 to June 2002
Residency in Occupational Medicine
Honors: ACOEM Residents Research Presentation Award
Chief Resident July 1, 2001 – December 31, 2001

West Virginia University, Morgantown, West Virginia. June, 1997 to June, 2000.
Residency in Internal Medicine, Primary Care Track.
Honors: Department of Medicine Community Service Award 1999

Community General Osteopathic Hospital, Harrisburg, PA. July 1996 to June 1997
Traditional rotating internship with weekly half-day ambulatory care experience.

EMPLOYMENT

Morgantown Occupational Medicine, PLLC, Morgantown, WV
July, 2018 – Present. Principal, Physician, and Consultant.

- Occupational Medicine consulting, focusing on community exposures, medical monitoring programs, occupational injuries, and diseases
- Regulatory Exams (Senior Aviation Medical Examiner, Commercial Drivers, Medical Review Officer, Respirator Examinations)
- Independent Medical Evaluations (4th, 5th, and 6th editions of AMA Guides)
- Occupational surveillance program design and implementation
- Federal Black Lung Examinations at Preston Memorial Hospital
- Morgantown Clinic at Pro Medical Rehabilitation

Cabin Creek Health Systems, Dawes, WV
July 2018 – Present - Physician (Part time) – performing Department of Labor Black Lung exams.

National Institutes for Occupational Safety and Health, Morgantown, WV
November 2002-Present (Part time). Intermittent Consultant in Surveillance Branch of the Division of Respiratory Health, Coal Worker Health Surveillance Program. Contacting miners with abnormal x-ray finding, and providing physician support for the spirometry monitoring program.

West Virginia University / West Virginia University Medical Corporation
August 2002 to February 2003. Clinical Instructor

March 2003 to June 2009. Assistant Professor (Clinical Emphasis).
July 2009 – June 2018. Associate Professor (Clinical Emphasis)

- Program Director ACGME Occupational Medicine Residency (2012-2015)
- Clinical care for injured/exposed workers
- Independent Medical Evaluations (4th, 5th, and 6th editions of AMA Guides)
- Medical support of WVU animal handler & Biosafety health programs
- Medical Review Officer (MROCC)
- FAA Senior Aviation Medical Examiner, FAA Employee Examiner
- Surveillance exams for federal and state agencies
- Program Director – AOA Occupational Medicine Residency 2008-11
- On-site fitness for duty and wellness exams
- DOL Black Lung Examiner (413b)
- Formal Teaching (WVU – for-credit classes):
  - Medical Toxicology for Occupational Medicine Residents
  - Occupational Health Class
  - Small Group Facilitator – MS 1 Clinical Skills Course
  - Global Public Health
- University Biosafety Committee – voting member
- Consultant on health effects of workplace & environmental exposures

Louis A Johnson VA Medical Center, Clarksburg, WV
October 2000 to January 2003. Fee-Basis Medical-Officer-of-the-Day. Provide outpatient urgent care and hospital inpatient coverage 1-2 shifts each month.

MG Industries Gas Products
April 1991 to August 1992. Production Scheduler. – Fairless Hills, PA
Coordinated production schedules, programmed on-site RF data system for a computerized manufacturing management system. Member of company HazMat response team (Specialist in Gases & Cryogenics).
January 1990 to April 1991. Second Shift Supervisor. – Fairless Hills, PA
Responsible for second shift plant operations, 13 direct report employees.
February 1987 to January 1990. Cylinder Control Coord. – Valley Forge, PA
Maximized utilization of a fleet of 300,000 compressed gas cylinders.

General Electric Co Re-Entry Systems Operation, Philadelphia, PA.
June 1985 to January 1986. Co-op student, Procurement Expediter.
March 1984 to December 1984. Co-op student, Production Controller
December 1982 to June 1983. Co-op student, Laboratory Technician.

PROFESSIONAL LICENSES
Osteopathic Medicine - West Virginia 1602
Osteopathic Medicine - Pennsylvania OS-009608-L

PROFESSIONAL CERTIFICATION
Board Certified in Occupational Medicine (ABPM, expires 2023)
Board Certified in Occupational and Environmental Medicine (AOA, expires 2025)
Medical Review Officer (MROCC)
FAA Senior Aviation Medical Examiner Designee
FAA Employee Examiner Designee
Certified Driver Medical Examiner (FMCSA/NRCME)
NIOSH Spirometry Technician
Breath Alcohol Technician (Phoenix)
Wilderness Command Physician/Wilderness EMT (WEMSI)

Basic Cardiac Life Support

FELLOWSHIP
American College of Occupational and Environmental Medicine (2006)
American Osteopathic College of Occupational and Preventive Medicine (2011)

PROFESSIONAL LEADERSHIP ACTIVITIES
Tristate Occupational Medicine Association – President 2009-10, BOD 2006-present
Monongalia County Medical Society – President 2009
American Osteopathic College of Occupational and Preventive Medicine
Board of Trustees – 2010-2012, 2013-2015
Education Evaluation Committee Chair 2014-2016
ACGME Preventive Medicine RRC - Member 7/1/2016-6/30/2022

PROFESSIONAL MEMBERSHIPS
American Osteopathic Association.
Monongalia County Medical Society (currently dormant)
American College of Occupational and Environmental Medicine
American Osteopathic College of Occupational and Preventive Medicine

TALKS GIVEN
"Obesity and Pulmonary Function Testing (or What Pickwickian Syndrome is, and what it is not). WV Chronic Pulmonary Disease ECHO, May 6, 2019.
"Black Lung Update", Fayette County Black Lung Coalition, Scarbro, WV November 13, 2018.
"Resurgence of Black Lung in Appalachia". Annual Meeting of the TriState Occupational Medicine Association, Columbus, OH. October 20, 2018.
"Occupational Health Hazards in 'Unconventional' Gas and Oil Production." PA Health Check-Up Health Impacts of Unconventional Gas Development Industry from Pittsburgh to Philadelphia. Chatham University, Pittsburgh, PA. October 13, 2018.
"Resurgence of Black Lung in Appalachia". Annual Meeting of the American Osteopathic Association, San Diego, CA October 7, 2018.
"Black Lung in West Virginia - 2018", West Virginia School of Osteopathic Medicine noon lecture series, Lewisburg, WV. May 16, 2018.
"Full" Pulmonary Function Testing in Assessing Lung Diseases, West Virginia Chronic Lung Disease (Black Lung) ECHO. April 2, 2018.
"Black Lung – An Introduction for Medical Students", West Virginia School of Osteopathic Medicine Rural Health Initiative, Beckley, WV. Dec 11, 2017.
"Mine Rescuer Health Hazards and Drug Testing Update". Tristate Occupational Medicine Association Meeting; Columbus, OH. October 14, 2017.
"Post-Explosion Health Hazards for Mine Rescuers and Investigators", with Anna Allen, MD, West Virginia State Black Lung Conference, Pipestem Resort WV, June 7, 2017
"Miner Health and Safety and Drug Testing Update", American Osteopathic College for Occupational and Preventive Medicine Mid-Year meeting, Chattanooga, TN; March 9, 2017.
"Drug Testing Challenges – 2016", Bay County Society for Human Resource Management's Workers' Compensation & Occupational Healthcare Conference, Panama City, FL, October 13, 2016.
"Return to Work and Functional Capacity Evaluations", American Osteopathic College of Occupational and Preventive Medicine mid-year meeting, Fort Lauderdale, March 12, 2015.
"Return to Work and Healthy Spine Habits", WVU Spine Conference, Morgantown, WV, October 3, 2014.

"Human Health Concerns of Working with Research Animals", Loren Hatch Memorial Lecture for the American Osteopathic College of Occupational and Preventive Medicine mid-year meeting, Tulsa, March 6, 2014.

"Is this OSHA Recordable?", Brent Lovejoy Memorial Lecture for the American Osteopathic College of Occupational and Preventive Medicine mid-year meeting, Phoenix, February 13, 2013.

"Human Health Concerns from Hydraulic Fracturing", Grand Rounds – Fairmont Clinic, Fairmont, WV. February 29, 2012.

"Occupational Health Concerns from Hydraulic Fracturing", 2nd Annual Conference on Health Effects of Shale Gas Extraction, Pittsburgh Graduate School of Public Health, November 18, 2011.

"Human Health Concerns from Hydraulic Fracturing", Tristate Occupational Medicine Assn annual meeting, Cleveland, OH. October 22, 2011.

"Human Health Concerns from Hydraulic Fracturing", Pennsylvania Occupational and Environmental Medical Society annual meeting, Harrisburg, PA. September 19, 2011.

"Human Health Concerns from Hydraulic Fracturing", Cambria-Summerset Health Council CME Conference, Seven Springs, PA. September 17, 2011.

"Case Studies from Residency" (2 Hour Interactive session) American Osteopathic College of Occupational and Preventative Medicine mid-year meeting, Atlanta, March 2011.

"Slurry and Tetryl and Fracking – OH MY! – New Environmental Health Concerns in WV", WV School of Osteopathic Medicine Mid-Year CME meeting, Charleston, WV, February 2011.

"Slurry and Tetryl and Fracking – OH MY! – New Environmental Health Concerns in WV", Tristate Occupational Medicine Annual Session, Columbus, OH, October 2010.

"Slurry and Tetryl and Fracking – OH MY! – New Environmental Health Concerns in WV", American Osteopathic Association Annual Meeting, San Francisco, October 2010.

"Finding a Needle in a Haystack – The Search for Jacob Allen in Dolly Sods, October, 2007", Appalachian Wilderness Medicine Conference, Morgantown, WV, August, 2008.

"Land Navigation using GPS, map, and compass", Appalachian Wilderness Medicine Conference, Coopers Rock State Forest, August, 2008.

"Human Health Concerns for Research Animal Workers" American Osteopathic College of Occupational and Preventative Medicine mid-year meeting, Savannah, GA, March 27, 2008.

"Cave Rescue", Appalachian Wilderness Medicine Conference, Morgantown, WV, August, 2007.

"Land Navigation using GPS, map, and compass", Appalachian Wilderness Medicine Conference, Coopers Rock State Forest, August, 2007.

"Occupational Health with research animals", Occupational Medicine Grand Rounds, July 2007.

International Occupational and Environmental Medicine (2 Hours) for WVU certificate course in tropical and travel medicine, June 2007.

"Respirator Medical Clearance", American Osteopathic College of Occupational and Preventative Medicine annual meeting, Las Vegas, NV, October 2006

"Wilderness EMS and Field Treatment of Hypothermia", Appalachian Wilderness Medicine Conference, Canaan Valley, August, 2006.

"International Occupational and Environmental Medicine" (4 Hours) for WVU certificate course in tropical and travel medicine, June 2006.

"What's new in Spirometry", American Osteopathic College of Occupational and Preventative Medicine, annual meeting, Orlando FL, October 2005.
"The Community Practitioner's Role in Outbreak Response", West Virginia University Public Health Grand Rounds, February, 2005.
"Drug Testing for the non-MRO", Occupational Medicine Grand Rounds, August, 2004.
"Occupational Health in Chile", West Virginia University Certificate Course in Tropical Medicine, Morgantown, WV, June 26, 2002.
"Zinc Protoporphyrin Changes Following Acute Lead Intoxication", American Occupational Health Conference, Chicago, IL April 16, 2002.
"Wilderness Emergency Medical Services", Marshall University Wilderness Medicine Grand Rounds, Huntington WV, February 21, 2002.
"Medical Mission to Guatemala", West Virginia University Certificate Course in Tropical Medicine, Morgantown, WV, July 16, 2001.
"Wilderness Emergency Medical Services", West Virginia University Department of Emergency Medicine Grand Rounds, April 20, 2000.
"Case report of gastric ulcerations after electrocution without significant external injury"; American College of Physicians - West Virginia Chapter, Lakeview Resort, Morgantown, WV, May 21, 1999.

COURSE FACULTY American Osteopathic College of Occupational and Preventive Medicine-Basic Course in Occupational Medicine – [Rotating series of 3 sessions, each offered every 18 months]. I provide lectures all three sessions, including Introduction to Occupational Medicine, Medical Surveillance, Hearing Conservation, Substance Abuse and Drug Testing, Biologic Hazards, Metal Toxicology, Solvent Toxicology, Introduction to Toxicology, Reproductive Hazards, Facility Walkthroughs, and ADA/FMLA/GINA.

American Osteopathic College of Occupational and Preventive Medicine – Commercial Driver Medical Examiner Course - Lead Instructor and lecturer on diabetes, hypertension, cardiovascular, respiratory, neurologic, and psychiatric diseases, vision, hearing, waivers and the SPE process.

2002 – 2018: WVU Residency program in Occupational Medicine – I provided education sessions on: Medical Surveillance, Hearing Conservation, ADA/GINA/FMLA, Biologic Hazards, Non-Conventional Gas Production, WV Environmental Health "disasters", Return to work and FCEs, Biosafety and Viral Vectors, OSHA Logs, Recordability and Reportability, Drug testing for the non-MRO, Commercial Driver Medical Examiners, Dysbarisms & Altitude, Payors in the US healthcare system, Cultural Competency in WV, coke oven worker surveillance, Benzene medical surveillance, Emergency Response for public health, Firefighter & emergency responder medical standards.

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AUTHORSHIP

"Fourteen Year Old Caught in Chain Hoist", NIOSH FACE report 2001-13 Available at http://www.cdc.gov/niosh/face/In-house/full200113.html

ACADEMIC ACTIVITIES

Student Ambassador, Kirksville College of Osteopathic Medicine, 1992-96.
President, Drexel University Amateur Radio Club, 1982 to 1985
Assistant Chief Engineer, Radio Station WKDU, Drexel University, 1982-88.

COMMUNITY ACTIVITIES

Mountaineer Area Rescue Group, Inc. (Appalachian Search and Rescue Conf.)
Search Manager. 1997-Present
Camp Physician, Camp Mountaineer, Boy Scouts of America, summer camps 1998 - present.
Staff Physician – BSA Summit Bechtel Reserve, Glen Jean, WV. 2014-present.
Community Ambulance Association of Ambler, PA. Volunteer Driver/Attendant (EMT-MAST), 1981 to 1997.
Eagle Scout, Boy Scouts of America.

Amateur Radio Operator, Advanced Class License.

PERSONAL DATA

Fluent in English & German.
Functional in Spanish.
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Report of Charles L. Werntz III, D.O., MPH

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QUALIFICATIONS:

My name is Charles L Werntz, D.O., MPH. My CV is attached. I am a physician, Board Certified in Preventive Medicine, specializing in Occupational and Environmental Medicine, plus previously completed residency training in Internal Medicine. I served on the faculty at West Virginia University (WVU) for 16 years. Throughout my time at WVU I provided clinical Occupational Medicine services to the community, developed and implemented medical monitoring programs for the University, and provided consultative services for employers, insurance companies, and attorneys. Medical monitoring programs I have developed or implemented included:

- Asbestos-Exposed University employees (WVU Asbestos Class Action)
- Asbestos-Exposed employees doing building renovations (EPA Criminal Division – Martinsburg, WV)
- Radiation Therapy workers working with lead (< OSHA limits for lead exposure) (WVU Hospitals & affiliated Cancer Centers)
- Community Members exposed to zinc smelter effluent and waste piles (Spelter, WV)
- Research animal workers and researchers with animal contact (WVU)
- Community members exposed to coal slurry impacted drinking water (Rawl, Mingo County, WV)
- Community members exposed to dioxins (Nitro, WV)
- Community members exposed to coal mining impacted water (Prenter, WV)
- Researchers, students, and employees working with sheep (WVU)
- Researchers working with lentiviral vector systems (WVU)
- Asbestos-exposed maintenance workers (Alderson-Broadus/Sodexho)
- Researchers working with Tuberculosis (WVU)
- Community Members exposed to coal mining impacted water (Harts, WV)
- Researchers working with Rock Mountain Spotted Fever virus (WVU)
- Researchers working with Human Papilloma Virus (WVU)
- Researchers working with wild-caught mammals (WVU)
- Community members exposed to Pb, Cd, As, Zn (Donora, PA)

EXPOSURE REVIEW AND HEALTH HAZARDS

Children who were exposed to narcotics prior to birth suffer a condition called Neonatal Abstinence Syndrome (NAS). The clinical features and biochemical and physiologic impacts have been elegantly reviewed and explained by Drs. Anand and Howard in their reports. While there is some variability among individuals, it is clear that the effects of NAS are common to those diagnosed and treated for NAS. It is also clear that these effects continue throughout a lifetime.

Prenatal opioid exposure can cause impacts in several spheres impacting the child, some of which are overt, and others which can be occult. Many of these effects can impact the child throughout their lifetime. The goal of this program is to facilitate early detection of NAS-associated impacts so that earlier intervention can help minimize the lifelong impacts.

In a study by Desai[1], they looked at the risk of a newborn developing NAS based on duration and timing of maternal opioid prescriptions. They found that there were cases of NAS found following all timings of maternal opioid prescriptions, although some timings of maternal opioid use conveyed greater risk. On this basis, I would recommend to use a definition of NAS that will allow consideration of children clinically diagnosed with NAS, based both on either test results or clinical findings, without a need to pre-screening for admitted maternal opioid use. Over the last two decades several different diagnostic codes and notations in the medical record have been used to indicate a medical diagnosis of impacts on the newborn following maternal opioids use. NAS is a fairly recent diagnostic code but for ease of reference, "NAS" is used herein to identify patients that has been medically determined to have suffered exposure to opioids in utero.

For the purposes of this report I am using the following definition of NAS:

> *Children born after March 16, 2000, who were medically diagnosed with opioid-related "Neonatal Abstinence Syndrome" ("NAS") at or near birth and whose birth mother received a prescription for opioids or opiates while pregnant.*

This recommended program in this report considers NAS from opioids as a child, diagnosed as being exposed to opioids in utero, who required treatment in the

perinatal period for NAS. "Treatment" would include opioid replacement therapy of the newborn, plus other treatments such as intentional changes in stimulus of the newborn to reduce the effects of NAS. In the article by Ernst[2], they report "Many exposed infants can be treated with non-pharmacological methods, such as limited visitors, low lighting, swaddling, ear muffs, and cuddlers, without the need for pharmacological treatment." All of these would be considered treatment.

The medical literature identifies several other maternal medication uses/exposures that can cause abstinence symptoms in newborns[3]. The recommendations in this report are intended to apply only to children where the in-utero exposure included opioids. Non-opioid withdrawl syndromes are not addressed in this report.

SCOPE OF NAS EFFECTS

NAS is classically thought of as a medical condition that impacts newborns immediately after birth. This typically includes the effort to replace and then wean newborns off opioids while medically managing the physiologic impacts of both the narcotics and their withdrawal. These efforts can require treatment from a matter of weeks to months or even longer.

However, it is clear that the effects of NAS can be far more serious and continue well beyond the weaning the child off opioids.

Prenatal opiate exposure is associated with several congenital defects[4,5]. Some of these are pervasive and can be detected shortly after birth, but others can only be diagnosed later in childhood, sometimes only via testing. Examples of these impacts are outlined in table 5 of Dr. Howard's report.

There are well-established protocols for the assessment and management of these infants, which should be followed. One important concept is that treatment of NAS in infants often requires giving them slowly decreasing doses of narcotics for a period of time. While medically necessary, this prolongs their exposure time, and thus prolongs the "time under the curve" of exposure to opioids for their developing organs. In his report, Dr. Howard outlines these effects in the section of his affidavit titled CNS and apoptosis, focusing on the impacts on the developing brain.

Given the clear evidence of persistent effects of NAS impacting school performance, a primary goal of this program is to give these children the best opportunity for success in school and later in life. Dr. Anand discusses the educational and social impacts of NAD in sections 7, 8, and 9 of his report. There is copious literature (reviewed below) that discuss the breadth and importance of the educational impacts of NAS.

PHYSIOLOGICAL IMPACT OF PERINATAL NARCOTIC EXPOSURE

The development of the human brain before and after birth is complex, and multifactorial. There are general themes about the timing of organ development, but the development of the pathways and mechanisms necessary for learning, understanding, decision making, and behavior control are not completely understood.

In his report, Dr. Anand notes the various physiologic processes of the development of the infant, both pre- and post-delivery, that are impacted by exposure to opioids. There is a growing body of evidence that there are lifelong impacts from the exposure to narcotics during the time of organogenesis, especially the development and maturation of the brain.

The long-term consequences of NAS for each child is multifactorial, depending on individual differences expected between humans that are difficult to determine with specificity but a medical monitoring program is necessary for all of NAS victims they all face common risks of latent disease that can be mitigated and abated through medical monitoring.

Because of these children face a common risk, the best approach is to establish a program where each child is periodically assessed and provided access to the specific resources and treatment(s) that they need to overcome the long-term impacts of NAS.

LITERATURE REVIEW

In his report, Dr. Howard provides an overview of the toxicology of exposure to opiates in the neonate. Please refer to this document for a review of the biochemical description of the impacts of prenatal opiate exposure on the child.

As outlined in Dr. Howard's report, laboratory scientists have identified several impacts of opioids on the developing brain. Epidemiologists have studied cohorts of exposed children and identified impacts in educational success specifically impacting NAS survivors. This literature[6,7,8,9,10] is based upon following cohorts of NAS children over time and comparing the effects/outcomes with those seen in socioeconomically similar children who were not NAS survivors. This is not new information, as there were several studies[11] during the 1990s looking at this issue.

There is a suggestion in the literature that exposed children can exhibit impacts of maternal opioid use, even if the baby did not develop clinical NAS[6]. This study identified opioids in maternal drug testing, then monitored children whose mothers had positive and negative drug tests over time. This study found impacts in the children, including those who did not manifest acute symptoms of NAS. The observed effects in this group include increased prevalence of behavioral or emotional disorders, developmental delay, speech disorder, and strabismus. These findings are similar to those found in survivors of NAS. I fully endorse the conclusion of this study: "Awareness of the increased risk for certain developmental delays and medical conditions is critical to early intervention and treatment supporting improved outcomes."

LIFELONG IMPACTS OF MATERNAL OPIOID USE

Documented lifelong impacts includes:

- Delayed achievement of early developmental milestones[12,13]
- Impacts on high school academic performance below that accounted for by socioeconomic status[14]
- Increased rates of hospitalization[15]
- Delayed/impaired Speech
- Impaired Hearing (reported frequently)
- Strabismus ("crossed" eyes)[13]
- Smaller brain size on imaging (shows permanent physiologic impact)

Additionally, there are other effects mentioned repeatedly in review and summary articles, but for which I did not locate primary literature. These include increased prevalence of Attention Deficit diseases (ADHD & ADD), increased risk of addiction as a teen, and increased rates of incarceration. Many studies discuss "behavioral" problems, which may be a catch-all for these outcomes. Other than annual assessment of drug use risk (and referrals for further interventions if increased risk is identified), these conditions were not considered in the development of this program. If evidence becomes available supporting these (or any other) conditions in NAS survivors, it would be appropriate to update the program to include appropriate screening and interventions for those additional conditions. An important part of this medical monitoring program must include medical surveillance for those individuals who are part of the program's registry.

The authors of the study of High School academic performance[14] opine that their study "adds to medical knowledge":

> *Australian children with NAS perform poorly at school from grade 3, and results deteriorate even more by high school, suggesting that children with NAS must be supported beyond withdrawal to minimize the risk of school failure and its consequences.*

The recent trends in the increased prevalence of NAS limits the long-term data on exposed cohort. Pre-term babies have been long known to have impacts that, while differing in the details, are generally parallel to those in NAS. On this basis, it should be useful to look at how specific interventions are used assist preterm infants. One clear lesson from this literature is that when developmental impacts are identified and treated earlier, the child will do better over their lifetime[17].

Because of the uncertainty of the specific impacts on an individual child, the best approach would be to monitor each impacted child via appropriate periodic testing, and ensure they have access to needed interventions as early as possible for identified abnormalities.

There is clear impairment in school performance, documented both in primary school[7] and then more profoundly in high school[14], but also identified in pre-school children. Because of the impacts seen across the educational spectrum, a program

that assesses children annually, focusing on age-specific impacts and potential interventions, is recommended.

Additionally, parenting a NAS survivor is difficult, with an increased risk of hospitalization of the child[15], some of which seem related to parenting difficulties. An educational program aimed at increasing the understanding of NAS in parents and other caregivers is recommended, including access (or referral) to resources for both the caregiver and the child.

This program is intended to yield the earliest possible identification of roadblocks the child is experiencing, allowing the earliest possible initiation of treatment to aid the child in overcoming the difficulty, and providing them the best opportunity for success in society as an adult.

GOALS OF A MEDICAL MONITORING PROGRAM

The nature of the exposure(s) and the known outcomes from prenatal opiate exposure drives the structure of the program. Goals of the program include biologic monitoring of known exposures, testing for the development of known diseases/effects, monitoring for development of disease(s) in the exposed population so that early interventions can be undertaken.

The first step in a monitoring program is to identify NAS survivors and collect their information in a registry. This will allow for the program to reach out to impacted families at the appropriate times and to understand the geographic distribution of survivors to coordinate the delivery of services to the impacted population. The registry may also support ongoing data analysis to support identifying problems, assessing the effectiveness of interventions, and adjusting the program to maximize benefit to those affected.

There are several variables that make the design of this program complex. There is considerable variability between individuals regarding the timing of their prenatal exposures, their individual tolerance for specific exposures, and the duration and effectiveness of treatment both in the hospital and after discharge. Variability between humans means that even with similar exposures there can be different outcomes.

The goal of this medical monitoring programs is to do routine focused assessments to identify the individual NAS survivors to identify those who are actually suffering a specific impact so that they can receive rapid referral for appropriate interventions. Interventions will need to be tailored to the specific deficit(s) in a given child, and could include specific treatments, education for the child or caregiver, assistance with accessing existing school-based services, or (when there is an unconfirmed suspicion of a deficit) providing additional screenings.

In the past, medical monitoring programs have also been designed to monitor and surveil for actual impacts in scenarios where the human health effect of an exposure were not entirely clear, such as a the PFOA/PFOS program around in the Little Hocking, OH/Parkersburg, WV and adjacent areas of Ohio and West Virginia. That program studied the exposed communities then used a panel of scientists to look for effects that were, and were not, found in the population. The results were then published in the scientific literature. In environmental exposure settings, the EPA has set forth criteria when medical surveillance is recommended under CERCLA[16]. Although this exposure is not covered in CERCLA, the exposures scenario in NAS is an analogous contamination of the environment of the fetus and would likely meet the criteria for establishment of a medical monitoring program if this scenario was covered under CERCLA. These criteria also provide for medical surveillance to determine as yet undiscovered associations between exposures and negative health outcomes.

Medical monitoring of exposed populations has been used for decades to track people with workplace exposures. Examples of common workplace medical monitoring programs include hearing conservation where noise-exposed workers get annual hearing tests, and if they develop hearing changes then they are further protected from noise exposure, and if their hearing loss is severe, the worker may be referred for hearing aids or even sign language classes in an effort to limit disability. Coal miners are offered chest x-rays every few years, and those developing evidence of black lung are given the opportunity to transfer to a job with lower dust exposure, with the goal of preventing progression of the black lung. A community-based example is screening children for lead poisoning in communities with lead contaminated drinking water, hosting battery manufacturers

or smelters, or with older homes with leaded paint. In the past I have crafted medical monitoring programs for a variety of scenarios listed under qualifications.

Monitoring is especially important for exposures involving children, as these can yield lifelong impacts on the children. Programs with special monitoring for children I have been involved with included Smelter impacts in Spelter WV, coal slurry injection impacted drinking water in Rawl WV, and coal mining impacted water in Seth/Prenter WV and Harts WV, and lead contamination of the community around Donora, PA.

Medical monitoring is not meant to replace usual medical care and programs should include only assessments and testing that are not routinely recommended for a similar person. Care must be used in selecting minimally invasive assessments that are acceptable to the community to promote participation.

In this case there are two goals for a medical monitoring program, the first, and most important, being to detect known long-term effects to enable early treatment, and the second is to collect data about the long-term impacts of NAS.

NOTE: There are current protocols for the assessment and treatment of narcotic-exposed children through their first year of life. It is recommended that these recommendations be followed. The first year of life will not be addressed in this recommendation.

There is no literature specifically focusing on interventions for NAS survivors. However, there is copious literature on interventions for other similar perinatal impacts, specifically prematurity. A recent Cochrine Review identified benefits from early interventions[17] in premature infants, another condition causing developmental impacts.

PROPOSED MEDICAL MONITORING AND INTERVENTION PROGRAM

The following specific program is recommended to assess and treat the lifelong effects of prenatal opioid exposure, including NAS, with the goal of giving the exposed children the best opportunity to live a normal life.

It is recommended that starting at 1 year of age a 7-part program be established and made available to impacted children, including the following (expanded below):

1. Development and delivery of an educational program for parents and caregivers focusing on potential outcomes and benefits of interventions
2. Annual Pediatrician Assessment, including specific topics
3. Specialist assessment for deficits known to be associated with NAS
4. Annual Social Worker Assessment through starting school
5. Specialty medical evaluations at appropriate intervals
6. Vocational Rehabilitation assessment and assistance
7. Data collection, analysis, and publication on the long-term effects seen in these children

1. EDUCATIONAL COMPONENT FOR CARETAKERS

Children who survived NAS are at risk of developing a broad range of developmental hazards, and often live with their parents in difficult circumstances[18], some of which are obvious while others are more subtle. The goal of this educational program, in more-or-less annual installments throughout childhood to provide information on the effects of NAS, effective strategies to address specific behaviors/manifestations, and anticipatory guidance to parents and caretakers of NAS survivors. The goal of this effort is to make caretakers more aware of the NAS-related special challenges these children may present, responses and interventions that are helpful, additional support that is available, and how/when to access additional assessments and treatment. This education program must include resources for participants with limited literacy, and no written materials should ever be above the 8th grade reading level.

2. ANNUAL ASSESSMENT - PEDIATRICIAN

Annual assessment with a pediatrician or other physician familiar with NAS through age 10. This should include:

- Growth and nutritional Assessment
- Assessment for strabismus (the cover/uncover test)
- Assessment of substance abuse risk and participation, with referral to treatment for any identified substance use

- Transportation to and from this assessment should be provided upon request.

3. EDUCATIONAL READINESS ASSESSMENT

From age 1 through starting school, the child (and their family) shall have an Annual Family Support Assessment performed by a Social Worker or other child welfare specialist. The initial screen could be done by the pediatrician, with immediate access to a social worker for further assessment for any "yellow flags".

4. ADDITIONAL (SPECIALIST) ASSESSMENTS
   - Age - about 12 months - Neurodevelopmental Assessment. This screening could be performed by local "birth-to-three" program personnel.
   - Age - about 12 months – echocardiogram to assess for Atrial Septal Defect (if not done previously)
   - Age 2 – Audiology Assessment
   - Age 3 - Ophthalmologic assessment for strabismus (per literature, limited effectiveness at younger ages[19])
   - Age 5-6 - Psychosocial Assessment (or at any age if symptomatic) Specifically looking for symptoms of ADHD and other developmental problems that could interfere with education.
   - Age 5-7 years old - Ophthalmologic Re-assessment for strabismus and need for vision correction[19].

   NOTE: Any child with a potential NAS-related abnormality identified during either the pediatrician or social worker annual assessment or in another setting (for example during an illness visit or at school), should have access to the indicated specialty assessment and treatment.

5. ADDICTION/SOCIAL RISK ASSESSMENT

   From ages 10-18, each participant shall be screened annually by a practitioner specializing in adolescent addiction and behavioral risk. The goal of this assessment is to assess overall success of the child, including home support, risk for opiate use/abuse. Any participant deemed to be at increased risk would be referred to a specialist in adolescent addiction for

assessment and potential treatment. This may include drug and alcohol testing at the discretion of the practitioner.

6. VOCATIONAL ASSESSSMENT AND RECOMMENDATIONS
   At ages 12, 15, and for 1 year following high school graduation. This assessment is intended to assist impacted children with career choice and preparation. The poor academic performance seen in studies may make post-secondary education difficult for many of these children. Early assessment will aid those children unlikely to enter college in finding a career path and preparing for a career while they are in high school to provide impacted children the best opportunity for a successful transition to adult life.

7. DATA COLLECTION, ANALYSIS, AND PUBLICATION As mentioned several times, there is limited information on the long-term effects of NAS, and effectiveness of specific interventions. The final aspect of this program would be a funded arrangement with an academic or public health organization to collect, curate, analyze, and publish the results of the assessments, interventions, and outcomes of NAS survivors. This epidemiologic component confers a medical benefit to the population.

OVERALL PROGRAM RECOMMENDATIONS:

- Participation in the entire program is voluntary, and any participant can choose to participate or discontinue participation at any time. Note that enrollment in the Registry may occur without action by the child or their caregiver, but any further participation would be voluntary.
- To facilitate participation in this program, it is recommended that as many barriers to participation be addressed as possible, including:
  a. Providing funding for transportation for assessments
  b. Providing token compensation to participants
  c. Facilitating access by offering home visits (or at a location familiar and convenient to the patient) whenever possible to both facilitate participation and to allow the assessment to consider living situation.

- Delivery of this program on a nationwide basis will require a broad network of providers. To the extent possible, this network should be formed using providers familiar with the long-term impacts and treatment for NAS.
- That any participant who fails to participate in evaluations or treatment beyond the initial screening will receive a letter communicating the recommendations for the services that were missed and a mechanism to access those services.
- In all cases, the evaluating physician/provider shall have the freedom to repeat evaluations or order confirmatory testing if there are inconclusive results or evidence of a lab error or some other reason to question the result.
- If a patient has had any of the recommended tests within the past 6 months, and the written results these can be obtained, those tests will not be repeated, and the patient-provided results used for the screening program.
- Should a non-NAS-related condition be identified, the patient will be referred to their PCP for evaluation and care.
- A patient with an abnormal finding related to the exposures will be referred to the appropriate specialist with each screening cycle.
- That a central repository of the screening, referrals, and outcomes data will be maintained, and depersonalized data made available for epidemiological evaluations. This would ideally be a function of the registry, if established.
- The screening program described here is based upon the best available medical knowledge in 2019. It is certain that in the future new technology or better understandings of the long-term effects of NAS may require updating of this program. This could be based upon changes in medical knowledge, improvements in technology to detect diseases associated with these exposures, or additional conditions of concern that are identified by the epidemiologist. This protocol should be reviewed periodically by the supervising physician or a committee appointed for that purpose to ensure that the screenings and follow-up described here remain consistent with best medical practice.

This report is based upon the information available at the time it was prepared. With the unfortunate increase in NAS cases, the scientific understanding of NAS and outcomes in NAS survivors continues to evolve. I reserve the right to update this report to reflect changes in science and medicine as necessary.

Charles L. Werntz III, D.O., MPH, FACOEM, FAOCOPM
Morgantown Occupational Medicine, PLLC

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Deposition/Testimony History of Charles L. Werntz III, D.O.

Print Date 12/1/2019

DATE	Entered Matter Via	Vendor	Case/Claimant Name	CLAIM NO / Nature	Activity	Trial Venue	Case Number
6/4/03		Pullin	Green	410-046287	Depo		
6/26/03	WV WCC IME	WV WCC	Taylor	?	Depo		
10/6/03	WC WCC IME	WV WCC	Jeffries	2002015806-INJ	Depo		
6/14/04	US DOJ	US EPA Prosecutors	US v. Mauck/Rind	DOJ File 198-83-00393	Testimony	US District Ct - Martinsburg	
7/12/04	WV WCC IME	WV WCC	Hercules	2003050641	Depo		
9/9/04	WV WCC IME	WV WCC	Grimes	2003037318	Depo		
11/16/04	WV WCC IME	WV WCC	McFadden	940039531	Depo		
1/3/05	US DOJ	DOJ/ENRD	US v. Mauck & Rind	DOJ File 198-83-00393	Trial	US District Ct - Martinsburg	
2/18/05	WV WCC IME	WV WCC	Smith	200302822	Depo		
3/1/05	WV WCC IME	WV WCC	Baker	2003055479	Depo		
7/18/05		Yablonski, Costello & Leckie	Schultz	Railroad Injury	Depo		
4/22/05	Evidence Management	Evidence Management	Rawl, WV	Water	Depo	Mingo Co, WV	
10/11-12/06	Levin, Papantonio	Levin, Papantonio	Drummond v Dupont	Expert Report	Depo	Harrison Co, WV	
11/2/06	Treatment Patient	McNeer, Higland, Roberts	Davis (Higgins)	Car Wreck	Depo	Harrison Co, WV	
1/4/07	Levin, Papantonio	Levin, Papantonio	Drummond v Dupont	Expert Report	Depo	Harrison Co, WV	
4/11/07	Levin, Papantonio	Levin, Papantonio	Perrine (Spelter, WV)	Expert Report	Depo	Harrison Co, WV	
10/2/07	Levin, Papantonio	Levin, Papantonio	Perrine (Spelter, WV)	Expert Testimony	Testimony	Harrison Co, WV	
1/15/08	Levin, Papantonio	Levin, Papantonio	Perrine (Spelter, WV)	Expert Testimony	Testimony	Harrison Co, WV	
4/10-11/2008	Thompson-Barney	Jackson Kelly	Rawl, WV	Expert Reports	Depo	Mingo Co, WV	
4/28/08	Thompson-Barney	Jackson Kelly	Rawl, WV	Expert Reports	Depo	Mingo Co, WV	
5/2/08	Thompson-Barney	Jackson Kelly	Rawl, WV	Expert Reports	Depo	Mingo Co, WV	
May 2008	Thompson-Barney	Jackson Kelly	Rawl, WV	Expert Reports	Depo	Mingo Co, WV	
6/30/08	Thompson-Barney	Thompson Barney	Jones v Concord Coll	Atty IME Report	Depo		
11/17/08	Thompson-Barney	Jackson Kelly	Rawl, WV	Expert Reports	Depo	Mingo Co, WV	
1/15/09	Thompson-Barney	Jackson Kelly	Rawl, WV	Expert Reports	Depo	Mingo Co, WV	
1/29/09	Spine Center Eval	Cipriani & Werner	Cheryl Swihart	PA WC Treating	Depo		
7/13/09	Thompson-Barney	Jackson Kelly	Chauncey, WV	Expert Reports	Depo	Logan Co, WV	
7/15/09	Thompson-Barney	Jackson Kelly	Chauncey, WV	Expert Reports	Depo	Logan Co, WV	
11/17/09	Treating Physician	Neil J. Marcus, Esq	Anthony Burnsworth	PA WC Treating	Depo		
12/7/09	Barton, Kilgore, & Lazenby	Barton, Kilgore, & Lazenby	Lusk, et al	Expert Report	Depo		
2/8/10	Examining Physician	Bailey & Wyatt, PLLC	Elizabeth Julio	Examining Physician	Depo		
5/26/10	Caldwell Practice	Caldwell Practice	Nitro, WV	Expert Report	Depo	Kanawha Co, WV	
7/19/10	Examining Physician	Bailey & Wyatt, PLLC	Elizabeth Julio	Examining Physician	Video Testimony	Brooke Co, WV	
1/14/11	Thompson-Barney	Jackson Kelly	George Keller	Treating Physician	Phone Depo		
1/19/11	Thompson-Barney	Jackson Kelly	Marsh Fork School	Expert Report	Depo	Raleigh Co, WV	
2/24/11	Thompson-Barney	Jackson Kelly	Marsh Fork School	Expert Report	Depo	Raleigh Co, WV	
3/17/11	Thopmson-Barney	Thompson-Barney	Marsh Fork School	Expert Testimony	Daubert Hearing	Raleigh Co, WV	
3/18/11	Thompson-Barney	Thompson Barney	Marsh Fork School	Expert Testimony	Testimony	Raleigh Co, WV	
5/4/11	Levin, Papantonio	Levin, Papantonio	Callie Savage	Expert - Med Mal	Depo	Osceola Co, FL	
6/14/11	Thompson-Barney	Thompson Barney/JK Split	Rawl, WV	Expert Reports	Depo	Mingo Co, WV	
12/15/11	IME Physician	Jackson Kelly	Danielle Pettie	IME Report	Depo		
12/29/11	Treating Physician	Cipriani & Werner	Sal Bombardiere	Treating Physician	Depo	US Dist Ct N. WV (Wheeling)	
2/23/12	Smith Stag	Spilman Thomas	Hagy Family	Expert Reports	Depo		
3/1/12	Smith Stag	Spilman Thomas	Hagy Family	Expert Reports	Depo		
3/12/12	Sutter Law Firm	Jackson Kelly	Seth/Prenter	Examining Physician	Depo	Boone Co, WV	
3/19/12	Sutter Law Firm	Jackson Kelly	Seth/Prenter	Examining Physician	Depo	Boone Co, WV	
4/16/12	Sutter Law Firm	Jackson Kelly	Seth/Prenter	Expert Reports	Depo	Boone Co, WV	
4/26/12	Sutter Law Firm	Jackson Kelly	Seth/Prenter	Expert Reports	Depo	Boone Co, WV	
5/7/12	Sutter Law Firm	Jackson Kelly	Seth/Prenter	Expert Reports	Depo	Boone Co, WV	

Deposition/Testimony History of Charles L. Werntz III, D.O.				Print Date	12/1/2019			
DATE	**Entered Matter Via**	**Vendor**	**Case/Claimant Name**	**CLAIM NO / Nature**	**Activity**	**Trial Venue**	**Case Number**	
5/23/12	Treating Physician	Blank Rome	Sal Bombardiere	Treating Physician	Depo	US Dist Ct N. WV (Wheeling)		
7/11/12	Levin Papantonio	Levin Papantonio	Callie Savage	Expert Report	Trial Testimony	Escambia Co, FL		
9/18/12	Jackson Kelly	US DOL	David Thomas	Black Lung Exam	Depo	Federal Black Lung		
11/??/2012	Napoli Bern		Sal Bombardiere	Expert Report	Depo	US Dist Ct N. WV (Wheeling)		
3/4/13	US DOL Black Lung Exam	Jackson Kelly	Delmar Hagedorn	Examining Physician	Depo	Federal Black Lung		
3/4/13	Napoli Bern	Napoli Bern	Sal Bombardiere	Expert Physician	Trial Testimony	US Dist Ct N. WV (Wheeling)		
10/9/13	Mark McMillan		McGhee	Expert Physician	Depo			
9/3/14	Evaluating Physician	Steptoe & Johnson	Tetryl (Isaacs, Morris)	Examining Physician	Depo			
10/15/14	Treating Physician	Bowles Rice	Terry Henry	Treating Physician	Depo			
8/17/15	Record Review	Bland & Bland	Edna Brown	Records Review	Depo	Kanawha Co, WV	14-C-427	
10/21/16	Reed Smith	Spilman, Thomas & Battle	Francis Ice	Expert Reports	Depo	Harrison Co Circuit, WV		
2/27/17	Schrader, Byrd, & Companion	Schrader, Byrd, & Companion	Thomas Standiford	Expert Reports	Evidentiary Depo	Wetzel Co Circuit, WV	15-C-12	
6/12/17	Toriseva Law	Schrader, Byrd, & Companion	Gary Beagle	Examining Physician	Depo	Wetzel Co Circuit, WV	15-C-41	
4/17/18	Hartley Law Group	Bailey & Wyatt, PLLC	Dora Carbajal-de-Vences	Examining Physician	Depo	Berkeley Co, WV	17-C-98	
10/29/18	US DOL Black Lung Exam	Jackson Kelly	Jackie Easter	Examining Physician	Depo	Federal Black Lung		
12/20/18	Thompson-Barney	Bonnet Fairbourn Friedman & Balint PC	Arkema Chemicals	Expert Reports	Depo	Federal Court - Texas		
12/31/18	Angotti & Straface	Pullin, Fowler, Flannigan, et al	Dominic Muttillo	Treating Physician	Depo	Monongaalia Co Circuit WV	16-C-197	
11/4/19	US DOL Black Lung Exam	US Department of Labor	Daniel Baker	Examining Physician	Depo	US DOL ALJ	2019-BLA-05517	

Marc Dann Declaration in Support of Motion for Class Certification

Exhibit 7

CURRICULUM VITAE

PERSONAL DETAILS

Name: Professor Charles Vyvyan HOWARD

Address: Centre for Molecular Biosciences
University of Ulster
Cromore Road
Coleraine, BT52 1SA

Date/Place of Birth: 22nd May 1946, Blackpool, UK

Nationality: British

RESEARCH METRICES

Google Scholar 21/06/2019: Publications 140: citations 8662; h-index 38; i10-index 86

FURTHER/HIGHER EDUCATION

Education: 1965-70 University of Liverpool: Faculty of Medicine. MB ChB

Qualifications: 1970 MB ChB, Liverpool
1971 Full General Medical Council Registration
1983 Ph D, Liverpool in developmental neurobiology
1995 MRCPath
1999 FRCPath

WORK EXPERIENCE

1970 - 1971 House Officer, Sefton General Hospital, Liverpool
1971 - 1975 Demonstrator in Anatomy, University of Liverpool
1975 - 1991 Lecturer in Anatomy, University of Liverpool

1991 – 2005	Senior Lecturer in Anatomy, University of Liverpool
2005 - 2014	Professor of Bioimaging, University of Ulster
2014-	Emeritus Professor of Bioimaging, University of Ulster

MEMBERSIP OF PROFESSIONAL BODIES

Fellow: - Royal College of Pathologists
- Royal Microscopical Society
- Collegium Ramazzini

Member: - British Society of Toxicological Pathologists

POSITIONS HELD ON PROFESSIONAL BODIES

1985-1992 General Editor, Journal of Microscopy
1991-1995 President International Society for Stereology
1996-1998 President Royal Microscopical Society
2003-2009 Member DEFRA Advisory Committee on Pesticides
2004-2006 Founding Editor of the journal 'Nanotoxicology'
2007-2009 President International Society of Doctors for the Environment

RESEARCH INTERESTS

Vyvyan Howard is a medically qualified pathologist with interests in low dose minimal change toxicology, particularly of the fetus and neonate. He has worked for many years in the field of developmental neurotoxicology, including the actions of pharmaceutical agents, pesticides and environmental pollutants. He is an expert on the quantification of toxicological change with the use of stereology. He has a long founded interest and expertise in imaging living processes through the use of microscopy. Recently he has held major grants for investigating the toxicology of nano-particles in biological systems. He has experience in regulatory toxicology, having served 6 years on the Advisory Committee on Pesticides in the UK. He has recently been appointed an expert in toxicology by the National Standards Authority of Ireland (NSAI) as a Member of the CEN/TC 436 Technical Committee addressing cabin air quality in commercial aircraft.

RESEARCH FUNDING WHILE AT University of Ulster

2006 – 2008 £250,000 STREP project 'Nanointeract' under EU Framework 6. Part of a € 3.3 million multicentre study on the fate and toxicity of engineered nanoparticles

2008 -2011 Organix Foundation £120,000 to investigate the effect of low dose exposure to hormone disrupting pesticides on fetal development

2008 – 2011 €420,000 EU FP7 grant NeuroNano to investigate the effect of nano-particles on the progression of Alzheimer's disease in a mouse model.

2010-2013 NC3R/MRC £360,000 to develop a 3D tissue model of human breast tissue for the testing of xenoestrogens.

Honours:

1989 - Awarded Royal Microscopical Society 150th Anniversary Gold Medal for services to microscopy.

1999 - Overall Winner, Caroline Walker Trust 11th Annual Awards for improving public health through food.

PUBLICATIONS

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'The numerical densities of alpha and gamma motoneurons in the trigeminal motor nucleus of the rat: A method of determining the separate numerical densities of two populations of anatomically similar cells.' *Mikroskopie (Wien)*, **37** (Suppl.), 220236

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'Experimental and theoretical evaluation of size distributions'. *Stereol.Iugosl*., **3**/Supplement 1, 7988

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'On the functional significance of the third moment of size distribution in biological systems.' *Stereol.Iugosl*., **3**/Supplement 1, 503510

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'The determination of the length densities and size distributions of blood and air capillaries in the avian lung involving a log normal fitting procedure.' *Stereol.Iugosl*., **3**/Supplement 1, 673678

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'The numerical densities of alpha and gamma motoneurons in lamina IX of the cervical cord of the rat: a method of determining the separate numerical densities of two mixed populations of anatomically similar cells.' (1981). Eleventh International Congress of Anatomy: Advances in the Morphology of Cells and Tissues, 173-183. E.A. Vidrio & M. A. Galina (Eds.). Alan R. Liss, N.Y.

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'The separate numerical densities of alpha and gamma motor- neurones in the spinal cord of the rat.' (1981). *Sterol. Iugosl* **3**/suppl 1: 503510.

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'The concept of 'Neuromorphotaxis' based on a minimisation principle. A case for the critical analysis of biological variation.'. *Acta Stereol*.**1**: 241252.

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'The use of horseradish peroxidase (HRP) in the stereological analysis of motor nuclei.' *Acta Stereol.* **1**: 253258

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PhD THESIS: 'Neuromicrosis: a process affecting the phylo- and ontogenetic development of the brain. An hypothesis based on stereological studies of neurone population characteristics.' The University of Liverpool. 1983.

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'Some empirical functions for use in the parametric modelling of stereological size distributions.' (1983). *Acta Stereol*, **2**: 187192

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'The relationship between Purkinje cell diameter and position within the cerebellar folia of the rat: a stereological analysis.' (1983). *Acta Stereol*.**2**:219222

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'Software solutions to problems in stereology.' (1984). *Acta Stereol*, **3**: 139158

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'Population characteristics of nerve cell bodies illustrated by the postnatal development of cerebellar granule cells in the rat.'. Quantitative Neuroanatomy in Transmitter Research. Eds. Agnati L.F. and Fuxe K. Macmillan, London. pp 4154

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'Unbiased estimation of particle density in the Tandem Scanning Reflected Light Microscope.' (1985). *J. Microsc*. **138**, 203 212

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'Rapid nuclear volume estimation in malignant melanoma using point-ampled intercepts in vertical sections.'. In: Quantitative Image Analysis in Cancer Cytology and Histology. Eds. Mary, J.Y. and Rigaut, J.P. Elsevier Science Publications B.V. pp. 245254

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'Unbiased measurements in electron microscopy.'. *Inst. Phys. Conf. Ser*. **93**, 4957.

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'A simplification of the step method for measuring mean section thickness.'. *J. Microscopy*. **154**: 289293

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'An interactive image analysis system for measuring mean particle volume.' . *J. Microscopy*. **156**: 7990

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'The total numbers of neurons in human neocortex unbiasedly estimated using optical disectors.'. *J. Microscopy*.**157**: 285304

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'Correlating structure with function in developmental neurology using stereological and confocal microscopical techniques.'. Science on Form. Ed. S. Ishizaka. KTK Scientific Publishers, Tokyo. pp 3137.

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'Improvements of 3D confocal microscope images by geostatistical filters.'. *Trans Roy Mic Soc*. **1**: 281284.

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'The use of basic morphological operations for 3D biological image analysis.'. *Trans Roy Mic Soc* **1**: 293296.

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'Digital stereology - a comparative study of digital stereological surface density estimators.'. *Trans Roy Mic Soc* **1**: 315319.

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'Human Intrauterine Renal Growth expressed in absolute number of glomeruli assessed by the 'Disector' method and Cavalieri principle.'. *Lab Invest* **64**: 777784.

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'Estimating the length of a bounded curve in 3D using total vertical projections.' *J. Microsc*. **163**: 101114.

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'Digital probes for three dimensional microstructural analysis.'. *Machine Vision and Application* **4**: 255261.

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'Automatic 3-D disector sampling for volume distribution measurements.' *Acta Stereol* **11**: 215220.

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DR. C. V. HOWARD'S DECLARATION IN SUPPORT OF CLASS CERTIFICATION

1)Background

This is a report is prepared for the benefit of the Court.[1] I have been asked to prepare a report addressing the effects of opioids on the developing fetus. I understand my duties as an Expert witness pursuant to Part 35 of the Civil Procedure Rules; a statement of truth is enclosed following my opinion below.

I am a medically qualified toxico-pathologist specialising in the problems associated with the action of toxic substances on health, particularly during the period of development in the womb. My PhD Thesis addressed mechanisms of the selective stabilisation of neurons in developing mammalian brain. I am currently Emeritus Professor of Bioimaging at the University of Ulster and have authored/co-authored over 130 peer reviewed scientific papers, predominantly in the field of quantitative developmental toxicology. I append my Curriculum Vitae.

I am a Fellow of the Royal College of Pathologists, Fellow of the Collegium Ramazzini, Past President of the Royal Microscopical Society, Member of the British Society of Toxico-Pathologists, Past President of the International Society of Doctors for the Environment. I served for 6 years as a toxicologist on the United Kingdom Government DEFRA Advisory Committee on Pesticides which was the statutory body responsible for recommending licensing of agro-chemicals. I have addressed the House of Lords Select Committee on Science and Technology investigating the use of nanotechnology in food. More recently I have given evidence to the House of Commons Environmental Audit Committee on the toxicology of neonicotinoid pesticides to pollinating insects. This resulted in their report 'Pollinators and Pesticides' (HC 668, 2012-13).

Toxico-pathologists are skilled in assessing the effects of toxic substances on health. This includes consideration of routes of entry for toxic substances into the body, assessing the relevance of dose and timing of administration, target organ susceptibility, mechanism of action of toxins, types of pathology induced and dose response, with respect to single substances and mixtures. Such expertise is of relevance in this action because it concerns exposure of the fetus during intra-uterine life to opioids taken by the mother. Opioids have been shown to be able to increase the rate of apoptosis in developing neurons and this has a number of long-term sequelae. This pathological mechanism is within the scope and expertise of toxico-pathologists.

2)The Opioid Receptor (OR)

The opioid receptor system is ubiquitous throughout all vertebrate (animals with backbones) life. Opioid receptors consist of a family of four related proteins which are part of a large superfamily, the rhodopsin-like G-protein coupled receptors. Of the four related proteins, three types of opioid receptor unequivocally are associated with the control of pain in animal models.

[1] This report was developed in collaboration with Dr. Christopher Busby.

These are the □(MOR), □ (DOR) and □ (KOR) opioid receptor proteins. There is a fourth opioid receptor protein which is termed the nociception or orphanin (ORL) whose function is less well defined than the other three. The receptors have natural internally produced (endogenous) opioid peptide ligands which include beta-endorphin, met-and leu-enkephalin and dynorphin. The role of the endogenous opioid receptors on normal physiological activity is extensive; in addition to the obvious role in decreasing painful (nociceptive) sensations they are involved in reproduction, growth, development, respiration, blood pressure regulation, renal function, temperature control, hormonal regulation, seizures, stress, immune response, pregnancy and aging.

Phylogeny:
The OR developed at least 450 million years ago, at the time of the evolutionary emergence of vertebrates with jaws. Early in the evolution of animals there was a single opioid receptor. The first round of genome duplication, which occurred early in cordate evolution, produced the ancestral DOR/MOR and ORL/KOR genes. A further round of genome duplication led to the four opioid receptors found in all living vertebrates (Stevens, 2011). These four ORs are ubiquitous throughout vertebrate phylogeny and intimately involved in the control of reward responses and pain modulation as well as controlling aspects of ontogeny.

3)Opioid Drugs: pharmacology and commonality

Opioids have been used to alleviate pain for thousands of years and remain the most important class of pain-relieving drugs. Opioids exert their effects by mimicking naturally occurring substances in the body, called *endogenous opioid peptides* including *endorphins*. The different functions of this system include
(1) the best-known sensory role—prominent in inhibiting sensory responses to pain
(2) a modulatory role in gastrointestinal, endocrine and autonomic functions, and
(3) and an emotional role, evidenced in powerful rewarding and addictive properties.

Therefore, opioid activity is not restricted to pain relieving effects but in addition exhibit powerful and wide-ranging regulatory roles throughout the organism (Gutstein and Akil, 2006; Stein (2016); Stevens 2011).

In order to understand the effects of the opioids we begin with the production and distribution of the endogenous opioid peptides, since it is these which are mimicked by the opioid drugs which interact with the natural receptors (biological switches). The endogenous opioids are in three distinct families, *the enkephalins, the endorphins and the dynorphins* (Gutstein and Akil, 2006). These substances are small peptides which share a common amino terminal sequence of Tyr-Gly-Gly-Phe-Met (or Leu). This has been termed the *opioid motif* and is followed by various C-terminal extensions yielding peptides ranging from 5 to 31 residues (Gutstein and Akil, 2006).
The precursor protein for Beta Endorphin, *prepro-opiomelanocortin* (POMC) is relatively limited within the Central Nervous System, occurring mainly in the arcuate nucleus and nucleus of the tractus solitarius. These neurons project widely to limbic and brainstem areas and to the spinal cord (Gutstein and Akil, 2006).

The endogenous opioids exert their functions at protein receptors distributed in the brain, and these are the points where the opioid drug molecules, whether natural or synthetic also bind and have pharmacological activity. Opioid receptors consist of a family of four closely related proteins belonging to a large family of receptors called the G-protein coupled receptors. Receptors are large protein molecules which selectively bind pharmacological agents in order to switch on cellular activity that results in a measurable change in some aspect of the cell and the organism. The receptor can be seen as a molecular specific switch. It is believed that specific affinity between the active molecule and the receptor, which occurs only for molecules which can affect the receptor switch positively (termed *agonists*) and produce the effect, defines a class of compounds which have commonality. That is, they have the common molecular nature of causing the process being measured to occur (to a greater or lesser extent). This greater or lesser extent is a function of their *activity* and is measurable. Pharmacologists measure the effect, and plot this against the logarithm of the drug Dose. If the substance is acting at the same receptor, the result is a straight line, (for technical reasons which will not be addressed here). They are termed agonist (for the specific receptor). Compounds which bind to the same receptors but do not cause effects, rather they block the effects of the agonist, are termed antagonists. These also help define a common receptor. More recently, genetic approaches have also characterised families of opioid receptors and described their evolution in both mammalian and invertebrate evolution. Therefore, it is possible to say that the opioids and synthetic opioids, whatever their molecular structure, exert their influence at the same receptor(s) and may thus be considered as a common group (Creeley et al, 2013; Gutstein and Akil, 2006).

There are now considered to be three main types of receptor, termed classical types, the μ, κ and δ. All three have analgesic properties, the μ type causes euphoria, decreases respiratory function and gastrointestinal tract transit (constipation), increases feeding, increases sedation, increases release of growth hormone and prolactin, inhibits neurotransmitter release (acetylcholine and dopamine) and has various other peripheral effects. These examples show the profoundly powerful effects throughout the organism which are modulated by the opioids. It also shows how exposure to, and withdrawal from these species exhibits such wide-ranging effects. All three opioid receptors can modulate pre- and post- synaptic Ca++ channels, supress Ca++ influx and thereby attenuate the excitability of neurons and the release of pro-nociceptive neuropeptides (Gutstein and Akil, 2006). This behaviour is revisited below.

Identity and molecular structure of the opioids (https://webbook.nist.gov/cgi/cbook/).

The medicinally developed opioids are in two groups, those derived from natural products by chemical treatment or separation and those developed by chemical synthesis in order to have affinity and access to the various opioid receptors discussed. The search by pharmaceutical companies and others for substances which produced the analgesic and other valuable effects without side effects or the induction of dependence has been largely unsuccessful. Investment in research into substances which would act as treatments for addiction to morphine and the more powerful narcotic opioids resulted in the discovery and use of methadone and buprenorphine. However, these themselves also result in addiction and withdrawal effects. They are the agents of choice in some schemes of treatment for NAS. The molecular structures of all these compounds are designed to have affinity for the opioid receptors and therefore may

be considered to be one group for the purposes of arguing their membership of the "NAS producing group" of chemical substances. Most of them are semi-synthetic compounds made by chemical treatment of morphine itself or morphine alkaloids like Thebaine (Gutstein and Akil, 2006; O'Brien, 2006; Oates, 2006).

The principal opioids of concern in the current discussion are given in Table 1.

Table 1. Principal opioids associated with NAS (*examples of trade preparations*) [https://webbook.nist.gov/cgi/cbook/].

Opioid	**Nature**	**Note**
Morphine	Main alkaloid constituent of opium; historic medicinal compound. *Avinza, Morphabond, Roxanol-T, Kadian, Mscontin*	Natural substance, main member of the opium poppy alkaloids which also include Thebaine Papaverine.
Hydrocodone	derived from morphine alkaloids. Semi synthetic. *Zohydro ER, Hysingla, Anexsia, Co-gesic, Ibudone, Norco*	Semisynthetic hydrogenated codeine derivative and opioid agonist with analgesic and antitussive effects. Hydrocodone primarily binds to and activates the mu-opioid receptor in the central nervous system (CNS).
Hydromorphone	Also called Dilaudid. Hydromorphone is the hydrogenated ketone of morphine, semi synthetic. *Dilaudid, Palladone,*	Hydromorphone selectively binds the mu-opioid receptor which is linked through G-proteins. Binding stimulates the exchange of guanosine triphosphate (GTP) for guanosine diphosphate (GDP) on the G-protein complex and interacts with and inhibits adenylate cyclase located at the inner surface of the plasma membrane. This leads to a reduction in intracellular cyclic 3',5'-adenosine monophosphate (cAMP). Further, voltage-gated potassium channels are activated, thereby causing hyperpolarization and reducing neuronal excitability. In addition, the opening of voltage-gated calcium channels is inhibited, thereby leading to an inhibition of calcium entry and a reduction in the release of various neurotransmitters, including GABA, vasopressin, somatostatin, insulin and glucagons.
Meperidine	Synthetic *Demerol*	Meperidine is a synthetic piperidine ester with opioid analgesic activity. Meperidine mimics the actions of endogenous neuropeptides via opioid receptors, thereby producing the characteristic morphine-like effects on the mu-opioid receptor, including analgesia, euphoria, sedation, respiratory depression, miosis, bradycardia and physical dependence.
Fentanyl	Synthetic *Abstral, Actiq, Fentora, Onsolis, Sublimaze, Duralgesic*	Powerful synthetic opioid 100 times more powerful than morphine in pain relief
Codeine	Derived from morphine by methylation of the phenolic -OH.	Naturally occurring phenanthrene alkaloid and opioid agonist with analgesic, antidiarrheal and antitussive activities. Codeine mimics the actions of endogenous

		opioids by binding to the opioid receptors at many sites within the central nervous system (CNS). Stimulation of mu-subtype opioid receptors results in a decrease in the release of nociceptive neurotransmitters such as substance P, GABA, dopamine, acetylcholine and noradrenaline; in addition, the codeine metabolite morphine induces opening of G-protein-coupled inwardly rectifying potassium (GIRK) channels and blocks the opening of N-type voltage-gated calcium channels, resulting in hyperpolarization and reduced neuronal excitability. Stimulation of gut mu-subtype opioid receptors results in a reduction in intestinal motility and delayed intestinal transit times. Antitussive activity is mediated through codeine's action on the cough center in the medulla
Buprenorphine	Synthetic analogue of Thebaine from poppy alkaloids *Butrans*	Buprenorphine is a morphinane alkaloid that is 7,8-dihydromorphine 6-O-methyl ether in which positions 6 and 14 are joined by a -CH2CH2- bridge, one of the hydrogens of the N-methyl group is substituted by cyclopropyl, and a hydrogen at position 7 is substituted by a 2-hydroxy-3,3-dimethylbutan-2-yl group. It has a role as an opioid analgesic, a mu-opioid receptor agonist, a kappa-opioid receptor agonist and a delta-opioid receptor antagonist.
Methadone	Synthetic *Dolophine, Methadose*	Methadone is a synthetic opioid with analgesic activity. Methadone mimics the actions of endogenous peptides at CNS opioid receptors, primarily on the mu-receptor and has actions similar to those of morphine and morphine-like agents. The characteristic morphine-like effects include analgesia, euphoria, sedation, respiratory depression, miosis, bradycardia and physical dependence. However, the detoxification symptoms between morphine-like agents and methadone differ in that the onset of methadone's withdrawal symptoms is slower, the course is more prolonged and the symptoms are less severe.
Oxycodone	Semi synthetic. Derived from opium alkaloid Thebaine. *Oxaydo, Xtampza ER, Oxycontin, Percodan, Percoset,*	Oxycodone is a semi-synthetic, morphine-like opioid alkaloid with analgesic activity. Oxycodone exerts its analgesic activity by binding to the mu-receptors in the central nervous system (CNS), thereby mimicking the effects of endogenous opioids.
Oxymorphone	Semi synthetic. Now taken off market in USA (2017) *Opana, OpanaER*	A semisynthetic opioid with a potent analgesic property. Oxymorphone hydrochloride binds to and activates opiate receptors, specifically mu-receptors, in the central nervous system (CNS).
Heroin	Semi synthetic. Illegal in USA.	Heroin is a morphinane alkaloid that is morphine bearing two acetyl substituents on the O-3 and O-6 positions. As with other opioids, heroin is used as both an analgesic and a recreational drug.

Summary of pharmacology

The opioid compounds all act at the same biological receptors and mimic natural peptides which have powerful and wide-ranging activity in living systems. Thus, they can be considered a class of chemical drugs both in terms of their pharmacological dosage activity relationships and also their overall chemical structure. They produce common effects, bind to common receptors, the opioid receptors and also have similar chemical structures. They all produce addiction and dependence and cause withdrawal symptoms on removal. Their activity as modulators of neurological signalling make them especially hazardous in adults due to rebound effects but also they are now known to have significant effects on foetal development since they alter the cellular signalling environment. This issue will be considered below.

4)Dependence and withdrawal in opioids: pharmacology (O'Brien, 2006)

All perturbations of homeostatic systems that last a significant length of time result in two responses. The first is acquired tolerance, which results in a situation where larger doses of the stressor (in this case the opioid drug) are required to effect the same physiological response. The second results from the homeostatic pressure developed by the organism to retain the system's biological status prior to the disturbances created by the perturbation, in this case the chronic use of an opioid drug and the changes brought about in the various systems affected by the receptors. This physical dependence is often termed "Rebound" and is a common feature of withdrawal of all drugs which have Central Nervous System (CNS) effects. Thus, CNS hyperarousal results from re-adaptation to the absence of the drug of dependence (O'Brien, 2006). Since the effects produced by the opioids are so widespread (due to the systems that are perturbed through the 3 natural opiate receptors (at least these: more have been described) the withdrawal of the opioid alteration pressure leads to profound and painful mental and physical effects across a wide spectrum of conditions. Examples of the effects seen in adults are given in Table 2. In Table 3 are listed withdrawal effects seen in babies manifesting NAS. Naturally the same rebound effects are manifest in the babies as exist in the adults.

Table 2 Withdrawal effects in adults seen in opioid removal after chronic use **(O'Brien, 2006)**

Regular withdrawal	**Protracted withdrawal (persist up to 6 months after removal of drug)**
Craving for opioids	Anxiety
Restlessness, irritability	Insomnia
Increased sensitivity to pain	Drug craving

Nausea	Pupillary dilation
Cramps	Sweating
Muscle aches	Piloerection
Dysphoric mood	Tachycardia
Insomnia	Vomiting
Anxiety	Diarrhia
	Yawning
	Fever
	Cyclic changes in weight
	Pupil size

Table 3 Observed NAS withdrawal effects (Wolff K, Perez Montenajo R, 2014)

Effect	**Number of studies reporting 1972-2007**
Neurological Excitability	
High pitched crying	8
Irritability	8
Increased wakefulness/sleep disturbance	8
Hyperactive deep tendon reflexes	9
Hypertonia	6
Exaggerated Moro Reflex	3
Tremors	9
Seizures	9
Myoclonic jerks/ opisthotonic posturing	5
Hyperacusis	1
Intraventricular haemorrhage	1
EEG abnormalities	1
Gastrointestinal dysfunction	
Poor feeding	8
Uncoordinated and constant sucking	7
Vomiting	10
Diarrhoea	10
Dehydration	4
Regurgitation	1
Poor weight gain/ weight loss	6
Hyperphagic (2^{nd} week)	0
Excessive salivation	1
Central nervous system	
Increased sweating	8
Yawning	9
Nasal stuffiness	5
Sneezing	9
Tachypnea	6
Mottled skin	5
Fever	7
Temperature instability	3
Other	
Increased REM sleep	2

Skin excoriating/ scratching	5
Tachycardia/ hypertension	1

These effects are common to withdrawal in the case of all the opioids since these substances act on the same receptors. Of course, there are differences in activity between the various opioid drugs, some having very powerful effects at very low doses relative to morphine, the parent substance, and there is also a variation in the length of time the compound has its effect owing to variations in length of binding to receptors and other factors. The drug Methadone has a much longer period of action so it was chosen (or indeed developed) to act as a drug of choice for dealing with withdrawal from the more immediate effects of morphine and in particular the street drug Heroin. Buprenorphine also has a similar long lasting effect and is used as an alternative to Methadone for reducing the withdrawal effects listed in Tables 2 and 3. However, since both these drugs affect the same receptors that cause the withdrawal effects, it is arguable that their use may produce the same conditions that they are intended to treat. A list of analgesic activity for the various opioids is given in Table 4.

Table 4 Equianalgesic doses for some opioids.

Compound	**Route**	**Dose mg**
Codeine	PO	200
Hydrocodone	PO	20-30
Hydromorphone	PO	7.5
Hydromorphone	IV	1.5
Morphine	PO	30
Morphine	IV	10
Oxycodone	PO	20
Oxycodone	IV	10
Oxymorphone	PO	10
Oxymorphone	IV	1
Fentanyl	Nasal spray/ lozenge	0.1-0.2

5)Apoptosis

It is important to introduce an aspect of basic biology which is of fundamental significance in fetal development. There are two ways in which cells in multicellular organisms can die. One is called ‘necrosis’ – for example if one of the coronary arteries blocks and deprives the heart muscle of oxygen, it will die by necrosis – which is a pathological process. The other mechanism is called ‘apoptosis’, otherwise known as ‘programmed cell death’. This is part of normal biology, particularly during development. For example, almost all individuals had a tail at one stage of fetal life but in almost everybody it melts away by the process of programmed cell death. The hands were solid discs of tissue in their early development but the fissures between the digits appear because of apoptosis remodelling the original disc. There are three basic functions that apoptosis serves:

1) Phylogenetic apoptosis – deletion of vestigial structures
2) Histogenetic apoptosis – controlling cell numbers in the body

3) Morphogenetic apoptosis – remodelling structures

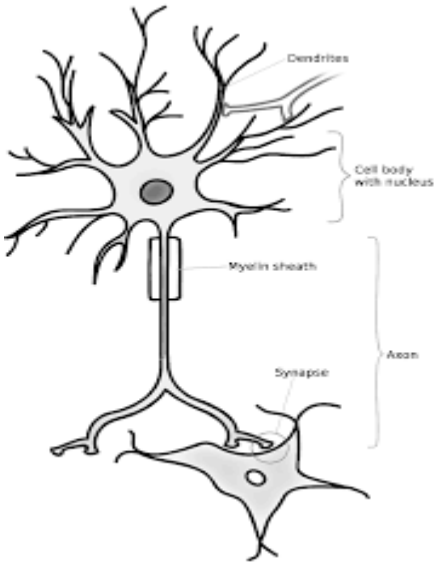
Histogenetic apoptosis is the predominant mode found in the adult. Phylogenetic and morphogenetic apoptosis predominate in the fetus and are indispensable for normal development. Sub optimal brain development and gross malformations (birth defects) have been associated with perturbations of apoptosis.

The Central Nervous System (CNS)

It is important that animal experimental data, as well as human data, is considered when addressing the impact of opioids on developing human brain. Opioid receptors are present in a number of different brain regions and there are several possible mechanisms that opioid exposure could perturb brain development (Yanai et al., 2003). Alterations in the migration and survival of neurons in rat embryos has been demonstrated with exposure to opiates (Harlan, R. E. & Song, D. D., 1994). In vitro studies on human fetal neurons and microglia responses to morphine have been shown to have increased levels of apoptosis [Hu et al., 2002). Reduction in anatomical volumes and cortical thickness when compared to controls in children with heroin and polysubstance exposure

The central nervous system is particularly vulnerable to toxic insult for a number of reasons. The nerve cells that are a component of the adult brain have to last a life time. The adult neuron has a cell body from which a single axon (final common pathway) arises and this conducts a pulse modulated signal on to the next nerve cell in the chain. Whether or not a neuron depolarises to produce the next pulse in the signal chain going down the axon depends on an averaging of all synaptic inputs, excitatory and inhibitory, over the whole receptive surface of the nerve cell, which includes the cell body and the dendritic tree.

Many other organs in the body, for example the liver, can repair by cell proliferation. This does not apply to the nerve cells in the adult CNS, by far the majority of which cannot reproduce themselves. This statement does not hold true for the fetal brain nerve cells, as will be outlined below. The CNS has a very high metabolic rate and neurons have to maintain their microstructures over long distances. For example the axon, which carries outgoing signals from the neuron can be over 1 meter long. To maintain such structures in a healthy state there is a mechanism called ‘axonal transport’ which will deliver a number of substances and structures – in both directions to and from the neuron cell body. Transmitter substances help to deliver information across synapses to the next neurons in the neuronal chain by acting in either an excitatory or an inhibitory manner. The influence of a particular synaptic input onto a neuron will depend on its position on the target neuron and on the firing rate of the axon. ‘Neurotrophins’ are also secreted across the synapse and are essential to maintain the target neurons in good health. Mitochondria are the ‘powerhouses’ in which glucose is metabolised and maintain the high metabolic rate essential for neuronal health, even in the most distant parts of the nerve cell. ‘Neuromodulators’ are a class of biomolecules, to which the endogenous opioids belong, modify the action of transmitter substances at synapses.



6)The relevance of perturbing apoptosis in fetal brain

There are of the order 1015 connections between nerve cells in the adult human central nervous system (CNS). However, humans only have ~ 20,000 genes, which in addition also have to control many other aspects of development. This inevitably means that the development of the brain cannot be determined by the genome alone – there is a massive numerical mismatch. Therefore, nature has evolved a method of arriving at an intact functioning CNS which depends upon a highly probabilistic (chance) based mechanism, which is relatively loosely specified by the genes. The genes control the overall global form of the brain while, at the local level, whether developing cells live or die is decided predominantly by chance.

The importance of synapse formation in the development of brain circuitry was first posited by Changeaux and Danchin (1976) in their theory of 'selective stabilisation'. A more contemporary review has been written by Tau & Peterson (2010). Selective stabilisation involves the loss of a proportion the neurons in a developing brain region, based upon their functional status during critical developmental windows.

In the developing nervous systems of animals (including humans) there is an overproduction of neuroblasts (immature potential neurons) – often more than twice as many as will be finally required in the adult. These start to push out neurites (fibre-like feelers) that make contact with other developing nerve cells in that brain region. Some of the contacts they make at random will be excitatory and others will be inhibitory. At certain developmental times, cell signalling instructions will be broadcast within regions of the CNS and those nerve cells with the correct physiological properties (for example the firing rate of the nerve cell) will carry on with their normal development and the other developing nerve cells which are either under-responsive or over-responsive will undergo apoptosis and melt away. This process is known as 'selective stabilisation'. From this description it can be appreciated that this is largely based on chance connections between too many potential neurons and it leads to a stable functioning circuitry within the CNS with minimal deterministic instructions at the local level from the genes. The mechanism(s) controlling apoptosis in the developing fetal

brain are incompletely understood. However, many cell signalling molecules –including transmitter substances, neuromodulators and hormones are known to be involved. An important harbinger of impending apoptosis in a cell is the appearance of Fas protein being expressed on the cell surface. When this binds with Fas protein ligand (FasL) apoptosis is initiated.

From all of the above it is possible to appreciate how a drug that stimulates nerve cells could act as an 'excitotoxin' in the fetal brain while a neuronal depressant would work the other way. Both of these scenarios result in increases in the proportion of nerve cells undergoing cell death though apoptosis during windows of vulnerability as fetal development progresses. The final outcome in the adult, if this happens, will be sub-optimal development. Reed et al (2010) provide a morphological example. Opioids appear to increase the rate of apoptosis in fetal brain. This is a potential mechanism for neurological damage in the fetus.

Important points to note are:

1) Adverse changes incurred through increased apoptosis are irreversible
2) They generally take place at toxicant concentrations orders of magnitude lower than required to produce damage in an adult.
3) The timing of the toxic insult in the fetal developmental timetable is critical, as it passed through sequential windows of vulnerability

The effects of prenatal exposure to opioids has been reviewed by Anand and Cambell-Yeo (2015). It leads to changes in the temporal sequencing and quality of myelination by disrupting oligodendrocyte development (Svensson et al, 2008). It also decreases the dendritic growth (Nassogne et al, 1885)) and branching pattern complexity (Broussard et al, 2011) of pyramidal neurons in the cortex and suppresses cell proliferation and neuronal migration to the cortical plate. These effects may reduce regional brain volumes in the basal ganglia (McCarthy, 2015) and other brain areas (Yazdy et al, 2015), with long-term changes in subsequent behaviour (Patrick et al, 2015; Bignami et al, 1996; Kavlock et al, 1995), autonomic regulation (Patrick et al, 2015), visual-motor (Moe, 2002), strabismus (Gill et al, 2003), or swallowing (Gewolb et al, 2004) dysfunctions and lower developmental potential (McGlone & Mactier, 2015; Robinson, 2002; Tempel & Espinoza, 1992). Current data cannot clearly differentiate between the long-term neonatal outcomes resulting from the prenatal use of prescription opioids, illicit drugs or opioid maintenance therapy. Buprenorphine and methadone form the mainstay of opioid maintenance therapy during pregnancy. Buprenorphine is considered an attractive alternative, partly due to more favourable neonatal brain growth patterns (Welle-Strand et al, 2009); however, its long-term use cannot be considered benign and has been associated with poor child outcomes to three years of age (Kivisto et al, 2015).

7)The relevance of perturbing apoptosis to gross anatomical malformations

Beginning in the late 1990's the understanding of the mechanism of foetal development began to undergo a significant change through research which identified and defined the concept of

Apoptosis, or programmed cell death (Kerr et al, 1972; Jacobsen et al, 1997; Bartlett, 2018; Mazarakis et al, 1997; Olney et al, 2000). Jacobsen identified the importance of apoptosis in foetal development in 1997. The process itself was described by Kerr et al in 1972 and the Nobel prize for the discoveries was awarded in 2002. It appeared that the foetus developed though the various foetal stages (which have been likened to evolutionary development of the human) by producing an enormous number of pluripotential cells, hugely more than are necessary, which are then selected though signalling from a set of chosen or pre-programmed cells to commit suicide. Research using animal and cell culture models illustrated a developmental plasticity which was controlled by signalling between cellular communities which became ultimately part of organ systems and neurological and other systems through switching off what were deemed to be superfluous or incorrect cells.

The system was controlled by signalling between cells. And since signalling between cells is also the domain of cell receptors and endogenous molecular ligands (for example the neurotransmitter molecules, the small peptide hormones like the endogenous opioids) it was clear that alteration of the developmental landscape through the addition of foreign agents with the ability to alter the sensitivity of the cell communication systems must also carry a serious risk of causing developmental effects, both hidden and morphologically clear in the baby at or after birth.

This problem was quickly addressed through research in the late 1990s and early 2000s since it was clear at that stage that theoretically, the possible causes of major congenital malformations but also hidden neurological, neuropsychiatric and psychosocial effects in children might follow from agents which were not themselves mutagens but which acted by altering the signalling environment during foetal development. It turned out very quickly that almost any agent which affected the homeostatic equilibrium of neurological (and indeed all) development when introduced to the foetus because of the mothers' exposure could cause such effects (Olney et al, 2000). The "teratogenic" effects of alcohol intake and smoking had already been described, though not explained mechanistically.

The opioids operate at the endogenous opioid receptors in the brain, the nervous system and other parts of the organism, as has been pointed out above. The opioid receptors are G-protein coupled receptors. Neural stem cells (cells that develop into the brain and nervous system) are self-renewing and pluripotent cells which give rise to the cells that ultimately make up the brain and nervous system: neurons, astrocytes, oligodendrocytes. In the developing cerebral cortex, neural stem cells differentiate into more committed progenitor cells and migrate into the regions where they lay down the basic structures that finally define the individual. Time lapse images show that cells migrate to the positions where they finally remain in various ways. G-Protein coupled receptors constitute the largest family of transmembrane receptors and are responsible for converting a diverse array of extracellular stimuli into intracellular signalling events. They are involved in a variety of physiological processes such as proliferation, differentiation and migration.

It would therefore have been predictable that the perturbation of the developmental environment by the addition of powerful agents to the extracellular matrix, compounds which have affinity and activity at the G-protein opioid receptors would result in developmental

alterations. And laboratory studies demonstrated such effects (Mizuno et al, 2005). The essential nature of apoptosis in the normal development of palatal fusion is provided by Cuervo (2002). Mid-line fusion defects result from perturbed apoptosis. The importance of apoptosis in the normal development of the heart has been reviewed by van den Hoffa et al (2000). They also reviewed the importance of apoptosis in the effects of teratogens in the production of cardiac malformations.

As pointed out, the role of apoptosis in neural development and disease was described by 1997. This is of interest for the current case since the pharmaceutical companies which were marketing the opioids to pregnant mothers should have realised the potential for serious developmental problems in the foetus which were clear from the reviews which appeared by then (Mazarakis et al, 1997).

However, by the early 1990s it had been already suggested, through a significant body of research, that Cocaine (another G-protein agonist) exposure in utero caused serious alterations in the development of the central nervous system, with major downstream effects implied for the baby and child, including microcephaly and post-natal signs and conditions which were largely the same as those reported for the NAS babies (Nassogne et al, 1995). The question of occult neurophysiological and psychosocial sequelae was clearly implicit.

Evidence that opioids behaved as they were predicted to and caused major birth defects appeared in the results of the National Birth Defect Prevention Study published in 2010 (Broussard et al, 2011; McCarthy, 2015). The study looked at 17,449 cases and 6701 controls. Statistically Significant effects were found for associations between early pregnancy maternal opioid analgesic treatment and certain birth defects, notably heart defects, anencephaly, cleft palate and spina bifida. A list of the most notable birth defects and their Odds Ratios (the ratio between cases and controls) is given in Table 5.

Table 5 Association between maternal opioid analgesic treatment and specific major birth defects in National Birth Defects Prevention Study of 17449 cases and 6701 controls. Significance is starred * in the usual way (Broussard et al, 2011). Odds ratios were adjusted for maternal age, race/ethnicity, education, pre-pregnancy obesity, smoking.

Birth defect	Total no	Odds Ratio (95%CI)
Anencephaly	9	1.7 (0.84-3.4)
Spina bifida**	26	2.0 (1.3-3.2)
Any included heart defect***	211	1.4 (1.1-1.7)
Atrioventricular septal defect*	9	2.4 (1.2-4.8)
Conotruncal defects*	41	1.5 (1.0-2.1)
Tetrology of Fallot*	21	1.7 (1.1-2.8)
Ventricular septal defect*	6	2.7 (1.1-6.3)
L ventricular outflow obstruction*	36	1.5 (1.0-2.2)
Hypoplastic Left heart syndrome**	17	2.4 (1.4-4.1)
R ventricular outflow obstruction*	40	1.6 (1.1-2.3)
Pulmonary valve stenosis**	34	1.7 (1.2-2.6)
Cleft palate	25	1.3 (0.84-2.4)
Hydrocephaly*	11	2.0 (1.0-3.7)

Esophageal atresia	12	1.4 (0.76-2.5)
Gastroschisis*	26	1.8 (1.1-2.9)
Anorectal atresia/ stenosis	18	1.5 (0.9-2.4)
Diaphragmatic hernia	12	1.2 (0.66-2.2)

The study noted that the main results were associated with exposures to Codeine but positive results were also found for Hydrocodone, Oxycodone and Meperidine. Since the mechanism for these effects was by then well described and implicit in the research that had emerged from 1990 onward about neurodevelopment mechanisms, it should have been apparent to those marketing and selling the opioid drugs that warnings should have been given to those prescribing them and to those women taking them. These warnings should have been included in the labelling of the preparations.

8)Communications between the FDA and pharmaceutical companies on opioid teratogenesis.

In connection with this, I have read the following documents:

[redacted]
-JAN-0003-0002176 - Proposed Label Changes for Pregnancy- Tapentadol
-Acquired_Actavis_00184044_-Suboxone/Bupenorphine Labelling
-ACTAVIS0229401 -Actavis Fentanyl Transdermal Patch labelling
[redacted]
INSYS-MDL-000325903_-Morphine Sulphate Provider Insert
PAR_OPIOID_MDL_0000331039-Hydrocodone Ibuprofen Insert

Observations

The responses of the different companies are remarkably consistent, there is very little variation in what has been presented. There are warnings about the consumption of opioids in women who are pregnant or are of child bearing age. The general advice is that the risks to the fetus have to be weighed up against other possible clinical benefits. Nowhere is there the suggestion that any opioid should not be prescribed during pregnancy.

The risk of teratogenesis in the animal studies cited by the manufacturers is largely explained through the mechanism of maternal toxicity rather than a direct teratogenic effect. I have not seen the studies that were relied upon but understand that these studies have not been released under discovery and are not available in the public domain. It is therefore difficult to make an objective assessment of the methodologies applied and the conclusions drawn.

However, it has been argued that if there is no teratognesis at the equivalent of 2x the human dose (on a body surface area basis) or ~ 5 x (on a body weight basis) then it is implied that there is nothing of concern and that opioid medicines should be safe for the medical profession to prescribe to pregnant women. Only gross anatomical malformations seem to

have been considered as toxicological endpoints. Functional deficits, particularly in the nervous system, generally occur at lower doses that those required to produce gross malformations and this has not been alluded to in communications between the FDA and the pharmaceutical companies.

There are a number of criticisms of this approach. Allometric scaling between different species is routine in toxicology. Some of the reasons for needing to do this are:

- Larger animals have lower metabolic rates
- Physiological process of larger animals is slower
- Larger animals required smaller drug dose on weight basis
- Allometry accounts for the difference in physiological time among species
- Allometric scaling is not valid to convert adult doses to fetal or infant doses.

Commonly accepted allometric conversion factors between species are:

Human dose (mg/kg) to mouse dose (mg/kg) - multiply by 12.3

Human dose (mg/kg) to rat dose (mg/kg) - multiply by 7.4

Human dose (mg/kg) to guinea pig dose (mg/kg) - multiply by 4.6

Human dose (mg/kg) to rabbit dose (mg/kg) - multiply by 3.1

Human dose (mg/kg) to dog dose (mg/kg) - multiply by 1.8

For rat and mouse, these allometric scaling ratios of 7.4 and 12.3 respectively, seem to have been ignored in communications to the FDA.

Examples of physiological differences between children and adults that may be significant in terms of toxicological response and which may not scale proportionally or continuously with body weight include the following:

• Respiration rate,

• Glomerular filtration rate,

• Active gastrointestinal absorption of nutrients,

• Composition and activity of intestinal flora

• Percentages of body fat and body water,

• Levels of CYP 450 isoforms and other phase I enzymes,

• Glucuronic acid conjugating ability, Phase 2 enzymes do not reach an efficient level in the infant until about 6 months post-natally.

• Biliary excretion ability, and

• Rates and patterns of growth in particular organs (bones, brain, immune system, etc.) which represent windows of vulnerability for damage during the developmental process.

Regulatory Toxicology

As well as the standard toxicology outlined above, there is an additional consideration that needs to be addressed. The rules of acceptance of a medication under informed consent, though they do apply to the mother, they do not apply to the fetus. In this scenario the fetus is receiving an outside agent, an opioid, which is certainly not being administered for the therapeutic benefit of the fetus. It could therefore be regarded, in this respect, as an external toxic agent.

When considering toxic agents in other life settings, for example pesticide residues on food, regulatory toxicologists try to estimate a 'No Effect Level' (NOEL) from the experimental evidence for a particular toxic agent. This NOEL is then subject to 'Uncertainty Factors' (UFs) which are typically x10 for species difference (when the data comes from a laboratory animal) and a further x10 because of inter-individual variability between humans. Therefore, the NOEL is divided by 10 x 10 = 100 to arrive at Tolerable Daily Intake (TDI). However, in the case of infants and fetuses there is sometimes an additional UF of x 10 applied to account for the additional vulnerability to harm associated with the developmental period. Under this condition the NOEL would have to be divided by 10 x 10 x 10 = 1,000 to arrive at a TDI. An example of this is provided under the US EPA Food Quality Protection Act (FQPA) which applies a UF of 1,000 in the case of infant exposures to toxic xenobiotics in food.

If the experimental data indicate that there is no safe dose then a NOEL cannot be determined and a regulatory TDI cannot be set. Examples of this is are provided by radiation exposure and genotoxic substances.

This brief overview of the regulatory toxicology approach highlights the inadequacy of the safety data put forward by the pharmaceutical industry to the FDA. In my opinion, the risk to the fetus has been understated.

9)Epigenetic effects of opioids

A Mini-Review by Gilardi et al (2018) 'Will Widespread Synthetic Opioid Consumption Induce Epigenetic Consequences in Future Generations?' discusses the animal experimental and human data currently available. Epigenetic changes can alter and regulate the way certain genes express themselves in the absence of mutations. This is achieved by remodelling the structure of the chromatin from 'open' (transcriptionally active) to 'closed' (transcriptionally inactive). A number of molecular mechanisms exist, including DNA methylation and post-translational modification of histones.

The review, while acknowledging the lack of transgenerational studies, "converging evidence suggests that opioids can induce long-lasting transgenerational changes in subsequent generations, particularly concerning drug sensitivity and tolerance, with possible implications for drug abuse vulnerability". A major part of this 'converging evidence' is the animal experimental data that Is available.

It is my opinion that epigenetic transgenerational effects should be considered in any future monitoring program of NAS sufferers

10)Causation – Sir Bradford Hill's methodology

In Bradford Hill's still widely used seminal paper of 1965i, which focuses on how we can move from an observed association to a robust causal inference, he identified nine "features" (often misnamed as "criteria") of the available, and often "ragged", evidence (Vandenbroucke J, Broadbent A & Pearce N, 2015) which, if present, could help justify a robust causal inference. Bradford Hill was careful to point out that even if these features of the evidence (Table 6) were absent, then that did not justify concluding that the agent being evaluated was not causing harm. In other words, the features of the evidence were asymmetrical, a word he did not use despite making the conceptual point very explicit when discussing several of the features of the evidence (Gee, 2008).

Bradford Hill would have approached the evidence with: "the decisive question… whether the frequency of the undesirable event B will be influenced by a change in the environmental feature A?". In this case event B is the diagnosis of NAS and the subsequent negative sequelae. Event A is the exposure of the pregnant mother to opioids.

From Table 6 I conclude that the overall weight of evidence supports a causal link between maternal opioid exposure during pregnancy and the appearance of NAS in the neonate. In my opinion, the causal relationship is strong and is beyond 'more likely than not' i.e. at or around the "balance of probabilities", or the "fair" strength of evidence, which Bradford Hill considered a sufficiency of evidence to justify preventative measures.

Table 6 - The Bradford Hill Approach Applied to NAS

Strength of association: case studies & clinical data indicate clear health impacts in significant proportions of exposed groups
Consistency: The clinical data is consistent with the known action of opioids and is similar across international boundaries.
Specificity: NAS is a syndrome with common neurological symptoms linked to maternal opioid exposure during pregnancy.

Temporality: Opioids have been present throughout recorded human history and therefore it is not possible to establish the position prior to regular human exposure. There is a temporal link in that there has to be maternal opioid exposure prior to the appearance of NAS in the resulting neonate.

Biological gradient: higher maternal opioid exposure often causes greater health effects; but lower dose effects also apparent, suggesting non -linearity

Plausibility: the known effects of opioids through the opioid receptor, which is universally present, support a causal link.

Coherence: animal/human data support a causal link

Experiment: animal experimental data supports a causal relationship between maternal opiate exposure and teratogenic effects (fetal malformations, functional neurological damage) through the principal mechanism of increased apoptosis.

Analogy: Maternal exposure to other teratogenic agents during pregnancy leading to both functional and anatomical teratogenesis; eg lead, mercury, di-ethyl stilbestrol, thalidomide.

11)Summary and opinion

Opioids all act in common through the opioid receptor system, which is universally present in vertebrate life forms and is well conserved throughout their evolutionary history. Therefore, this class of drugs has a common mode of action.

Opioid pharmaceutical agents affect the rate of apoptosis in development. The rate of apoptosis (programmed cell death) is critical for the normal development of the fetus and perturbing that rate will lead to teratogenesis, both morphological and functional. Therefore, there is a recognised pathological mechanism in common across this class of pharmaceutical agents.

There are no questions concerning foetal opioid dose to address. The Plaintiffs in this Class Action all had significant exposure to pre-natal opioid pharmaceuticals via their mothers. This was at a level which subsequently led to the postpartum diagnosis of NAS. This diagnosis is casually linked with a higher risk of suffering a congenital malformation. It also causally linked with a higher risk of neurological damage which could be expressed through various latent negative health impacts. These are the reasonably certain consequences of their

exposures, which are the result of subcellular or other physiological changes and can also be manifested in physical or mental injury or disease.

Prescribing opioids to women during pregnancy will lead to fetal damage. This is because of the known toxicity of opioids to the fetus which leads to increased risk of latent disease in the child post-natally. This should be made clear to women of child bearing age who are on opioid maintenance therapy and who are at risk of becoming pregnant. In my opinion, regimes for maternal opioid withdrawal should be considered as a primary part of any risk benefit considerations. The manufacturer's submissions to the FDA do not indicate any support for this approach which, in my opinion, did not reflect known risks of neurologic, developmental or teratogenic effects.

The establishment of Scientific Panels to participate in a medical monitoring program would, in my opinion, be beneficial for the following reasons. Monitoring for the post-natal consequences NAS is reasonable and necessary, according to contemporary scientific principles. The monitoring program should include periodic diagnostic medical examinations as there is clinical value in early detection and diagnosis. Therefore, this is different from a typical post-natal monitoring regime in the absence of exposure. The collection of prospective epidemiological data from a large cohort of NAS sufferers will lead to very robust studies that will deliver a medical benefit to a wider group of NAS sufferers than just those who have received prescription opioids during pregnancy. There will be beneficial read-across data that is relevant to other classes of opioid exposed fetuses. Such Scientific Panels should be composed of experts from the multiple medical and scientific disciplines that are required to fully understand this complex condition, including (but not necessarily restricted to): paediatricians, epidemiologists, physicians specialising in opioid addiction, psychiatrists, behavioural psychologists, toxico-pathologists, neurobiologists.

In my opinion, on the balance of scientific and medical probabilities, these negative outcomes are attributable to the treatment of the mothers with opioids. This includes treatment of mothers-to-be prior to pregnancy, when addictions can be established, and then during pregnancy at a dose adequate to induce NAS in their infant, via the common mode of action of this class of medicines and through the common pathological mechanism identified.

12)Statement of Truth

I confirm that I have made clear which facts and matters referred to in this report are within my own knowledge and which are not. Those that are within my own knowledge I confirm to be true. The opinions I have expressed represent my true and complete professional opinions on the matters to which they refer.

Dr. C.V. Howard 02/12/2019

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Marc Dann Declaration in Support of Motion for Class Certification

Exhibit 8

Format: Abstract

Obstet Gynecol. 2014 May;123(5):997-1002. doi: 10.1097/AOG.0000000000000208

Increase in prescription opioid use during pregnancy among Medicaid-enrolled women.

Desai RJ[1], Hernandez-Diaz S, Bateman BT, Huybrechts KF.

Author information

Abstract

OBJECTIVE: To report the prevalence of prescription opioid use and evaluate the trends in a large cohort of Medicaid-enrolled pregnant women.

METHODS: A cohort of pregnancies was identified using data from the Medicaid Analytical eXtract for the period of 2000-2007. Dispensing of opioids, as a class and separately for individual agents, was evaluated using claims from filled prescriptions. Variations in patterns of prescription opioid fills were examined by demographic characteristics, by geographic region, and over time. Median number of opioid prescriptions dispensed and cumulative days of availability for prescription opioids during pregnancy were reported.

RESULTS: The study population consisted of more than 1.1 million women with completed pregnancies from 46 U.S. states and Washington, DC. One of five women from our cohort (21.6%) filled a prescription for an opioid during pregnancy; this proportion increased from 18.5% in 2000 to 22.8% in 2007. Substantial regional variation was seen with the proportion of women who filled a prescription during pregnancy, ranging between 9.5% and 41.6% across the states. Codeine and hydrocodone were the most commonly prescribed opioids. Among women filling at least one opioid prescription, the median (interquartile range) number of prescriptions filled was 1 (1-2) and the median (interquartile range) cumulative days of opioid availability during pregnancy were 5 (3-13) days.

CONCLUSION: We observed high and increasing number of filled prescriptions for opioids during pregnancy among Medicaid-enrolled women. These findings call for further safety evaluations of these drugs and their effects on the developing fetus to inform clinical practice.

LEVEL OF EVIDENCE: II.

Comment in

Increase in prescription opioid use during pregnancy among medicaid-enrolled women. [Obstet Gynecol. 2014]

In Reply: Cho et al. [Obstet Gynecol. 2014]

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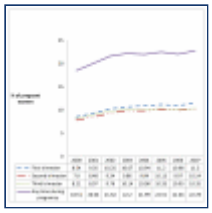

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Exhibit 9

NCHS Data Brief ■ No. 329 ■ November 2018

Drug Overdose Deaths in the United States, 1999–2017

Holly Hedegaard, M.D., Arialdi M. Miniño, M.P.H., and Margaret Warner, Ph.D.

Key findings

Data from the National Vital Statistics System, Mortality

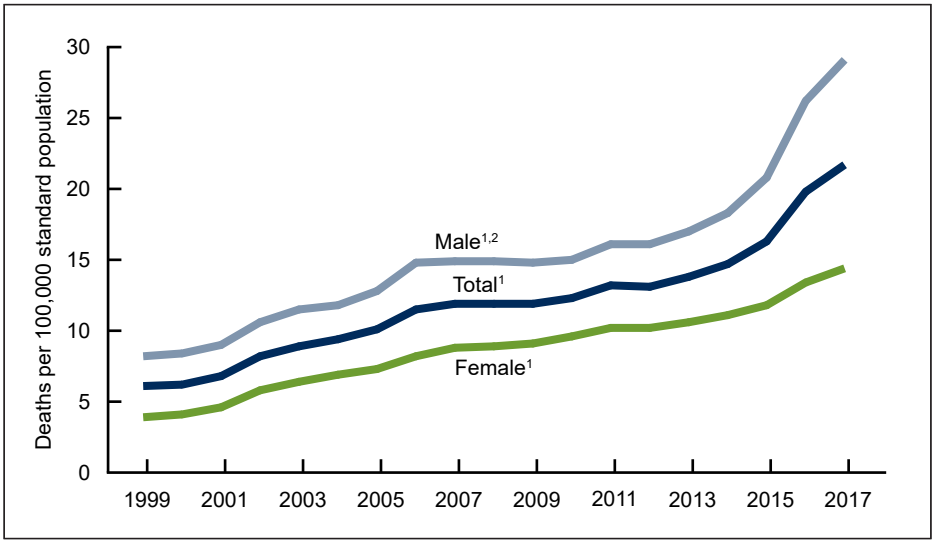
- In 2017, there were 70,237 drug overdose deaths in the United States.
- The age-adjusted rate of drug overdose deaths in 2017 (21.7 per 100,000) was 9.6% higher than the rate in 2016 (19.8).
- Adults aged 25–34, 35–44, and 45–54 had higher rates of drug overdose deaths in 2017 than those aged 15–24, 55–64, and 65 and over.
- West Virginia (57.8 per 100,000), Ohio (46.3), Pennsylvania (44.3), and the District of Columbia (44.0) had the highest age-adjusted drug overdose death rates in 2017.
- The age-adjusted rate of drug overdose deaths involving synthetic opioids other than methadone (drugs such as fentanyl, fentanyl analogs, and tramadol) increased by 45% between 2016 and 2017, from 6.2 to 9.0 per 100,000.

Deaths from drug overdose continue to be a public health burden in the United States (1–5). This report uses the most recent final mortality data from the National Vital Statistics System (NVSS) to update trends in drug overdose deaths, describe demographic and geographic patterns, and identify shifts in the types of drugs involved.

In 2017, the age-adjusted rate of drug overdose deaths in the United States was 9.6% higher than the rate in 2016.

- In 2017, there were 70,237 drug overdose deaths in the United States (Figure 1).
- The age-adjusted rate of drug overdose deaths increased from 6.1 per 100,000 standard population in 1999 to 21.7 in 2017. The rate increased

Figure 1. Age-adjusted drug overdose death rates: United States, 1999–2017



[1]Significant increasing trend from 1999 through 2017 with different rates of change over time, $p < 0.05$.
[2]Male rates were significantly higher than female rates for all years, $p < 0.05$.
NOTES: Deaths are classified using the *International Classification of Diseases, 10th Revision*. Drug-poisoning (overdose) deaths are identified using underlying cause-of-death codes X40–X44, X60–X64, X85, and Y10–Y14. The number of drug overdose deaths in 2017 was 70,237. Access data table for Figure 1 at: https://www.cdc.gov/nchs/data/databriefs/db329_tables-508.pdf#1.
SOURCE: NCHS, National Vital Statistics System, Mortality.

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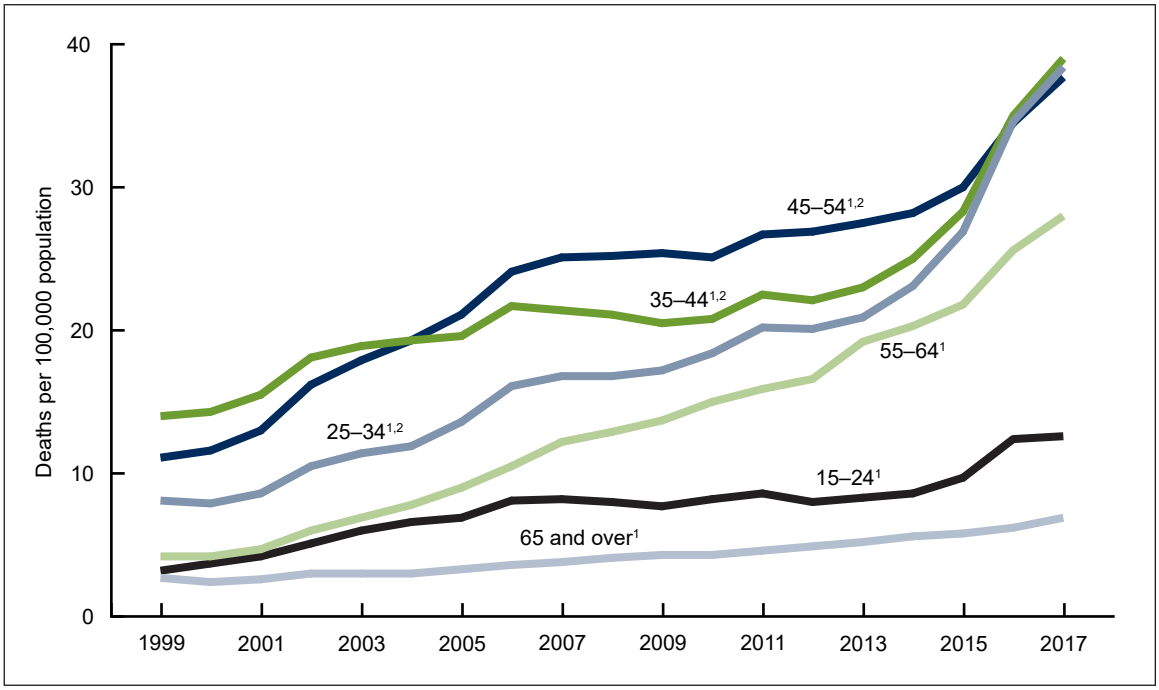
on average by 10% per year from 1999 through 2006, by 3% per year from 2006 through 2014, and by 16% per year from 2014 through 2017.

- For each year, rates were significantly higher for males than females. For males, the rate increased from 8.2 in 1999 to 29.1 in 2017. For females, the rate increased from 3.9 in 1999 to 14.4 in 2017.

Among persons aged 15 and over, adults aged 25–34, 35–44, and 45–54 had higher rates of drug overdose deaths in 2017 than those aged 15–24, 55–64, and 65 and over, while those aged 65 and over had the lowest rates.

- The rates of drug overdose deaths increased from 1999 to 2017 for all age groups studied (Figure 2).
- In 2017, rates were significantly higher for age groups 25–34 (38.4 per 100,000), 35–44 (39.0), and 45–54 (37.7) than for those aged 15–24 (12.6), 55–64 (28.0), and 65 and over (6.9).
- In 2017, rates were lowest for adults aged 65 and over (6.9).
- From 1999 to 2017, the greatest percentage change in drug overdose death rates occurred among adults aged 55–64, increasing from 4.2 per 100,000 in 1999 to 28.0 in 2017, a more than 6-fold increase.

Figure 2. Drug overdose death rates, by selected age group: United States, 1999–2017

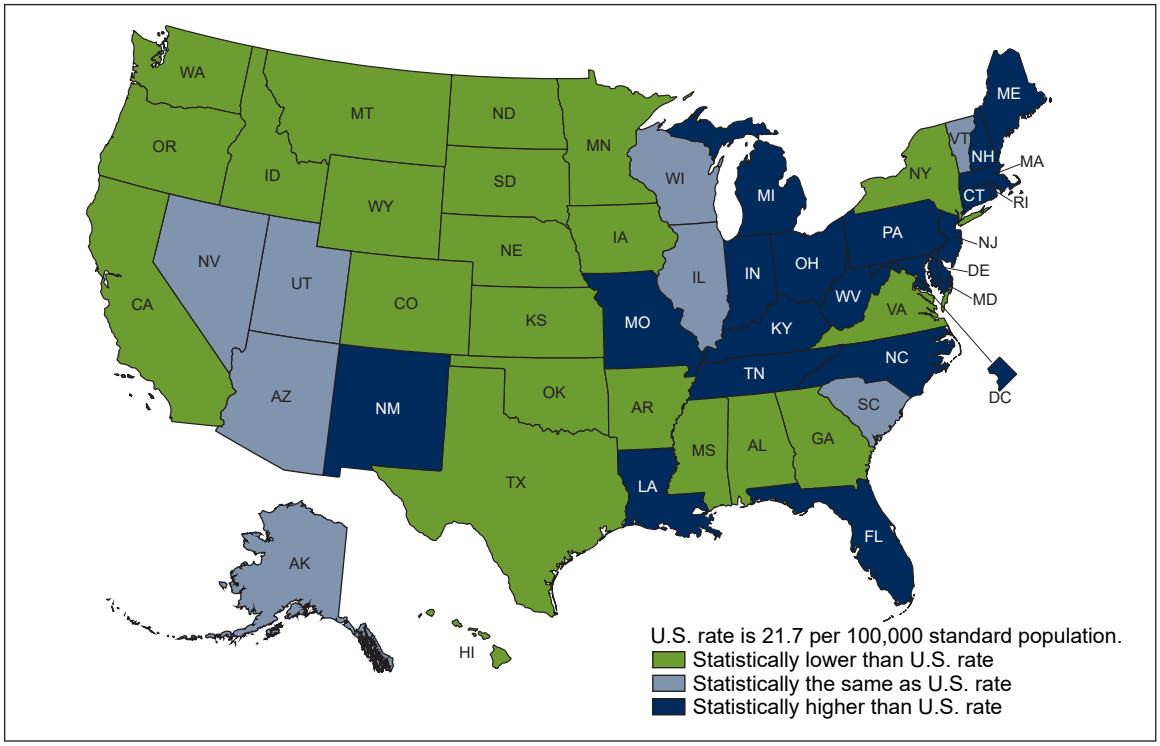


[1]Significant increasing trend from 1999 through 2017 with different rates of change over time, $p < 0.005$.
[2]2017 rates were significantly higher for age groups 25–34, 35–44, and 45–54 than for age groups 15–24, 55–64, and 65 and over, $p < 0.05$. The rate for age group 35–44 was significantly higher than the rate for age group 45–54 and statistically the same as the rate for age group 25–34.
NOTES: Deaths are classified using the *International Classification of Diseases, 10th Revision*. Drug-poisoning (overdose) deaths are identified using underlying cause-of-death codes X40–X44, X60–X64, X85, and Y10–Y14. Access data table for Figure 2 at: https://www.cdc.gov/nchs/data/databriefs/db329_tables-508.pdf#2.
SOURCE: NCHS, National Vital Statistics System, Mortality.

In 2017, 20 states and the District of Columbia had age-adjusted drug overdose death rates that were statistically higher than the national rate.

- In 2017, 20 states and the District of Columbia had drug overdose death rates that were higher than the national rate (21.7 per 100,000); 8 states had rates that were comparable to the national rate; and 22 states had lower rates (Figure 3).
- West Virginia (57.8), Ohio (46.3), and Pennsylvania (44.3) were the three states with the highest observed age-adjusted drug overdose death rates in 2017. The District of Columbia had a rate of 44.0 per 100,000.
- Texas (10.5), North Dakota (9.2), South Dakota (8.5), and Nebraska (8.1) were the four states with the lowest observed age-adjusted drug overdose death rates in 2017.

Figure 3. Age-adjusted drug overdose death rates, by state: United States, 2017

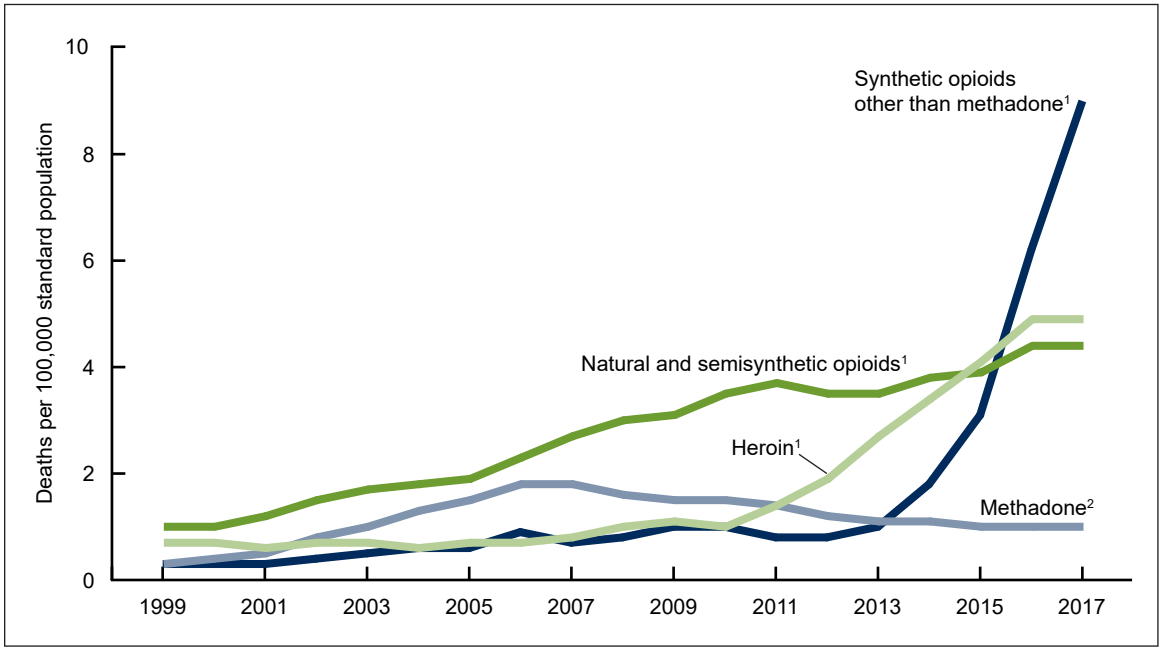


NOTES: Deaths are classified using the *International Classification of Diseases, 10th Revision*. Drug-poisoning (overdose) deaths are identified using underlying cause-of-death codes X40–X44, X60–X64, X85, and Y10–Y14. Access data table for Figure 3 at: https://www.cdc.gov/nchs/data/databriefs/db329_tables-508.pdf#3.
SOURCE: NCHS, National Vital Statistics System, Mortality.

The age-adjusted rate of drug overdose deaths involving synthetic opioids other than methadone increased by 45% from 2016 to 2017.

- The rate of drug overdose deaths involving synthetic opioids other than methadone, which include drugs such as fentanyl, fentanyl analogs, and tramadol, increased from 0.3 per 100,000 in 1999 to 1.0 in 2013, 1.8 in 2014, 3.1 in 2015, 6.2 in 2016, and 9.0 in 2017 (Figure 4). The rate increased on average by 8% per year from 1999 through 2013 and by 71% per year from 2013 through 2017.
- The rate of drug overdose deaths involving heroin increased from 0.7 in 1999 to 1.0 in 2008 to 4.9 in 2016. The rate in 2017 was the same as in 2016 (4.9).
- The rate of drug overdose deaths involving natural and semisynthetic opioids, which include drugs such as oxycodone and hydrocodone, increased from 1.0 in 1999 to 4.4 in 2016. The rate in 2017 was the same as in 2016 (4.4).
- The rate of drug overdose deaths involving methadone increased from 0.3 in 1999 to 1.8 in 2006, then declined to 1.0 in 2016. The rate in 2017 was the same as in 2016 (1.0).

Figure 4. Age-adjusted drug overdose death rates, by opioid category: United States, 1999–2017



[1]Significant increasing trend from 1999 through 2017 with different rates of change over time, $p < 0.05$.
[2]Significant increasing trend from 1999 through 2006, then decreasing trend from 2006 through 2017, $p < 0.05$.
NOTES: Deaths are classified using the *International Classification of Diseases, 10th Revision*. Drug-poisoning (overdose) deaths are identified using underlying cause-of-death codes X40–X44, X60–X64, X85, and Y10–Y14. Drug overdose deaths involving selected drug categories are identified by specific multiple-cause-of-death codes: heroin, T40.1; natural and semisynthetic opioids, T40.2; methadone, T40.3; and synthetic opioids other than methadone, T40.4. Deaths involving more than one opioid category (e.g., a death involving both methadone and a natural and semisynthetic opioid) are counted in both categories. The percentage of drug overdose deaths that identified the specific drugs involved varied by year, with ranges of 75%–79% from 1999 through 2013 and 81%–88% from 2014 through 2017. Access data table for Figure 4 at: https://www.cdc.gov/nchs/data/databriefs/db329_tables-508.pdf#4.
SOURCE: NCHS, National Vital Statistics System, Mortality.

Summary

This report updates statistics on deaths from drug overdoses in the United States and includes information on trends since 1999 as well as key statistics for 2017.

Rates of drug overdose deaths continued to increase. In 2017, the age-adjusted rate of drug overdose deaths (21.7 per 100,000) was 3.6 times the rate in 1999 (6.1). Rates increased for both males (from 8.2 in 1999 to 29.1 in 2017) and females (from 3.9 in 1999 to 14.4 in 2017). Rates also increased for all age groups studied. In 2017, among persons aged 15 and over, rates were highest for adults aged 25–34 and 35–44 at 38.4 and 39.0 per 100,000, respectively. In 2017, 20 states and the District of Columbia had age-adjusted drug overdose death rates that were statistically higher than the national rate, 8 states had rates that were comparable to the national rate, and 22 states had lower rates.

The pattern of drugs involved in drug overdose deaths has changed in recent years. The rate of drug overdose deaths involving synthetic opioids other than methadone (drugs such as fentanyl, fentanyl analogs, and tramadol) increased 45% from 6.2 per 100,000 in 2016 to 9.0 in 2017. The rates of drug overdose deaths involving heroin (4.9 per 100,000), natural and semisynthetic opioids (4.4), and methadone (1.0) were the same in 2016 and 2017.

Definitions

Drug poisoning (overdose) deaths: Includes deaths resulting from unintentional or intentional overdose of a drug, being given the wrong drug, taking a drug in error, or taking a drug inadvertently.

Natural and semisynthetic opioids: Includes such drugs as morphine, codeine, hydrocodone, and oxycodone.

Synthetic opioids other than methadone: Includes such drugs as fentanyl, fentanyl analogs, and tramadol.

Data source and methods

Estimates are based on the NVSS multiple-cause-of-death mortality files (6). Drug poisoning (overdose) deaths were defined as having an *International Classification of Diseases, 10th Revision* (ICD–10) underlying-cause-of-death code of X40–X44 (unintentional), X60–X64 (suicide), X85 (homicide), or Y10–Y14 (undetermined intent). Of the drug overdose deaths in 2017, 87% were unintentional, 7% were suicides, 5% were of undetermined intent, and less than 1% were homicides. The type of drug(s) involved are indicated by ICD–10 multiple-cause-of-death codes: heroin (T40.1); natural and semisynthetic opioids (T40.2); methadone (T40.3); and synthetic opioids other than methadone (T40.4).

Age-adjusted death rates were calculated using the direct method and adjusted to the 2000 U.S. standard population (7). Trends in age-adjusted death rates were evaluated using the Joinpoint Regression Program (Version 4.3.1.0) (8). Joinpoint software fitted weighted least-squares regression models to the rates on the log transform scale. Analyses were set to allow a maximum of three joinpoints across the period, a minimum of three observed time points from any given joinpoint to either end of the data, and a minimum of four observed time points between any two joinpoints. The permutation tests for model (number of joinpoints) significance were set at an overall alpha level of 0.05 (9). Differences between national and state estimates were evaluated using two-sided significance tests at the 0.05 level, with the national rate treated as a fixed parameter. References to rates being higher or lower indicate that differences are statistically significant at the 0.05 level. References to rates being similar or not different indicate a lack of statistical significance even though rates may appear to differ (7).

Several factors related to death investigation and reporting may affect measurement of death rates involving specific drugs. At autopsy, the substances tested for and the circumstances under which the toxicology tests are performed vary by jurisdiction. This variability is more likely to affect substance-specific death rates than the overall drug overdose death rate. The percentage of drug overdose deaths for which at least one specific drug was identified as being involved varied by year, ranging from 75%–79% from 1999 through 2013 and from 81%–88% from 2014 through 2017.

Additionally, drug overdose deaths may involve multiple drugs; therefore, a single death might be included in more than one category when describing the rate of drug overdose deaths involving specific drugs. For example, a death that involved both heroin and fentanyl would be included in both the rate of drug overdose deaths involving heroin and the rate of drug overdose deaths involving synthetic opioids other than methadone.

About the authors

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Keywords: poisoning • opioids • heroin • National Vital Statistics System Mortality File

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Marc Dann Declaration in Support of Motion for Class Certification

Exhibit 10

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Duties of a Guardian

Duties of a Guardian of the Person

Before you decide to become a guardian, ask yourself these questions:

1. **Do you want legal responsibility for the child?**
   You will have the same legal responsibilities as a parent, including responsibility for intentional damages the child may cause or for negligent supervision of the child. As guardian, you must also manage the child's finances, keep careful records, give the court reports and ask the court for permission to handle certain financial matters.

2. **How will the guardianship affect you and your family?**
   You will be like the child's parent. This can affect your relationship with other family members. Think about your time, energy, and health to decide if you want to be, or can be, a guardian.

3. **Do you have enough money?**
   The child may get income from social security, public assistance, child support from the parents, or an inheritance from a deceased parent. But child support does not always arrive, even if it is ordered by the court, and the money you get for the minor may not be enough. You may have to spend your own money to raise the child.

4. **Will there be problems with the child's relatives?**
   If the child's parents are alive, will they support you as guardian, or will they be angry with you and try to interfere? Some parents may fight the guardianship, or the court may say that they can have regular visitation.

Rights and responsibilities of guardians

As guardian of the person, you will have these responsibilities:

- You decide where the child lives. If you move, you must tell the court in writing right away. If you want to move out of California, you have to get the court's permission.
- You decide where the child goes to school. You must stay involved in the child's education, and help the child get any special services, like tutoring, that he or she needs.
- You must take care of the child's medical and dental needs, making sure he or she gets proper care. In most cases, you can also make decisions about any medical treatment the child needs.
- You must get the child counseling or other mental health services if the child needs them. But you cannot place the child in a mental health institution without a court order unless the child agrees.
- At least once a year, you will turn in a status report to the court. You must also meet with any court investigators or social workers sent by the court and come to court when the court tells you to. The court can also order you to take on other duties or can place special conditions on you as guardian, if needed.

Also:

- In most cases, guardians, like parents, are responsible for harm or damages the child causes, including graffiti or getting in a car accident. Like a parent, a guardian is responsible for the intentional acts of the minor, and also for negligent supervision of the minor or the negligent entrustment of a motor vehicle (giving the child access to a car when he or she is unlicensed or otherwise not capable of handling the responsibility).
- You cannot let the child live with his or her parents or anyone else. The child must live with you unless the judge says otherwise. You can let the child stay with other people for visits or short periods of time without a court order, as long as the child continues to primarily live with you, the guardian.
- The parents may be able to visit and see their child, but you (or the court) decide when and how often. The parents may get custody of their child back in the future if the court decides that the child no longer needs to have a guardian.

You will have the right to make these decisions affecting the child:

- You may give the child permission to apply for a driver's license. Or you may choose to not give him or her permission.
    - If you let the child apply for a license, you must also get car insurance for the child.
    - If the child has an accident while driving your car, you may be responsible for any damages caused by the accident.
- You may give the child permission to enlist in the military.
    - If the child enters into active duty with the armed forces, the guardianship will end. California law will consider the child to be an adult (emancipated).
- Both you and the court must give permission for the child to get married.
    - If the child gets married, the guardianship will end. California law will consider the child to be an adult (emancipated).

Help for guardians

If, as guardian of the child, you need help, there may be resources to help you:

Financial help
You may be able to get child support from the parents or help from the government, like TANF (Temporary Aid to Needy Families), CalWorks, social security, Department of Veterans Affairs, or Indian Child Welfare Act benefits.

For more information, call:

Social Security Administration 1-800-772-1213 TTY 800-325-0778

Department of Veterans Affairs 1-800-827-1000 TTY 800-829-4833

Department of Child Support Services 1-866-249-0773 (toll free) TDD 1-866-223-9529 (toll free)

You can also contact your local child support agency. Or find your local county social services or human services department.

Remember: Any money you get for the child must be used for the child's benefit. The court may ask you to file reports from time to time showing how much money you received for the child and how it was spent. This is called "an accounting."

Help if the child is having problems

Every county has agencies to help children who come from troubled homes. Some children have physical or learning disabilities. Some have been abused. Some may need counseling or other services. Try to meet the special needs of the child in your care and get them the services they need.

Ask the court, or the child protective services agency near you, to tell you where you can get help.

Find your county's child protective services agency and check your county's website. You can also check the county listings in your telephone book.

Duties of a Guardian of the Estate

As a guardian of the estate of the minor, you owe the highest duty the law recognizes to protect the assets of the child's estate. This duty is called a *fiduciary duty*. It is easy to violate this duty if you do not have special training or a probate lawyer giving you advice. For this reason, it is better to have a lawyer represent you when you are asking the court to appoint you guardian of the estate. The lawyer's fees are paid for by the estate, and must be approved by the court so there is protection for the minor.

Within 90 days after being appointed guardian, you must file financial reports with the court, including an inventory and appraisal signed by a referee showing the value of the assets in the estate. You must:

- Collect and make a list of all the child's property and find, get, and protect all money and property that are part of the estate; then
- Put all property in the estate's name; and,
- Record copies of the *Letters of Guardianship* (Form GC-250) with the County Recorder in every county where the child owns real property (land, houses or buildings).

To determine the value of the child's property, first, get a court-appointed referee, called a "probate referee," who will figure out how much the property was worth when you were appointed.

- You must do this unless the court specifically tells you not to.
- You, not the probate referee, have to figure out the value or worth of certain "cash items."

Managing the child's estate

- Keep all the child's money and property separate from everyone else's money and property, including your own. Unless there is a court order, a guardian cannot:
    - Pay him or herself or his or her lawyer with the estate's funds;
    - Give away any part of the estate;
    - Borrow money from the estate; or
    - Spend the estate's money.
- If the child has a parent who is still alive, or the child gets money or can get support from elsewhere, then you need the court's permission to use the estate money to pay for the child's support, maintenance, or education.

- You can file a petition explaining why you need to use the estate's money to support the child. Generally, the court can give you permission to use the minor's money for less than a year and for specific things.
- Keep complete and accurate financial records, including records of every transaction that has to do with the estate. Write down all of the money that comes in and all money that goes out, and keep receipts for everything you buy using estate money.
- Get and/or keep insurance coverage on the child's property.
- Prepare a report, called an "accounting," of:
    - All money collected and all interest earned;
    - All money you spent and for what;
    - The date of every transaction;
    - The purpose of every transaction; and
    - What is left after the estate's expenses are paid. (See Probate Code section 1061 for what the accounting must say.)
- File an accounting 1 year after you become guardian. After that, you must file a report every 2 years, unless:
    - The estate is worth less than $7,000 and there is less than $1,000 per month income from sources other than public assistance.
    - All guardianship funds are in blocked accounts.
    - If you do not file the accounting, the court could order you to do so or could remove you as the guardian.
    - If you believe you fall within an exception to the requirement for an accounting, you can file a motion with the court asking that you be relieved of the duty to file an annual accounting. You must file one unless the court orders that you do not have to.

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Exhibit 11

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Understanding the scale of the opioid epidemic within the insurance industry

Over 25 million American adults report suffering from chronic pain on a daily basis, and a range of adverse health outcomes accompanies their pain.

This is according to a study of 2012 National Health Interview Survey data, which also found that adults with severe pain were more likely to report taking medication for depression, feeling exhausted, nervous, or anxious every day, and were more likely to miss work for health-related reasons.[1] Adults with severe pain also accessed medical care more frequently and reported having poorer health, which is associated with increased mortality.[2]

With the health, well-being, and daily functioning of millions of Americans on the line, our health care system has found itself walking a tightrope between crises of under-treatment and over-treatment for those who suffer from pain. Beginning in the early 2000s, opioid analgesics were increasingly seen as a solution to the problem of under-treatment that had been a concern in the 1990s.[3] From 1991 to 2011, the number of opioid prescriptions filled at U.S. retail pharmacies nearly tripled, increasing from 76 million to 219 million per year, though those numbers have started to decrease since the peak in 2011 (see Figure 1).[4]

Despite the recent decrease in prescriptions of opioids, the human toll of the opioid crisis has continued to intensify. Illegally acquired heroin and synthetic opioids such as fentanyl have become the leading cause of overdose deaths.[5] From 2000 to 2015, the rate of opioid overdose deaths increased 347% (from 3.0 deaths per 100,000 population to 10.4), with over 33,000 people dying from opioid overdoses in 2015.[6] The latest data from the Centers for Disease Control and Prevention (CDC) suggests that the crisis may still be accelerating, with a 28% increase in opioid overdose deaths in just one year from 2015 to 2016.[7] Opioid overdose deaths are now the single largest factor slowing the growth in U.S. life expectancy, and if current trends continue, opioid overdose deaths could outnumber suicides by 2019.[8]

Figure 1: Opioid prescriptions dispensed by U.S. retail pharmacies

Source: IMS's National Prescription Audit (NPA) & Vector One ®: National (VONA).

While the CDC carefully tracks opioid overdose deaths, less is known about the scale of intermediate outcomes such as diagnosed opioid use disorder. According to extrapolations from the 2014 National Survey on Drug Use and Health, 2 million Americans reported having a substance use disorder involving prescription pain relievers and 591,000 had a substance use disorder involving heroin.[9]

Diagnosed opioid use disorder

In order to build upon these self-reported metrics and provide a perspective on the scale of medically acknowledged opioid use disorder (meaning opioid use disorder that has been diagnosed in a healthcare setting), we have undertaken a cross-sectional study of the diagnosed prevalence of opioid abuse, dependence, or poisoning[10] (hereafter referred to as opioid use disorder) within privately and publicly insured populations in the United States.

The actual prevalence of opioid use disorder may be much higher than the *diagnosed* prevalence rates presented throughout this report, as only a subset of those with opioid use disorder have had their disorder recognized by a medical professional. This subset is the population that health plans and providers can most readily identify and work to manage. These distinctions are further described in Figure 2.

Figure 2: Opioid use among U.S. adults in 2015

Opioid use	• 92 million people were prescribed an opioid • Some may be at risk for developing problem opioid use behaviors

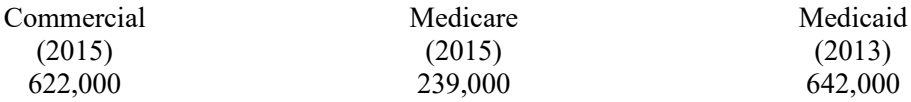
Opioid use disorder	• 11.5 million people reported misusing opioids, and 1.9 million reported being addicted to opioids • May or may not have discussed their opioid use with a clinician or be ready to begin treatment
Diagnosed opioid use disorder	• 1.5 million people with public or private insurance were diagnosed with opioid abuse, opioid dependence, or opioid poisoning • Easiest subset to identify for management and enhanced care

Source: 2015 National Survey on Drug Use and Health and Milliman analysis.[11]

We used several large national research databases containing administrative claims data for millions of people with both Medicare and private insurance plans. We also incorporated findings from a similar analysis performed by the Kaiser Family Foundation for Medicaid beneficiaries to develop a more complete perspective on opioid use disorder across the three major insurance payers in the United States.

Based on a sample of over 42 million people with commercial insurance, nearly 1.3 million Medicare beneficiaries, and a Kaiser Family Foundation analysis of Medicaid beneficiaries in 49 states, we estimate that over 1.5 million insured Americans were diagnosed with an opioid use disorder in 2015 (the most recent year available). Figures 3 and 4 summarize these findings by payer. These results (and others presented throughout this report) have been age- and area-adjusted to be representative of the U.S. insured population as of 2015 using U.S. Census Bureau data.[12]

Figure 3: Diagnosed opioid use disorder by payer, 2015 (or most recent year)



We found that about 41.4% of those with diagnosed opioid use disorder were commercially insured, 15.9% were Medicare beneficiaries, and 42.7% were Medicaid beneficiaries. Overall, the diagnosed prevalence rate of opioid use disorder was 3.28 per 1,000 for the commercially insured, 5.39 per 1,000 for those with Medicare, and 8.90 per 1,000 for those with Medicaid. Across all insurance payers, we found that the prevalence of opioid use disorder was 4.91 per 1,000.

Figure 4: National estimates of opioid use disorder diagnosis by payer, 2015 (or most recent year)

Payer	Diagnosed prevalence per 1,000	Total diagnosed nationally No. (%)
Commercial (2015)	3.28	622,000 (41.4)
Medicare (2015)	5.39	239,000 (15.9)
Medicaid (2013)	8.90	642,000 (42.7)
Total	4.91	1,503,000 (100.0)

Opioid use disorder by age and sex

Rates of opioid use disorder varied widely by age and sex, with men generally experiencing higher rates of opioid use disorder through age 65, and women experiencing higher rates from 66 and older. Rates were quite

low through childhood, followed by a marked increase in the late teen years, peaking in the mid-20s at a rate of 5.47 per 1,000 for women (at age 24) and 10.00 per 1,000 for men (at age 25). Rates showed a sharp drop-off in the late 20s, followed by a rise to another peak in the mid-30s of about 3.76 per 1,000 for women (at age 35) and 6.37 per 1,000 for men (at age 36). From the late 30s through age 64, the gap between men and women closed and both experienced prevalence rates hovering between 3.50 to 4.00 per 1,000 through retirement age. Opioid use disorder rates for Medicare beneficiaries were generally higher for women than for men, and tapered off with advancing age. Comparable data for Medicaid were not available.

The sharp decline in the prevalence rate after age 26 coincides with the expiration of dependent coverage eligibility on a parent's plan under the Patient Protection and Affordable Care Act (ACA). We found that 87% of those diagnosed with opioid use disorder under age 26 were dependent children or young adults. Other studies have found that heroin use tends to be more common than prescription abuse for this demographic.[13]

Figure 5 provides the prevalence rates by age and sex, both for the commercially insured (ages 0-64) and for Medicare beneficiaries (ages 65+).

Figure 5: Diagnosed prevalence of opioid use disorder for commercial insurance (ages 0-64) and Medicare (ages 65+) by age, 2015

click to enlarge

Variations between states

We found substantial variation between states, with a nearly tenfold difference in the diagnosed prevalence of opioid use disorder between the most and least impacted states (12.56 vs. 1.32 per 1,000 for Vermont vs. South Dakota, respectively). The most and least impacted showed an eight-fold difference for commercial insurance (7.36 vs. 0.87 per 1,000 for Tennessee vs. Washington, D.C, respectively), an 11-fold difference for Medicare (11.43 vs. 1.00 per 1,000 for Nevada vs. South Dakota, respectively), and a 22-fold difference for Medicaid (35.53 vs. 1.59 per 1,000 for Massachusetts vs. Arkansas, respectively).

Figure 6 provides prevalence rates by payer and state, as well as the overall prevalence rate across each insurance type.

Figure 6: Diagnosed prevalence of opioid use disorder by state and payer, 2015 (or most recent year)[14]

click to enlarge

For those with commercial insurance, high opioid use disorder rates are clustered in the Appalachia region, as well as Louisiana, New England, and Washington state. For Medicaid beneficiaries, high opioid use disorder rates are heavily clustered in New England, while for Medicare beneficiaries the hardest-hit states include Nevada, Mississippi, Louisiana, Oklahoma, and Tennessee. When considering all three insurance types together, the northeastern United States is experiencing the worst of the crisis, although there is reason for significant concern across much of the country.

Figure 7 provides a heat map of opioid use disorder prevalence rates by payer.

Figure 7: Diagnosed prevalence of opioid use disorder by state and payer, 2015 (or most recent year)[15]

Data sources and methodology

This analysis is based on three large national research databases, as well as a prior study completed by the Kaiser Family Foundation:

- 2015 Truven MarketScan Commercial Claims and Encounters Database®
- 2015 Milliman Consolidated Health Cost Guidelines™ Database
- 2015 Centers for Medicare and Medicaid Services (CMS) 5% Sample Standard Analytical File
- Kaiser Family Foundation analysis of 2013 Medicaid Statistical Information System and Urban Institute estimates from CMS-64 reports[16]

The Truven MarketScan research database reflects the healthcare experience of employees and dependents covered by the health benefit programs of large employers, health plans, and government organizations. These claims data are collected from approximately 350 payers. The MarketScan Commercial Claims and Encounters Database includes data from active employees, early retirees, COBRA continuees, and dependents insured by employer-sponsored plans.

The Milliman Consolidated Health Cost Guidelines Database contains healthcare experience primarily for large group commercial members, using data contributed from a number of payers with which Milliman has data purchase or trade agreements. Milliman collects this data from various health plans for use in product development, research, and client projects.

The CMS 5% Sample Standard Analytical File contains healthcare experience for a random 5% sample of Medicare beneficiaries across the United States.

All of the Medicaid results presented in this report are derived from a report produced by the Kaiser Family Foundation using 2012 and 2013 Medicaid data from the Medicaid Statistical Information System, which contains healthcare experience for Medicaid beneficiaries in participating states. For Rhode Island and Kansas, 2013 data were not available, so 2012 data were used instead. No data were available for Colorado. For the purpose of this analysis we have used the national average opioid use disorder rate as an estimate for Colorado's rate.

The results presented in this report for commercial insurance and Medicare beneficiaries have been age- and area-adjusted to reflect the 2015 U.S. insured population, using U.S. Census Bureau data. The differences between crude and adjusted rates were minimal.

Next steps

Those diagnosed with opioid use disorder likely represent just a fraction of those who have problematic opioid use at any given time. Some may not fully recognize the dangers of prescription opioid abuse, while others may try to evade diagnosis out of concern for their privacy or potential legal consequences. Others may be aware of their problem opioid use but have not yet reached out for help from a medical professional.

In an upcoming report, we will explore opioid use patterns both in those diagnosed with opioid use disorder, as well as in non-diagnosed "super-users" (those who fill extraordinarily high volumes of opioid prescriptions in a year but have not been diagnosed with an opioid use disorder).

We'll also expand on this report with some additional context on the healthcare settings that are most impacted by problem opioid use, including estimates of the direct costs of caring for those with opioid use disorder.

The opioid epidemic is a complex and growing phenomenon that needs careful study from a wide variety of perspectives in order to make progress. We look forward to contributing to this national conversation with unique analyses that combine actuarial and public health perspectives.

Caveats and limitations

The opioid epidemic has been growing at an alarming pace, and retrospective analyses will likely continue to understate the full magnitude of the problem until the tide turns and problem opioid use begins to decrease. The Medicaid results in this report are likely to be especially understated, as they pre-date the Medicaid expansion that occurred under the ACA in 2014, and because they are an additional two years older than the Medicare and commercial data. Additionally, Medicaid results were not available for Colorado, so national rates were used as an estimate. The actual rate in Colorado likely differs from this estimation.

The commercial results largely reflect large group, employer-sponsored insurance, and thus likely under-represent lower-income households that purchased individual coverage under the ACA. Additionally, while sampling errors are quite small due to the large sample sizes available in each data set used for this analysis, sampling bias could be present to the extent that health plans and payers that contribute to the research databases differ systematically from non-contributors.

Due to lack of available data, we were not able to include uninsured populations in this analysis.

This report presents an analysis of the prevalence of opioid use disorder in the United States as identified through diagnosis codes related to opioid abuse, dependence, or poisoning, without regard to prescription drug histories. There are likely additional patients with opioid use disorder who are not represented in this study who have prescription drug claims for opioid treatment therapies that do not have corresponding medical claims associated with an opioid use disorder diagnosis. The diagnosis codes used to identify opioid use disorder include a range of severities, including some cases of uncomplicated use and some in remission. Additionally, opioid poisoning doesn't always happen within the context of an opioid use disorder.

Milliman has not audited any of the research data sets used for this analysis, but we have extensive experience working with them, and have found them to be reasonable. To the extent that there are errors or omissions in any of the data sources relied upon for this analysis, these results may also be in error. This report does not represent conclusive recommendations regarding treatment of opioid use disorder or legal advice. Milliman does not intend to benefit or create a legal duty to any recipient of this work.

Guidelines issued by the American Academy of Actuaries require actuaries to include their professional qualifications in all actuarial communications. Katie Matthews is a member of the American Academy of Actuaries, and meets the qualification standards for performing the analyses in this report.

Milliman did not receive any external funding for this analysis. Any opinions or views expressed in this report are those of the authors, not of Milliman.

The authors would like to thank Steve Melek and Anne Jackson for their helpful input and peer review of this material.

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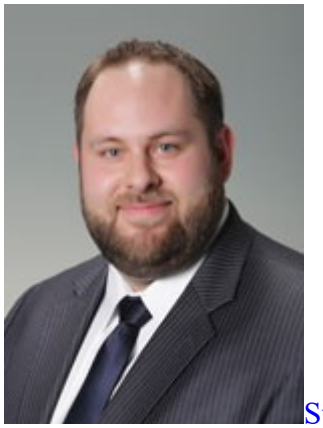

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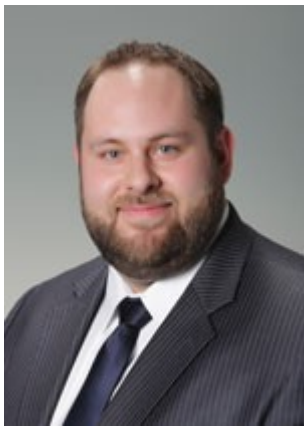

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Exhibit 12

SCENE & HEARD

Cuyahoga County Announces How It'll Use $23 Million in Opioid Settlement Money on Treatment and Prevention Services

Posted By Vince Grzegorek Email Us! on Fri, Oct 11, 2019 at 1:11 pm

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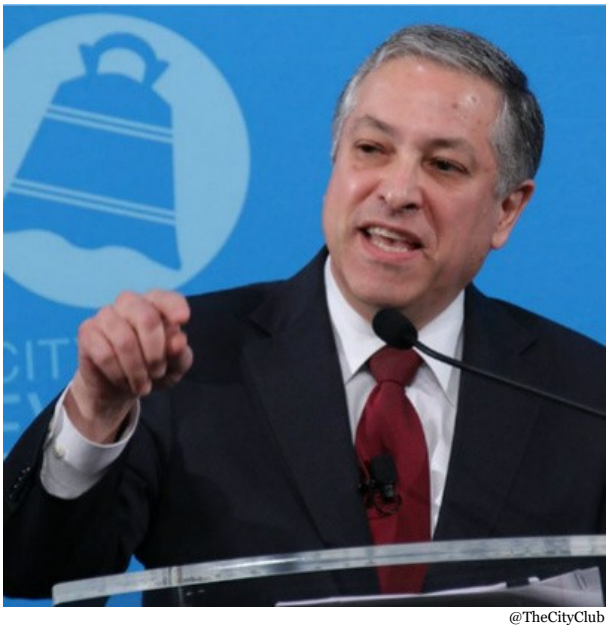

@TheCityClub

Cuyahoga County Executive Armond Budish yesterday announced how the county will spend $23 million it's received from four settlements in its lawsuit against opioid manufacturers and distributors. The trial against the rest is slated to begin on Oct. 21 with Summit County as co-plaintiff.

Phase One of the Cuyahoga County Opioid Crisis Mitigation Plan, the county said yesterday, will focus on "evidence-based, impactful, sustainable programs with a focus on prevention, treatment and recovery."

The grants so far:

PG&E Reaches $13.5 Billion Settlement Deal With Wildfire Victims

$5.4 million — For the Alcohol, Drug Addiction and Mental Health Services (ADAMHS) Board to create 32 new residential treatment beds and to fund the expansion of the Partial Hospitalization and Intensive Outpatient Program.\

$2 million — For St. Vincent Charity's Rosary Hall for peer recovery efforts and the expansion of their Partial Hospitalization Program (PHP) and Intensive Outpatient Program.

$1.7 million — For MetroHealth's treatment of inmates at the county jail, including care for addiction and mental health issues.

$931,000 — For MetroHealth to create a specific opioid treatment program unit at the jail.

$3 million — For the expansion of the Thrive ED Program across local emergency rooms. "Thrive ED is an innovative program linking individuals in an emergency room that survive an overdose for immediate withdrawal management, treatment and other recovery support services."

$3.5 million — For the Sobriety, Treatment and Recovery Teams (START) Program at the Cuyahoga County Division of Children and Family Services to increase staffing. START works with mothers and newborns who have chemical dependency issues.

$2.5 million — For a newly created diversion program for low-level offenders suffering from substance issues to receive support instead of simply sitting in the county jail as they await court dates.

The county has estimated in court documents that it's already incurred hundreds of millions of dollars in costs dealing with the aftermath of the opioid epidemic — from the coroner's office to foster kids, from treatment to the court system, etc.

How long this money lasts and what more might be coming once the trial is complete are two open questions.

“Due to a handful of corporations that put their desire for profits over the health and well-being of the community, our community is suffering the consequences of this plague,” Budish said in a statement. “We are working to recover some resources necessary to pay the costs which we’ve already incurred and are likely to incur for years to come."

"The settlement funds that we have received allow us to get started in the important work of providing services to help avoid the next wave of casualties,” added County Council President Dan Brady.

Tags: Opioids, Cuyahoga County, Image

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And cha-ching!!! Thief Budish now gets his hands on these millions and hands it all out to all of his government crony administrators with massive salaries at all of these numerous agencies!!!

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Exhibit 13

The Columbus Dispatch

Ohio voters could decide constitutional amendment to split up opioid lawsuit cash

By Darrel Rowland
The Columbus Dispatch

By Randy Ludlow
The Columbus Dispatch
Posted Dec 5, 2019 at 1:55 PM

Ohio Attorney General Dave Yost wants to ensure that money for any settlement of opioid lawsuits goes to fight drugs, not for politicians' pet projects.

Under a new plan being circulated at the highest levels of state government, Ohioans would vote on a constitutional amendment in the March primary to put money from a possible multimillion-dollar settlement of opioid lawsuits into a "lockbox" to make sure the money is actually spent to combat the drug scourge, The Dispatch has learned.

The biggest immediate hurdle to the proposal of Attorney General Dave Yost: The legislature must OK the proposed amendment by Dec. 18, the filing deadline for the March 17 ballot. Approval is needed from three-fifths of the membership of each chamber: 60 of 99 in the House, 20 of 33 in the Senate.

Hurdles No. 2 and 3: Neither the House nor the Senate GOP caucuses, which control the chambers, have even discussed the idea.

And hurdle No. 4: Gov. Mike DeWine opposes the measure.

DeWine told The Dispatch it is "frankly premature" to consider pursuit of a constitutional amendment before the state and local governments pressing claims in court reach agreement on how to handle and divide opioid settlement funds.

"The attorney general raised this with me the other day. I told him I would think about it. ... The discussion about that (a constitutional amendment) can't occur until we reach agreement with each other in Ohio.

"We need to finalize an agreement ... everyone needs to be united on this," the governor said. "We have made some very good progress in talking with the cities and counties. I think we are getting close. We are not there yet."

DeWine said a "real consensus" has been reached that settlement funds must be spent on addiction treatment programs to lessen opioids' hold on addicted Ohioans.

The governor did not directly respond when asked if he would support a constitutional amendment to lock in the long-term distribution of settlement funds once local and state officials strike a deal on how to allocate the money to help combat the crisis, which has eased but remains deadly.

The measure, which would divvy up money that has been or is still to be won in lawsuits filed by state and local governments in both state and federal courts, is designed to alleviate local governments' concerns that the state would fritter the money away like it did the state's tobacco lawsuit settlement in 1998.

Two years later, the legislature had diverted some of the money for tobacco cessation efforts to school construction, law enforcement, biomedical research and education technology. In 2008, lawmakers diverted more than $200 million into a "jobs fund." The state's total payments under the tobacco settlement were to reach $10 billion over 25 years.

"Ohio is unlikely to have access to this level of financial resources again," Yost's office has argued in private meetings — including one at the Governor's Residence in Bexley — with representatives of the governor, local governments and the General Assembly. "This is literally a once-in-a-lifetime, do-or-die moment."

The proposed constitutional amendment would split opioid settlement money three ways: to local governments, the state and a new Ohio State and Local Government Opioid Crisis Recovery Foundation. The latter would get the majority of the cash, and local governments would get about twice as much as the state. The foundation's 12-member board would be chosen by state and local officials.

While some of the money would go to meet immediate needs in the battle against opioids, most would be invested so the fund could grow and meet future needs as well. The amendment — which could only be changed by another constitutional amendment — is designed to ensure "settlement dollars are spent on abatement, not pet projects."

Yost's office says it is working on an "all Ohio" settlement. The state has filed suit in Madison and Ross counties, while about 70 local governments are involved in a massive group of lawsuits filed against opioid manufacturers and distributors and drug chains by governments across the

country that is now before a federal judge in Cleveland. A trial is set for October 2020 for two of the Ohio plaintiffs, Cuyahoga and Summit counties.

Kent Scarrett, executive director of the Ohio Municipal League, also said the group was unaware of the proposal until it received details Wednesday from Yost's office.

DeWine is scheduled to discuss the opioid crisis and potential settlements with the league's board Friday morning, Scarrett said.

"We don't have a position. This is a new thing that just landed on our radar yesterday," Scarrett said. "We need to look at how this would play out in the ability of local governments to receive relief from this epidemic."

Noting the disposition of Ohio's tobacco settlement, Scarrett said, "The legislature should have as little influence over the allocation process as possible."

Dispatch reporter Anna Staver contributed to this story.

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