BEFORE THE UNITED STATES JUDICIAL PANEL ON MULTIDISTRICT LITIGATION

IN RE: NATIONAL PRESCRIPTION OPIATE LITIGATION **MDL NO. 2804**

Doyle v. Actavis LLC, et al.
S.D. Ohio, C.A. No. 2:18-cv-00719

MEMORANDUM IN SUPPORT OF MOTION TO VACATE CTO-47

MAY IT PLEASE THE PANEL:

Counsel for Doyle NAS Baby Class submit the following Memorandum in Support of Motion to Vacate CTO-47.

I. INTRODUCTION

Counsel for the NAS Babies appear before this Honorable Panel in opposition to the transfer of this instant proceeding because unlike numerous cases already consolidated in Cleveland, the NAS Baby Classes have been denied any voice or participation in the on-going MDL. The state by state class actions filed, conservatively representing approximately 40% of the NAS Babies in the country,[1] are unique in that they seek damages by way of a medical monitoring trust to provide future care for these innocent and helpless children. By their very nature, such future care needs will often compete directly with other government priorities in allocating future damages. These competing claims share some common discovery objectives, however, as discussed below, the NAS Babies' claims do not wholly sound in public nuisance but also in state medical monitoring and product liability causes of action.

[1] Estimate based upon available state data compared to calculation by Plaintiffs' expert Dr. Anand of 31,330 NAS cases in 2016 nationwide. *See* Declaration of Dr. Kanwaljeet S. Anand, Exhibit 1.

The NAS Babies (babies born with neonatal abstinence syndrome, or "NAS"[3]) are a finite class of innocent children born addicted to opioids because their mothers took or were addicted to opioids during pregnancy. Excluding the present action, there are already eight NAS baby class actions presently pending in the MDL, all of which were filed by the undersigned.[4] Yet, despite undersigned counsel's efforts to work cooperatively within the MDL, the NAS Babies are presently denied any voice in the direction of this consolidated proceeding.[5] Instead, the original self-organized group of governmental entities which initially petitioned for its formation (and now corporate entities) exclusively control all opioid litigation, including discovery and settlement negotiations.

Although the named Plaintiffs' Executive Committee ("PEC") purports to represent the NAS Babies' interests by recouping past and capturing future reimbursable costs of care, as discussed *infra,* their clients' interests in this litigation and their settlement negotiation strategy directly conflict with the NAS Babies' interests and needs. Moreover, any efforts they may have undertaken on the NAS babies' behalf thus far have been shrouded in secrecy - so secretive in fact that counsel has been denied all notice of on-going discovery.

The District Court has likewise rejected the Babies' requests to create a separate NAS baby track within the MDL.[6] This has effectively denied the NAS Babies their due process right to fully pursue their interests without conflicting loyalties inherent in government allocation of funds. Absent full participation within the MDL, to avoid these conflicts, the NAS Babies respectfully request that the Panel vacate the motion to transfer and allow them to proceed on a separate track.

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[3] NAS has been defined as a "multisystem disorder characterized by disturbances in the central and autonomic nervous systems, the gastrointestinal tract, and the respiratory system due to in utero exposure to opioids." See *Id.*
[4] *See* Exhibit 2, the cases originate from West Virginia, Illinois, California, Missouri, Louisiana, Tennessee, Ohio and Maryland. An additional class action, *Moore v. Purdue,* 2:18-cv-01231 (S.WV), is subject of CTO-52.
[5] *See* Bickford Declaration attached as Exhibit 3.
[6] *Id., see also* Exhibit 4, 1:17-md-02804 Rec. Doc. 895 (Counsel renewed their request for a separate track on August 21, 2018. No action has yet been taken by the District Court.)

Meanwhile, the scope of the NAS Baby crisis cannot be overstated. Days ago, the President and First Lady visited a neonatal facility in Ohio to bring much-needed attention to this problem.[7] As further explained in Section IV, this year, tens of thousands of babies will be born in the United States with NAS.[8] NAS symptoms include seizures, respiratory instability, visual and auditory impairments, death, lower birth weights, smaller head circumferences, and long-term cognitive and behavioral deficits, all of which require active multi-disciplinary interventions initiated immediately after birth and continuing for the first 3-5 years of life for optimal outcomes.[9] While the District Court's litigation plan is to "just leave[s] them hanging,"[10] these children are suffering now, and the window for remedial medical intervention will be closed for tens of thousands of innocent children with each passing year. Undersigned counsel interpreted this to be a temporary state of affairs but it is becoming a permanent situation.

II PROCEDURAL HISTORY AND BACKGROUND

On December 17, 2017, the Panel created MDL 2804 on the motion of 46 governmental entities.[11] When formed, the MDL consisted solely of governmental entities, and this Panel raised the inevitable concerns about the potential inclusion of lawsuits by non-governmental entity plaintiffs as early as its November 30, 2017 hearing. As the following exchange from that hearing demonstrates, government (now PEC) counsel never envisioned that this MDL would encompass individual claims such as those brought by the NAS Babies, and then, as now, has no plans for their inclusion.

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[7] Lou Ann Stoia, Trump Stops by Children Hospitals to see special unit dealing with drug addicted babies, August 24, 2018), https://abc6onyourside.com/news/local/trump-stops-by-childrens-hospital-to-see-special-unit-dealing-with-drug-addict-babies.
[8] *See* Declaration of Dr. Kanwaljeet S. Anand, Exhibit 1.
[9] *See id.*
[10] Exhibit 5, 1:17-md-02804 Rec. Doc. 10 at p. 15 ll 4-5.
[11] JPML 2804 Rec. Doc. 1.

JUDGE VANCE: I understand that. But what about on
14 the plaintiffs' side? You've got governmental entities.
15 You've got personal injury plaintiffs. You've got hospitals.
16 You've got union trust funds. You've got third-party payors.
17 What do we do with them?

18 **MR. TELLIS:** *We have defined it so far as the*
19 *governmental entities*. Because what we're talking about is
20 the increased cost to deal with the addiction. Personal
21 injury plaintiffs don't have those costs. We're talking
22 about --

...

MR. TELLIS: The vast majority of the claims that
10 are pending thus far are public entity claims -- cities,
11 governments, public subdivisions. There may be -- I saw there
12 was a third-party payor claim and they support coordination.
13 And I agree with you. If it comes down to -- first of all, *I*
14 *don't think that if you just limit it to public entities, that*
15 *there would be all these others left out there. There might*
16 *be a category of third-party payors, there might be a hospital*
17 *or two,* but I think –[12]

Chief Judge Vance correctly observed that there were "serious threshold issues that are going to have to be sorted out with governmental entities that [personal injury] claims don't have to deal with."[13] Next, when Judge Vance asked government counsel whether he envisioned reconciling the disparate groups of plaintiffs within the putative MDL using separate tracks, he replied:

> We might need to track by category of plaintiff.... There may be a need to track by third-party payor plaintiffs or personal injury and public entity. I can see the wisdom of that. And we can put them on different tracks and shorten discovery, get some threshold issues up front...we use tracks to separate plaintiffs.[14]

Based on the representations by government counsel to this Panel and to the undersigned personally, counsel for NAS Babies have endeavored to work cooperatively within the MDL. However, despite numerous entreaties to the PEC, Special Masters, and District Court, the District

[12] Exhibit 6, JPML Rec. Doc. 382, pp. 7-10.
[13] *Id.* at p. 10:2-9.
[14] *Id.* at pp.10-11, 15.

Court has denied leave to move for the creation of a separate track for NAS Babies, and counsel for the NAS babies, since they are not members of the PEC, have been denied basic participation in the MDL. Presently, the MDL is being prosecuted by government, hospitals and third party payors.

During a December 13, 2017, telephonic conference with the District Court,[15] the government attorneys were directed to set a meeting to address plaintiff leadership issues. Government counsel were to seek consensus on leadership and address what to do with nongovernmental plaintiffs. The judge and defense counsel acknowledged that two or three tracks might be necessary.[17] The District Court also recognized that if early resolution failed, the case as structured could drag on for 5-10 years.[18]

On December 20, 2017, on the governments' motion to approve various plaintiff committees including the PEC,[19] three plaintiff subgroups objected: (1) various governmental entities, (2) third-party payors, and (3) hospitals.[20] The objections sought openness, fairness, and transparency and representation for certain clients in the PEC or a separate track.[21] The District Court denied these organizational motions and directed counsel to "include at least one attorney handling Third-Party Payor and one attorney handling Hospital cases."[22] The Court again noted that it had "not decided whether to keep non-government cases in [the] MDL, and if so, whether to create separate tracks."[23]

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[15] Exhibit 5, 1:17-md-02804 Rec. Doc. 10.
[17] *Id.* at p. 22 ll 22-23; p. 26.
[18] *Id.* at p. 42 ll14-16.
[19] Exhibit 7, 1:17-md-02084 Rec. Docs. 16 & 17.
[20] Exhibit 8, 1:17-md-02804 Rec. Docs. 18-20.
[21] *Id.*
[22] Exhibit 9, 1:17-md-02804 Rec. Doc. 22.
[23] *Id.*

Government counsel then renewed its organizational motions in which each objecting group was granted unique, individualized representation on the PEC.[26] In the motion, Government Counsel concurred with JPML's observation in the transfer order that "the transferee judge might find it useful …to establish different tracks for different types of parties or claims….Under each of the steering committee tracks, plaintiffs anticipated forming additional working groups to give multiple voices representation in decision making."[27] This new motion perfectly dovetailed the assertions before this Panel that separate tracks may be needed. Since January 4, 2018, when the District Court granted the renewed organizational motion, none of the promised separate tracks have been formed, nor have multiple voices been given representation in decision making.[28]

On January 9, 2018, the District Court directed the MDL parties to focus their efforts on settlement. The District Court's objective for 2018 was to accomplish meaningful abatement of the opioid crisis by reducing the amount and strength of prescription opioids and providing money resources to the governments for treatment.[29] To date, there has been no injunctive relief or settlement, and the resources for basic treatment have not been allocated.

On April 11, 2018, the District Court issued CMO number one establishing a litigation track for Counties, States, and Hospitals.[30]

On May 31, 2018, undersigned counsel filed their motion for leave to file a motion for a separate NAS Baby track.[31] On June 28, 2018, the District Court denied NAS counsel's motion

[26] Exhibit 10, 1:17-md-02804 Rec. Doc. 34.
[27] *Id.*
[28] Exhibit 11, 1:17-md-02804 Rec. Doc. 37.
[29] Exhibit 12, 1:17-md-02804 Rec. Doc. 71 p.5.
[30] Exhibit 13, 1:17-md-02804 Rec. Doc. 232.
[31] Exhibit 14, 1:17-md-02804 Rec. Doc. 540.

for leave to file a motion for creation of a separate NAS baby track through a marginal entry order without explanation or hearing.[32]

As of August 30, 2018, eight NAS-Baby class actions had been transferred to the MDL. Between May 14, 2018 and August 2, 2018, undersigned counsel communicated directly with the Court's Special Masters.[33] Undersigned counsel also conferred with members of the PEC by telephone and in person at the May 9, 2018 public status conference, espousing the need for the establishment of a separate track for NAS Babies.[34]

Having been denied representation in the MDL, NAS counsel sought to monitor discovery and offer suggested topics and questions. The PEC refused access to the discovery process to the point of even denying access to deposition notices. In specific response, the PEC wrote " … we believe that your interests are fully represented at any deposition by the PEC and therefore access or attendance is not necessary and burdensome to the process."[37] On August 17, 2018, at least one MDL-target defendant filed formal "notices on non-party fault", wherein that defendant claimed the governments involved in a bellwether trial, presumably seeking damages for care and treatment of NAS Babies, are responsible for the opioid crisis.[38] This notice demonstrates another conflict between government and governed and casts doubt on the PEC's suitability to protect the interests and needs of the NAS Babies as the PEC is presently constituted.

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[32] Exhibit 15, Order denying Motion for leave to File Motion for Order to Establish Separate Track for Opioid Baby Claims.
[33] Exhibit 16, Compilation of Plaintiffs' Correspondence with Special Masters and PEC.
[34] *Id.* at p.4. Among other things, undersigned counsel wrote (1) advising of their desire for "a separate trust(s), modeled after a medical monitoring trust, for prior and prospective injuries to the NAS Babies" (2) proposing numerous methods to achieve those ends, and (3) outlining the undersigned's experts retained for this litigation.
[37] *Id.* at p.10.
[38] Exhibit 17, 1:17 md 02804 Rec. Docs. 861-866. Although the defendants have yet to answer the NAS Babies' complaints, the undersigned anticipates that the defendants will affirmatively assert the fault of the government plaintiffs in their answers.

On August 8, 2018, the instant plaintiffs timely filed their notice of opposition to the conditional transfer order 47.[39] On August 21, 2018, the undersigned filed a renewed motion for leave to move for the creation of a separate NAS baby track.[40] In connection with that motion, and before deciding, on August 28, 2018, Mr. Bickford and Ms. Brustowicz were invited to participate in a conference call with leaders of the PEC. The call was ostensibly to explore common areas of discovery. A frank discussion was had concerning what NAS Babies' counsel believed are conflicting matters which make it essential that the NAS babies have their own voice in the litigation. The conflicts discussed included the direct competition between the NAS Babies and governments for common benefit (which the PEC acknowledges will be derived from a limited pool of funds), allegations of third-party fault (including the governmental entities), and similar but different causes of action available to NAS Babies which the governments and hospitals are not entitled to assert.[41] During this call, leaders of the PEC explained that the District Court was unlikely to create a separate NAS baby track or expand ranks of the PEC to include representatives for NAS babies.[42]

II. DUE PROCESS CONCERNS COMPEL THIS PANEL TO HOLD THE NAS BABY CASES OUT OF MDL 2804 AS IT IS PRESENTLY STRUCTURED

When the first set of NAS Babies' class actions were transferred into the general MDL, the Babies' counsel had high hopes for the fair and expeditious resolution of claims presented by this uniquely innocent and vulnerable group of plaintiffs based on the representations in this Panel and the District Court's records. Subsequent experience has dashed those hopes. The NAS Babies have no representation on the PEC, and that body has rebuffed all requests by the Babies' counsel to

[39] JPML 2804 Rec. Doc. 2150.
[40] Exhibit 4, 1:17-md-02804 Rec. Doc.895.
[41] Exhibit 3, Bickford Declaration.
[42] *Id.*

participate in discovery, monitor its progress, or review what has been produced. The District Court likewise rejected the NAS Babies' motion for a separate baby track within the MDL and has yet to rule on a renewed motion filed on August 21, 2018. This situation has effectively denied the NAS Babies due process. Absent a substantial alteration of the MDL's course, the only way to preserve the NAS Babies' due process rights is to hold the present case out of the MDL.

The Supreme Court has repeatedly acknowledged the "deep-rooted historic tradition that everyone should have his own day in court."[43] The Court has not considered how particular plaintiffs' due process rights play out in multidistrict litigation, but the Court's class action cases are highly instructive. In *Amchem Products, Inc. v. Windsor*, 521 U.S. 591, 627 (1997), the Court reversed certification of a settlement class action that "achieved a global compromise with no structural assurance of fair and adequate representation for the diverse groups and individuals affected." Likewise, in *Ortiz v. Fibreboard Corp.*, 527 U.S. 815, 856 (1999), the Court rejected another settlement class that failed to provide structural safeguards for divergent interests within the class, including "division into homogeneous subclasses" to protect those interests.[44] In neither case did the Court accept arguments that the settlement's substantive fairness could substitute for structural safeguards to protect divergent interests.[45]

The critical conflicts in *Amchem* and *Ortiz* both involved potential conflicts between holders of present and future claims. Both cases involved asbestos claimants, some of whom had present injuries and some who had been exposed but not yet manifested their harm. "[F]or the currently injured," the *Amchem* Court noted, "the critical goal is generous immediate payments.

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[43] *Taylor v. Sturgell*, 553 U.S. 880, 892-93 (2008) (*quoting Richards v. Jefferson Cty.*, 517 U.S. 793, 797 (1996)).
[44] *See also* In re Literary Works in Elec. Databases Copyright Litig. v. Thomson Corp., 654 F.3d 242, 253 (2d Cir. 2011) ("The Supreme Court counseled in *Ortiz* that subclasses may be necessary when categories of claims have different settlement values. The rationale is simple: how can the value of any subgroup of claims be properly assessed without independent counsel pressing its most compelling case?").
[45] *See Amchem*, 521 U.S. at 622; Ortiz, 527 U.S. at 857-58.

That goal tugs against the interest of exposure-only plaintiffs in ensuring an ample inflation-protected fund for the future."[46] Likewise, Justice Souter wrote in *Ortiz* that "it is obvious after *Amchem* that a class divided between holders of present and future claims (some of the latter involving no physical injury and attributable to claimants not yet born) requires division into homogeneous subclasses under Rule 23(c)(4)(B), with separate representation to eliminate conflicting interests of counsel."[47]

The same conflicts exist in the present case. Although the NAS Babies have present injuries, the extent of those injuries in some cases will not be clear for many years.[48] Because of these needs, and for other medical reasons, the NAS Babies' suits seek to create a separate trust fund to provide for medical monitoring and ongoing remediation of their injuries. The PEC, however, is comprised of counsel for state governments, hospitals and third-party payors that seek myriad competing damages. This is precisely the sort of conflict found problematic in *Amchem* and *Ortiz*. Moreover, it has now become apparent that this litigation will test the financial wherewithal of the certain defendants, exacerbating the internal competition among the MDL plaintiffs including the NAS Babies.[49]

If the question in the present matter were whether the various kinds of claims in the opioid MDL could be combined into a single class action, *Amchem* and *Ortiz* would plainly require sub-classing. That is not the present question or solution, of course, because this MDL is not a single

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[46] 521 U.S. at 626.

[47] 527 U.S. at 856; *see also* Samuel Issacharoff & Richard A. Nagareda, *Class Settlements Under Attack*, 156 U. PA. L. REV. 1649, 1684 (2008) (conflicts that matter are "those that give rise to a significant potential for negotiation on behalf of an undifferentiated class to skew in some predictable way the design of class-settlement terms in favor of one or another subgroup for reasons unrelated to evaluation of the relevant claims").

[48] *See* American Law Institute, *Principles of the Law of Aggregate Litigation*, § 3.10, cmt. a (2010) (recognizing that "there are cases (e.g., toxic exposures) in which some present claimants may be at risk of further disease progression, thereby rendering them both present and future claimants").

[49] *See, e.g.*, https://www.reuters.com/article/us-purdue-restructuring-exclusive/exclusive-oxycontin-maker-purdue-taps-financial-restructuring-adviser-sources-idUSKBN1L12OP.

class. But although those opinions spoke primarily in terms of Rule 23, the Court explicitly acknowledged that the "requirement that 'the named plaintiff at all times adequately represent the interests of the absent class members'" is constitutional in nature.[50] That requirement, and the Court's holdings concerning the sorts of conflicts that violate it, apply to multidistrict litigation no less than to class actions.[51] Indeed, because MDLs lack the formal procedural safeguards afforded by Rule 23 in class actions, courts must exercise even greater vigilance to ensure that due process requirements are observed. This is especially true where as here, the MDL was charged with pre-trial discovery coordination and global settlement efforts. Indeed, statements of MDL "best practices" acknowledge that "particularly when there are significant differences among identifiable groups of plaintiffs, the judge should ensure that the leadership is comprised of attorneys that reflect these variations in claims." Duke Law Center for Judicial Studies, *Standards and Best Practices for Large and Mass-Tort MDLs*, Dec. 19, 2014, at 59.[52]

Even setting *Amchem* and *Ortiz* aside, it is evident that due process entitles NAS Babies' full participation in the litigation. "The fundamental requirement of due process is the opportunity to be heard at a meaningful time and in a meaningful manner."[53] In this case, that means an opportunity to develop the evidence necessary to support the NAS Babies' claims, notice of developments in the litigation, and the chance to ensure that the Babies' unique needs are reflected in the relief sought and obtained in any eventual settlement. As in the class action context, it is

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[50] *See Amchem*, 527 U.S. at 846-48 & n.24; *see also Philips Petroleum Co. v. Shutts*, 472 U.S. 795, 812 (1985); *Hansberry v. Lee*, 311 U.S. 32, 42-43 (1940).

[51] *See, e.g.*, Jack B. Weinstein, *Ethical Dilemmas in Mass Tort Litigation*, 88 Nw. U. L. Rev. 469, 480-81 (1994) ("What is clear from the huge consolidations required in mass torts is that they have many of the characteristics of class actions. . .. It is my conclusion . . . that mass consolidations are in effect quasi-class actions. Obligations to claimants, defendants, and the public remain much the same whether the cases are gathered together by bankruptcy proceedings, class actions, or national or local consolidations.").

[52] *See also* ALI *Principles of Aggregate Litigation* § 2.07 cmt. d (recognizing that concerns about conflicts between interests within the class apply not only to class actions but also to other forms of aggregate litigation).

[53] *Matthews v. Eldridge*, 424 U.S. 319, 333 (1976).

both unrealistic and legally inadequate to expect the District Court to make up for the Babies' counsel's exclusion by evaluating the general fairness of the settlement at the close of proceedings.[54] And although the NAS Babies' representatives retain the ultimate right to reject any settlement, they will have lost years if they must wait until the MDL's conclusion to pursue these claims. For this class of plaintiffs—brought into this world in the throes of withdrawal and requiring immediate and costly monitoring treatment—that delay would be uniquely tragic. As *Mathews* made clear, due process requires not only the *eventual* right to be heard, but the right to be heard "at a meaningful time."[55]

This Panel's initial order creating the opioid MDL noted the diversity of claims arising within it and suggested that "[t]he transferee judge might find it useful . . . to establish different tracks for the different types of parties or claims."[56] Had the wisdom of that foreshadowing included meaningful representation of the Babies, that would have gone a long way toward avoiding any due process problems from arising from the obvious conflicts currently existing within the MDL.

IV. THE UNIQUE STATUS OF CHILDREN UNDER THE LAW COMPELS THIS PANEL TO HOLD THE NAS BABY CASES OUTSIDE OF THIS MDL AS IT PRESENTLY STRUCTURED.

The NAS Baby cases seek medical monitoring trust to provide for their future care[57] and to protect their financial interest from being co-opted by government. The NAS Baby counsel seek to protect these babies' share of any global settlement or other structure which seeks to address the future costs associated with their addiction to opiates at birth.

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[54] *See, e.g.*, S. Todd Brown, *Plaintiff Control and Domination in Multidistrict Mass Torts*, 61 Clev. St. L. Rev. 391, 416-18 (2013).
[55] 424 U.S. at 333.
[56] JPML 2804 Rec. Doc. 1.
[57] The NAS Babies have a personal injury cause of action but to the extent it is litigated it would be a subclass centered on liability and general causation.

The Supreme Court has long recognized that "[c]hildren have a very special place in life which law should reflect,"[58] and federal district courts possess inherent authority to "safeguard interests of persons entitled to the court's special protection," such as minor children.[59] Moreover, the Supreme Court has confirmed due process rights of children as being the point of departure for producing justice for children. *In re Gault*, 387 U.S. 1, 13 (1967) ("...neither the Fourteenth Amendment nor the Bill of Rights is for adults alone."); *Prince v. Massachusetts*, 321 U.S. 158, 170 (1944) ("Parents may be free to become martyrs themselves. But it does not follow they are free, in identical circumstances, to make martyrs of their children before they have reached the age of full and legal discretion when they can make that choice for themselves.").

The Panel should exercise its authority to ensure that these children have a direct voice in this litigation and that their unique interests are protected.[60] Indeed, children's right to self-determination, that is, the right of children to decide about those matters that concern them, is the cornerstone of Children's Rights Movement, which helped give rise to child protective law and policy.[61]

The "status of minors under the law is unique in many respects."[62] For that reason, and due to the vulnerability of children, courts have recognized that children should be provided separate protection in class action lawsuits.[63] Courts have recognized that children are entitled to their own

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[58] *May v. Anderson*, 345 U.S. 528, 536 (1953).
[59] *Green v. Nevers*, 111 F.3d 1295, 1301 (6th Cir. 1997).
[60] *See generally* Marvin Ventrell, From Cause to Profession: The Development of Children's Law and Practice, 32-JAN Colo. Law. 65, 68 (Jan. 2003) ("Children, even more than adults, are unable to speak for themselves in court."). The Children's Bill of Rights emphatically states that all children have the right to be born healthy and to grow in a society free of degrading circumstances. White House Conference on Children, 1970, The Rights of Children, Report of Forum 22, pp. 343-370.
[61] *See* Ventrell at 68; See Richard Farson, Birthrights: A Bill of Rights for Children (1974) (extensively analyzed in Philip Veerman, The Rights of the Child and the Changing Image of Childhood (1992), at chp. IX.); See generally Donald Bross, The Evolution of Independent Legal Representation for Children, Perspectives on Child Advocacy Law in the Early 21st Century (ABA 2000) at pp. 9-21.
[62] *Bellotti v. Baird*, 443 U.S. 622, 633 (1979).
[63] *Nicholson v. Williams*, 205 F.R.D. 92 (E.D.N.Y. 2001).

classes to protect their own unique interests.[64] Moreover, the most recent conference on child advocacy that achieved a national consensus promulgated practicing guidelines for children's attorneys, including those specifically for children lacking capacity. *Recommendations of the UNLV Conference on Representing Children in Families*, 6 NEV. L.J. 592 (2006) ("When the child lacks capacity to communicate a position, the child's attorney should effect a client-directed representation").[65]

V. THE MAGNTITUDE OF NAS BABY CRISIS CANNOT BE OVERSTATED.

On March 30, 2018, the CDC, declared that opioid use in pregnant women is a significant public health concern because of the adverse effects on their babies:

> Opioid use by pregnant women represents a significant public health concern, given the association of Opioid exposure and adverse maternal and neonatal outcomes, including preterm labor, still births, and neonatal mortality. There is an urgent need to implement a multi-faceted corroborative public health & public safety approach that is continued on a

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[64] *See, e.g.*, *Marisol A. v. Giuliani,* 126 F.3d 372, 379 (2d Cir. 1997) (affirming certification of a class of children suffering from abuse and neglect claiming that various governmental agencies failed to provide assistance in compliance with the ADA); *Alexander A. ex rel. Barr v. Novello*, 210 F.R.D. 27, 29 (E.D.N.Y. 2002) (granting class certification to a class of children with disabilities against governmental entities under the ADA and the Rehabilitation Act); *Kenny A. ex rel. Winn v. Perdue,* 2005 WL 332417, at *3-6 (N.D. Ga. Feb. 8, 2005) (granting class certification to a class of foster children, stating they have both a statutory and Due Process right to counsel under both Georgia and U.S. Constitutions). Such class certification for children resonates with The Report of the Working Group on the Best Interests of the Child and the Role of the Attorney, which emphasizes that "[A]ll children, regardless of age, were entitled to an attorney who zealously advocates for their expressed wishes." 6 Nev. L.J. (Special Issue) 682 (Spring 2006).

[65] The full practicing guideline for "Children Lacking Capacity" is as follows: "Children Lacking Capacity: When the child lacks capacity to communicate a position, the child's attorney should effect client-directed representation by performing the following non-exhaustive list of duties, in addition to those listed above in part IV.A.2.c above for the child with diminished capacity [i. Adopting a position requiring the least intrusive state intervention; ii. Being guided by goals that are respectful of and reflect what the client would want and the decision the child would make if the child could formulate a position; iii. Respecting the child's family and social connections; iv. Being familiar with the child's family, community and culture and take precautions to avoid imposing the attorney's personal standards and cultural values; v. Giving special weight to the parent's preference in the absence of conflict regarding the matter at issue, parental incapacity, or harm to the child; vi. Utilizing the following rights and values as further guidance: (A) Limitation of state intervention in the child's life; (B) The child's right to have his or her family respected; (C) The child's liberty interest to be free from state custody; and (D) The family's liberty interest in parental determination of what is in the child's interests]: i. Obtain additional pertinent information through investigation and consultation; ii. Involve parents in the process but recognize that parents cannot direct the representation; iii. Protect the child's legal interests." *Recommendations of the UNLV Conference on Representing Children in Families*, 6 NEV. L.J. 592 (2006).

> national/state level to prevent, monitor, and treat Opioid-use disorders among reproductive aged and pregnant women.[66]

Medical studies of the short and long-term consequences of opioid exposure in utero reveal a variety of debilitating conditions that, if untreated, will prevent babies born addicted from achieving productive adulthood.[67] NAS babies have a strong association with poor and deteriorating educational performance. Their ability to speak, to become socialized, to exhibit proper behavior and development are significantly diminished and motor skill dysfunction are all well-documented and recognized.[68] A study of brain MRIs reveals reduced skull and brain size.[69] The likelihood of future addiction in these children is substantial as they have a mother who was likely addicted to opioids, and they were also once addicted.

These problems along with the sheer number of known babies born in this country with the NAS diagnosis led the CDC to its conclusion that NAS babies presented a significant public health concern. The New England Journal of Medicine reported in 2016 that in 2012, NAS was diagnosed in 21,732 U.S. infants.[70] This represented a nearly 5-fold increase between 2000 and 2012.[71] The total reported NAS births may be significantly underreported.[72] The future incidence of NAS baby births is still on the rise.[73] In 2018, the United States can expect at least 75 NAS babies born every day.[74]

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[66] Exhibit 18, Center for Disease Control (CDC) Morbidity and Mortality Weekly Report, Vol. 67, No. 12, March 30, 2018, pages 849-858; and Exhibit 19, Center for Disease Control (CDC) Morbidity and Mortality Weekly Report, Vol. 67, No. 31, August 10, 2018, pages 845-849, and Summary pages 1-3.
[67] Exhibit 20, Pediatrics, Vol 139, #2, February 2017, "Neonatal Abstinence and High School Performance." Pages 1 through 10 cites 48 major works and studied that all are of interest. Special note to Articles 32, 39, 40, 41 and 42.
[68] *Id.*
[69] Exhibit 21, Journal of Perinatology (2014) 34, 909-913, "Do Maternal Opioids Reduce Neonatal Regional Brain Volume?" Pilot Study.
[70] McQueen, Karen, et al, Neonatal Abstinence Syndrome, N Engl J Med 2016; 375:2468-24-79.
[71] *Id.*
[72] See Exhibit 19, Center for Disease Control (CDC) Morbidity and Mortality Weekly Report, Vol. 67, No. 31, August 10, 2018. (Only 28 states, for example, require reporting of NAS baby births. The data from reporting states is alarming, and there is no reason to believe their findings would not be replicated in the remaining states.)
[73] Exhibit 1, Declaration of Dr. K.S. Anand.
[74] *Id.*

There are no other lawsuits on behalf of NAS Baby pending in the MDL other than those filed by undersigned counsel. The undersigned has assembled a team of the best, most-recognized and NAS-experienced medical professionals to create a scientifically-based medical monitoring program that can serve these children and their families throughout their lives no matter where they reside.[75]

VI. MEDICAL MONITORING TRUST

Medical monitoring trusts are allowed in every jurisdiction where the undersigned has filed lawsuits on behalf of NAS Babies.[76] In jurisdictions where medical monitoring is not traditionally allowed, it is only due to the absence of general causation or the likelihood that a future disease will never occur. Neither is the case here where each putative class member is born with an injury caused by an opiate.

Part of the CDC's call to action was the "urgent need to implement a multi-faceted corroborative public health & public safety approach that is continued on a national/state level to prevent, monitor, and treat Opioid-use disorders among reproductive aged and pregnant women."[77] Governmental (Medicaid) and insurance reimbursements only account for dollars actually spent on the NAS Babies (typically their NICU time being weaned off opioids) and does not reflect what these babies actually need and should receive for their future. The modeling the above expert team has worked up is entirely consistent with the CDC goals and fills in the large gaps the government,

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[75] Exhibit 22, Declaration of C. Werntz.

[76] *See* West Virginia- *Bower v. Westinghouse Electric Co.*, 522 S.E.2d 424 (1999); Illinois- *Lewis v. Lead Indus. Ass'n, Inc.*, 793 N.E.2d 869, 874 (2003); Missouri- *Meyer ex rel. Coplin v. Fluor Corp.*, 220 S.W.3d 712, 718 (Mo. 2007); California- *Potter v. Firestone Tire & Rubber Co.*, 863 P.2d 795 (Cal. 1993); Tennessee- *Bandy v. Trigen-Biopower, Inc.*, No. 3:02-CV-459, 2006 WL 5321815; Ohio- *Wilson v. Brush Wellman*, Inc., 103 Ohio St.3d 538, 817 N.E.2d 59, 63 (2004); Maryland- *Exxon Mobil Corp. v. Albright*, 433 Md. 303, 380, 71 A.3d 30, 77, on reconsideration in part, 433 Md. 502, 71 A.3d 150 (2013); New York- *Allen v. Gen. Elec. Co.*, 32 A.D.3d 1163, 1165, 821 N.Y.S.2d 692, 694–95 (2006); Louisiana- LSA-C.C. Art. 2315.

[77] Exhibit 18, Center for Disease Control (CDC) Morbidity and Mortality Weekly Report, Vol. 67, No. 12, March 30, 2018, pages 849-858; and Exhibit 19, Center for Disease Control (CDC) Morbidity and Mortality Weekly Report, Vol. 67, No. 31, August 10, 2018, pages 845-849, and Summary pages 1-3.

insurers, and hospitals systems simply cannot address. For instance, Charles L. Werntz III, one of our experts, has designed a medical monitoring system over the course of the child's lifetime which calls for specific assessments of all known areas of likely impairment.[78] This is the type of competing claim that the NAS Babies bring to the MDL.

In the end, this team's medical monitoring proposal will reduce overall governmental and institutional medical and addiction-related expenditures and provide these children with the relief they need and deserve.

CONCLUSION

For the foregoing reasons, the NAS Babies as litigants are entitled to access to the courts where their claims can be heard and adjudicated in a meaningful and timely manner. The present MDL has not only been charged with conducting pre-trial discovery in the opioid litigation but has also been charged to attempt to reach a global settlement. Depriving the NAS Babies a voice or seat at the table deprives them of fundamental due process rights. Barring full inclusion in the In Re: National Prescription Opiate Litigation, counsel requests their Motion to Vacate is granted.

[78] Exhibit 22, Declaration of C. Werntz.

Respectfully Submitted:

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CERTIFICATE OF SERVICE

I hereby certify that on this 30th day of August, 2018, a copy of the above and foregoing has been electronically filed with the Clerk of Court using the CM/ECF system, which provides an electronic service notification to all counsel of record registered as CM/ECF users.

/s/SCOTT R. BICKFORD
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