UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF OHIO
EASTERN DIVISION

IN RE: NATIONAL PRESCRIPTION OPIATE LITIGATION

MDL No. 2804

Master Docket No. 1:17-MD-02804-DAP

This document relates to:

Hon. Judge Dan A. Polster

AMANDA HANLON, INDIVIDUALLY AND ON BEHALF OF ALL OTHERS SIMILARLY SITUATED;

AMY GARDNER, INDIVIDUALLY AND ON BEHALF OF HER MINOR DAUGHTER A.L.D. AND ALL OTHERS SIMILARLY SITUATED,

Plaintiffs,

v.

PURDUE PHARMA L.P.;
PURDUE PHARMA, INC.;
THE PURDUE FREDERICK COMPANY, INC.;
TEVA PHARMACEUTICAL INDUSTRIES, LTD.;
TEVA PHARMACEUTICALS USA, INC.;
CEPHALON, INC.; JOHNSON & JOHNSON;
JANSSEN PHARMACEUTICALS, INC.;
ORTHO-MCNEIL-JANSSEN PHARMACEUTICALS, INC. n/k/a JANSSEN PHARMACEUTICALS, INC.;
JANSSEN PHARMACEUTICA INC. n/k/a JANSSEN PHARMACEUTICALS, INC.;
ENDO HEALTH SOLUTIONS INC.;
ENDO PHARMACEUTICALS, INC.;
ALLERGAN PLC f/k/a ACTAVIS PLC;
WATSON PHARMACEUTICALS, INC. n/k/a ACTAVIS, INC.;
WATSON LABORATORIES, INC.; ACTAVIS LLC; and
ACTAVIS PHARMA, INC. f/k/a WATSON PHARMA, INC.;

Defendants.

Case No. 1:19-op-45206

MOTION FOR PRELIMINARY INJUNCTION

Comes, Amanda Hanlon, individually and on behalf of all others similarly situated, and Amy Gardner, individually and on behalf of her minor daughter A.L.D. and on behalf of all others similarly situated, through undersigned counsel and moves pursuant to FRCP 65 for an order of preliminary injunction against Defendants[1] that during the pendency of the MDL Litigation *In Re: National Prescription Opiate Litigation*, 1:17-MD-02804, that they be prohibited from dispensing any opioid prescription[2] to any woman capable of becoming pregnant without first receiving notice/proof of a negative pregnancy test, dispensing only a seven-day supply, and if additional opioids are prescribed after those seven days, that there be another negative pregnancy test before dispensing the prescription because: (1) the plaintiffs will likely succeed on the merits; (2) the plaintiffs will suffer irreparable harm without the injunction; (3) granting the injunction will not cause substantial harm to others; and (4) the public interest will be well served by such a preliminary injunction, all as more fully set forth in the documents filed contemporaneously herewith:

- Memorandum Supporting Complaint for Preliminary Injunction
- Statement of Undisputed Facts Supporting Complaint for Preliminary Injunction
- Evidence Supporting Statement of Undisputed Facts Supporting Complaint for Preliminary Injunction

Wherefore, Mover prays that this motion be set for hearing and after proceedings are had that a preliminary injunction issue prohibiting Defendants from dispensing an opioid prescription to a woman capable of bearing children without first having received notice/proof of a negative pregnancy test, dispensing only a seven-day supply, and if additional opioids are prescribed after

[1] PURDUE PHARMA L.P.; PURDUE PHARMA, INC.; THE PURDUE FREDERICK COMPANY, INC.; TEVA PHARMACEUTICAL INDUSTRIES, LTD.; TEVA PHARMACEUTICALS USA, INC.; CEPHALON, INC.; JOHNSON & JOHNSON; JANSSEN PHARMACEUTICALS, INC.; ORTHO-MCNEIL-JANSSEN PHARMACEUTICALS, INC. n/k/a JANSSEN PHARMACEUTICALS, INC.; JANSSEN PHARMACEUTICA INC. n/k/a JANSSEN PHARMACEUTICALS, INC.; ENDO HEALTH SOLUTIONS INC.; ENDO PHARMACEUTICALS, INC.; ALLERGAN PLC f/k/a ACTAVIS PLC; WATSON PHARMACEUTICALS, INC. n/k/a ACTAVIS, INC.; WATSON LABORATORIES, INC.; ACTAVIS LLC; and ACTAVIS PHARMA, INC. f/k/a WATSON PHARMA, INC

[2] All medications Defendants manufacture containing opioids, whether natural, synthetic, or semi-synthetic.

seven days, that there be another negative pregnancy test before dispensing the prescription; and for all other relief necessary under the circumstances.

Respectfully submitted,

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CERTIFICATE OF SERVICE

The undersigned hereby certifies that on 28th of March, 2019, the foregoing document was served on all counsel of record by the CM/ECF system.

/s/Celeste Brustowicz

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WATSON PHARMACEUTICALS, INC. n/k/a ACTAVIS, INC.;
WATSON LABORATORIES, INC.; ACTAVIS LLC; and
ACTAVIS PHARMA, INC. f/k/a WATSON PHARMA, INC.;

Defendants.

Case No. 1:19-op-45206

MEMORANDUM IN SUPPORT OF PLAINTIFFS' MOTION FOR PRELIMINARY INJUNCTION

I. PRELIMINARY INJUNCTION DURING PENDENCY OF OPIOID LITIGATION IS NECESSARY TO ABATE NAS AND OUD BIRTHS

The incidence of opioid use and addiction was stable in this country until 1995 when a synthetic time-released opioid called Oxycontin was FDA approved.[1] This approval coupled with the advent of drugs similar to Oxycontin and aggressive marketing campaigns by the defendants led to sky-rocketing opioid use, addiction, misuse, and explosions of the diversionary and the illicit drug markets to the point where a national-opioid epidemic now exists.[2] This country's need for pain medications by chronic pain sufferers or those with acute pain needs did not, however, increase during this same time.[3]

The primary purpose of this suit, the others in this MDL, and those pending in state courts, is to permanently abate the opioid epidemic.[4] This motion seeks a preliminary injunction to assist abatement during the pendency of these actions by reducing the number of NAS[5] and OUD[6] births by requiring a negative pregnancy test before an opioid can be dispensed to a woman capable of becoming pregnant, dispensing only a seven-day supply, and if additional opioids are prescribed after seven days, that there be another negative pregnancy test before dispensing the prescription. This request is not unlike other programs established by drug manufacturers, distributors, pharmacies, and the FDA for drugs with teratogenic properties which successfully protect fetal development.[7]

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[1] See attached Undisputed Material Facts Supporting Motion for Preliminary Injunction (UMF): 6, 8
[2] UMF: 11, 14
[3] UMF: 10
[4] Rec. Doc 71 January 9, 2018 Telephone Conference; see also docket of these proceedings. Courts may take judicial notice of court dockets. Fed. R. Evid. 201.
[5] UMF: 34
[6] UMF: 34
[7] UMF: 59, 60; Isotretinoin (Accutane) is known to cause birth defects when taken during pregnancy. These birth defects can be severe and include deformities of the heart, face, and brain. These birth defects are like those caused by opioids.

Abatement of the opioid epidemic has always been this court's goal; this proposed preliminary injunction serves this goal:

> So, my objective is to do something meaningful to abate this crisis and to do it in 2018. And we have here -- we've got all the lawyers. I can get the parties, and I can involve the states. So, we'll have everyone who is in a position to do it. And with all of these smart people here and their clients, I'm confident we can do something to dramatically reduce the number of opioids that are being disseminated, manufactured, and distributed. Just dramatically reduce the quantity, and make sure that the pills that are manufactured and distributed go to the right people and no one else, and that there be an effective system in place to monitor the delivery and distribution, and if there's a problem, to immediately address it and to make sure that those pills are prescribed only when there's an appropriate diagnosis, and that we get some amount of money to the government agencies for treatment. Because sadly, every day more and more people are being addicted, and they need treatment. So that's what I am interested in doing.[8]

Anything a pregnant woman ingests or breathes is transmitted to her baby by the placenta.[9] Some things cross the placenta with ease; included among them, are opioids.[10] Opioids are lipid (fat) based and easily cross the placenta; they have an affinity for the developing brain structures which are also lipid based.[11] Science has not (yet) determined what dose of opioid or what length of time opioids are taken that will result in NAS or OUD.[12] Babies with in-utero opioid exposure are subject to addiction and brain and other organ insult.[13]

The CDC has concluded there are hundreds of thousands of children in this country with a NAS or OUD diagnosis.[14] The costs associated with these children in first weaning them from their addiction and then evaluation and services related to their injuries are astronomical.[15] These costs

[8] Rec. Doc. 71, pp 4-5 January 9, 2018 Telephone Conference
[9] UMF: 25
[10] UMF: 25
[11] UMF: 25
[12] UMF: 25
[13] UMF: 25, 34, 36, 37-44
[14] UMF: 51; Only 28 states reported these conditions.
[15] UMF: 99

threaten the budgets of every family with such a child and every political subdivision in the country. The only realistic means of reducing the NAS and OUD births is prevention.

What is proposed here is an economically and medically sound means of eliminating in-utero prescription-opioid exposure. This proposal serves the public by reducing the likelihood of addiction in women, reducing the incidence of medical treatments related to opioid misuse, and facilitating education of opioid dangers to healthcare professionals and the public, and reduces injury to babies not yet conceived.

Women are more likely to be prescribed opioids than men.[16] Women have a higher opioid plasma concentration (up to 25%) more than men on a body weight adjusted basis.[17] This means that the drugs' effects, including the likelihood of addiction, are higher in women than men.[18] The government reports that one third of all pregnant women in this country are prescribed opioids.[19] A natural consequence of opioid use in pregnant women is the tragic increase in the number of children exposed in-utero to opioids.[20] The incidence of children born in this country with a NAS or OUD diagnosis has surged to the point where we are at risk of a lost generation.[21] The problems from in-utero exposure may not end with the baby. A study suggests that opioids modify genes that make addiction more likely in the baby and this modification may carry on generations forward.[22]

The dangers from exposure occurs at any point during pregnancy, save the first 10 to 14 days.[23] In-utero opioid exposure leaves most children with physical, social, educational disabilities that require

[16] UMF: 20
[17] UMF: 21
[18] UMF: 22
[19] UMF: 22, 23
[20] UMF: 33
[21] UMF: 35
[22] UMF: 50
[23] UMF: 31

constant and regular interventions.[24] Most of these disabilities are considered permanent.[25] Medical understanding of NAS, OUD, and addiction remain poorly understood.[26] There is no cure. For those pregnant women who are opioid addicted, the only treatment protocol involves other opioids which also can cause NAS and OUD.[27]

Beyond the epidemic, another result of the defendants' aggressive marketing campaigns to healthcare professionals was to change the medical understanding of opioids from strong respect of their addictive nature and judicious use to more liberal and expansive use based on what we now know was false information that these engineered drugs would not result in addiction.[28] As a result, standards of care and practice concerning opioids changed and are continuing to change. Leading associations of healthcare professionals devoted to the care of women and children have announced practice guidelines covering opioids and pregnancy; caution is the guide.[29] Medical standards of care concerning opioids are evolving and are not consistent nationwide.[30] And, it is no understatement to say that the standards of care regarding opioid administration remain muddled as a result of defendants' conduct.

Sharp rises in addiction and crime resulting from opioid use were first identified in 2000.[31] At that time, the opioid problem was not an epidemic and was limited to a small handful of states.[32] Congress and the Executive Branch, through a number of agencies (FDA, DEA, NIH, SAMSHA and others), joined by states, medical organizations, and others (including some of the defendants)

[24] UMF: 35
[25] UMF: 36-43, 50
[26] UMF: 48
[27] UMF: 45-46
[28] UMF: 56-58
[29] UMF: 58
[30] UMF: 56-58
[31] UMF: 16
[32] UMF: 16

immediately implemented a series of policies and actions to curb the crisis.[33] Notwithstanding these substantial, expensive, and broad-based efforts, the crisis bloomed into our current nationwide disaster.[34] The proposal here- a negative pregnancy test and a seven day limit- was not a part of any of those efforts. It is not unreasonable to say that the first abatement efforts were geared to addiction and crime. No particular efforts were focused on the babies.

The negative pregnancy tests and seven-day limit requirements will protect future babies and their families. It will serve the public interest by assisting healthcare professionals in understanding and abating the opioid epidemic. The costs of reliable pregnancy tests are such that the burden they create is far outweighed by the benefits gained. What is proposed here is entirely consistent with what the FDA requires for Accutane, a non-opioid prescription medication with teratogenic properties.[35] That FDA program is a success and its tenants are followed here to the extent the law governing preliminary injunction allow.

II. PRELIMINARY INJUNCTION SEEKING TO ALTER STATUS QUO IS PERMISSIBLE IF PREVENTING IRREPARABLE INJURY

The purpose of a preliminary injunction is to maintain the status quo until the merits of the case are concluded.[36] Here, admittedly, Petitioners seek something different than maintaining the status quo.[37] But that is no impediment as courts have found that a preliminary injunction is not vulnerable to attack even if it changes the status quo.[38] However, "[i]f the currently existing status quo itself is causing one of the parties' irreparable injury, it is necessary to alter the situation so as to prevent the injury, either by returning to the last uncontested status quo between the parties, by the issuance

[33] UMF: 16
[34] UMF: 6, 14, 15, 16
[35] UMF: 40; https://www.birthinjuryguide.org/birth-injury/causes/medication/accutane/
[36] *Univ. of Texas v. Camenisch*, 451 U.S. 390, 395, 101 S. Ct. 1830, 68 L. Ed. 2d 175 (1981)
[37] *Dominion Video Satellite, Inc. v. EchoStar Satellite Corp.*, 269 F.3d 1149, 1154–55 (10th Cir. 2001); *Aoude v. Mobil Oil Corp.*, 862 F.2d 890, 893 (1st Cir. 1988)
[38] Plaintiffs seek a 'status quo' before the 1995 introduction of Oxycontin and its debilitating effects.

of a mandatory injunction, or by allowing the parties to take proposed action that the court finds will minimize the irreparable injury."[39] "Temporary restraining orders and preliminary injunctions are extraordinary remedies which should be granted only if the movant carries his burden of proving that the circumstances clearly demand it."[40] Where "a preliminary injunction is mandatory—that is, where its terms would alter, rather than preserve, the status quo by commanding some positive action...the requested relief should be denied unless the facts and law clearly favor the moving party."[41] The opioid epidemic is an extraordinary national crisis that requires the exercise of this extraordinary remedy. It is impossible to mandate a return to the pre-Oxycontin status quo. But this injunction realistically seeks to put plaintiffs' in a position where irreparable harm will be avoided during the pendency of this litigation.

III. LEGAL STANDARDS FOR PRELIMINARY INJUNCTION

A preliminary injunction is an extraordinary remedy that may only be awarded upon a clear showing that the plaintiff is entitled to such relief.[42] Plaintiff must prove "(1) whether the movant has a strong likelihood of success on the merits; (2) whether the movant would suffer irreparable injury absent the injunction; (3) whether the injunction would cause substantial harm to others; and (4) whether the public interest would be served by the issuance of an injunction."[43] These factors "simply guide the discretion of the court; they are not meant to be rigid and unbending requirements."[44]

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[39] *Stenberg v. Cheker Oil Co.*, 573 F.2d 921, 925 (6th Cir. 1978)
[40] *Ciavone v. McKee*, No. 1:08CV771, 2009 WL 2096281, at *1 (W.D. Mich. July 10, 2009) (citing *Overstreet v. Lexington-Fayette Urban Cty. Gov't*, 305 F.3d 566, 573 (6th Cir. 2002)
[41] *Glauser-Nagy v. Med. Mut. of Ohio*, 987 F. Supp. 1002, 1011 (N.D. Ohio 1997)
[42] *Winter v. Nat. Res. Def. Council, Inc.*, 555 U.S. 7, 129 S. Ct. 365, 172 L. Ed. 2d 249 (2008). 20 (2008) citing *Munaf v. Geren*, 553 U.S. 674, 689–90, 128 S. Ct. 2207, 171 L. Ed. 2d 1 (2008); *Amoco Prod. Co. v. Vill. of Gambell, AK*, 480 U.S. 531, 542, 107 S. Ct. 1396, 94 L. Ed. 2d 542 (1987); *Weinberger v. Romero-Barcelo*, 456 U.S. 305, 311–12, 102 S. Ct. 1798, 72 L. Ed. 2d 91 (1982)
[43] *Hall v. Edgewood Partners Ins. Ctr., Inc.*, 878 F.3d 524, 526–27 (6th Cir. 2017)
[44] *McPherson v. Michigan High Sch. Athletic Ass'n, Inc.*, 119 F.3d 453, 459 (6th Cir. 1997) (*en banc*)

Plaintiff bears the burden of production and persuasion when moving for preliminary injunction.[45] The Supreme Court in *Winter*[46] concluded that courts should weigh the preliminary injunction factors on a sliding scale, allowing a weak showing on one factor to be overcome by a strong showing on another factor. A failure to show a likelihood of irreparable harm remains, standing alone, is sufficient to defeat the motion.[47] The evidence supporting this motion is admissible and cannot be controverted.

IV. PLAINTIFFS VERY LIKELY TO SUCCEED ON MERITS

Plaintiff is Amanda Hanlon, she has sued individually and in a representative capacity for a NAS baby in her care and custody and she also sues here for preliminary and permanent injunction.[48] Amanda came to know the birth mother who was addicted from prescription opioids while pregnant. Amanda understood the baby was at risk and that the birth mother was unable to care for the child. Amanda worked with CPS authorities before birth. She has had sole custody of the baby since discharge from the NICU; she cares for the child along with her own children. She is capable of becoming pregnant and fears that what happened to the birth mother could happen to her. Amy Garner appears on her own behalf and that of her teen-age daughter A.L.D.; she is fearful of the risks like Amanda.

Amanda and Amy have standing to bring this motion.[49] And, they will likely prevail on the merits in their quest for abatement. The defendants' contribution to the opioid epidemic is a fact

[45] *Mazurek v. Armstrong*, 520 U.S. 968, 972, 117 S. Ct. 1865, 138 L. Ed. 2d 162 (1997); *Qualls v. Rumsfeld*, 357 F. Supp. 2d 274, 281 (D.D.C. 2005); *Cobell v. Norton*, 391 F.3d 251, 258 (D.C. Cir. 2004)
[46] *Winter*, 555 U.S. 7. 20 (2008); *Six Clinics Holding Corp., II v. Cafcomp Sys., Inc.*, 119 F.3d 393, 399 (6th Cir. 1997)
[47] *Id.*
[48] *See* Exhibit 57: Hanlon Declaration.
[49] *Warth v. Seldin*, 422 U.S. 490, 498, 95 S. Ct. 2197, 45 L. Ed. 2d 343 (1975) The essence of standing is whether the litigant is entitled to have the court decide the merits of the dispute. Since these plaintiffs could be prescribed opioids and are capable of becoming pregnant, they are entitled to have this court decide the merits of the dispute.

recognized by the FDA, the CDC, and the DEA.[50] Their regulatory and criminal settlements along with their many label changes is excellent evidence of their culpability.

V. IRREPARABLE INJURY WILL OCCUR IF A PRELIMINARY INJUNCTION DOES NOT ISSUE

A plaintiff's harm from the denial of a preliminary injunction is irreparable if it is not fully compensable by monetary damages.[51] Such harm must be likely, not just possible.[52] If the nature of plaintiffs' injuries or loss is such that they are difficult to calculate they are irreparable. "The concept of irreparable harm does not readily lend itself to definition,"[53] The harm claimed must be "beyond remediation."[54] 'The key word in this consideration is irreparable. Mere injuries, however substantial, in terms of money, time, and energy necessarily expended in the absence of an injunction are not enough.[55] Case law reveals that when a business seeks a preliminary injunction when the loss threatens the very existence of the movant's business or its reputation, irreparable injury exists."[56]

The risk of in utero exposure to opioids is that once born he or she will suffer a life fraught with physical, social, educational, and other permanent disability. The potential for opioid induced genetic modification may endanger and diminish the quality of life for that family in generations to come. There is no cure for the opioid caused injuries. And, the risk of developing future addiction in these children is real as they were once addicted, and their mother was as well.

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[50] UMF 15

[51] *Winter*, 555 U.S. 7. 20 (2008); *Overstreet*, 305 F.3d at 578; *Basicomputer Corp. v. Scott*, 973 F.2d 507, 511 (6th Cir. 1992); Loss of business goodwill may constitute irreparable harm because of the difficulty of calculating damages." *Langley v. Prudential Mortg. Capital Co., LLC*, 554 F.3d 647, 649 (6th Cir. 2009); *Certified Restoration Dry Cleaning Network, L.L.C. v. Tenke Corp.*, 511 F.3d 535, 550 (6th Cir. 2007); Loss of goodwill is not calculable *Collins Inkjet Corp. v. Eastman Kodak Co.*, 781 F.3d 264, 279 (6th Cir. 2015)

[52] *Id.*

[53] *Judicial Watch, Inc. v. U.S. Dep't of Homeland Sec.*, 514 F. Supp. 2d 7, 10 (D.D.C. 2007),

[54] *Chaplaincy of Full Gospel Churches v. England*, 454 F.3d 290, 297 (D.C. Cir. 2006).

[55] *Morgan v. Fletcher*, 518 F.2d 236, 240 (5th Cir. 1975) (quoting *Virginia Petroleum Jobbers Ass'n v. Fed. Power Comm'n*, 259 F.2d 921, 925 (D.C. Cir. 1958)).

[56] Loss of business goodwill may constitute irreparable harm because of the difficulty of calculating damages." *Langley*, 554 F.3d at 649; *Virginia Petroleum Jobbers Ass'n*, 259 F.2d at 925

The only remedy the law allows for physical and mental injuries is monetary compensation to those already injured. Women often times do not appreciate that they are pregnant for weeks, by then, an unwitting mother has exposed her child to a strong potential of permanent harm.[57] And she is also exposed to the risk of losing her addicted child to child protection services, her liberty, and anguish in the years ahead. This injunction will lessen, if not eliminate, this pathway of irreparable harm.

Irreparable injury is said to be flexible to the point of being elusive.[58] There is nothing elusive about the ability of opioids to adversely affect fetal development. It can occur at any time during the gestation period, save the first 10 to 14 days. Even the treatment protocol for pregnant women abusing, misusing, or taking opioids, involves medications themselves capable of causing NAS and OUD in the infant. Injury to an exposed fetus will occur; the only question is the extent of fetal injury.

The court may take judicial notice that a mother will suffer personal anguish by later learning her actions in taking opioids while pregnant contributed to her child's injury.[59] The costs associated with moderate to severe NAS are high and could easily bankrupt a family or social services. Injury to their offspring may also exist. This potential for permanent injury in children yet to be conceived is real, it is serious, and it is avoidable. The nature of the harm is a certainty.

If irreparable harm includes a loss that threatens the very existence of a business, it must surely include a threat to the quality of a human's very life and that potentially of their children and grandchildren.[60]

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[57] UMF: 24
[58] *Parks v. Dunlop*, 517 F.2d 785 (5th Cir. 1975)
[59] Fed. R. Evid. 201
[60] *Herrera v. Santa Fe Pub. Sch.*, 792 F. Supp. 2d 1174, 1198 (D.N.M. 2011)

VI. BALANCING OF INTERESTS

Crafting a preliminary injunction is an exercise of discretion and judgment, often dependent as much on the equities of a given case as the substance of the legal issues it presents.[61] The purpose of such interim equitable relief is not to conclusively determine the rights of the parties, but to balance the equities as the litigation moves forward. In awarding a preliminary injunction a court must also "conside[r] ... the overall public interest." [62] In the course of doing so, a court "need not grant the total relief sought by the applicant but may mold its decree to meet the exigencies of the particular case."[63]

In balancing these equities, the relative position of the parties is a worthy consideration. The babies have, of course, 'clean hands.' Those giving birth to them do as well as they began their addiction odyssey with a lawfully issued prescription opioid. The defendants' hands are, however, not clean. And this is so, even if we put aside the charge that defendants knew that their marketing campaigns and statements about addiction, pseudo-addiction, and the like, were knowingly falsely made. It is sufficient that the defendants were in a superior position to these plaintiffs and the information they provided was wrong and subject to much subsequent correction.

The doctrine of unclean hands is an equitable concept that allows a court to deny injunctive relief when the party applying for such relief is guilty of conduct involving fraud, deceit, unconscionability, or bad faith related to the matter at issue to the detriment of the other party. It works against defendants too who oppose the injunctive request.[64]

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[61] *Winter*, 555 U.S. at 20, 24; § 2948Grounds for Granting or Denying a Preliminary Injunction, 11A Fed. Prac. & Proc. Civ. § 2948 (3d ed.)

[62] *Winter*, 555 U.S. 7

[63] Wright, supra, § 2947, at 115

[64] Although the unclean hands doctrine is typically employed by a defendant against a plaintiff who seeks equitable relief, it applies equally to a defendant who seeks equitable relief; while it is not normally employed against a defendant merely brought to court by the suit of another, insofar as a defendant seeks to invoke the powers of the court to bar a plaintiff's claim due to laches, the unclean hands doctrine can foreclose a defendant's laches argument. *Osborn v. Griffin*, 865 F.3d 417 (6th Cir. 2017)

VII. PUBLIC INTERESTS SERVED BY NEGATIVE PREGNANCY TEST REQUIREMENT

Public interests are served by healthy babies and healthy adults. Government and professional efforts undertaken since the opioid problem was first identified have met with only a modicum of success.[65] The court may take judicial notice of the MDL pleadings and similar lawsuits around the country.[66] Most, if not all, seek reimbursement for the increased costs associated with foster care and NAS and OUD births. The negative costs associated with NAS and OUD births burden more than the public coffers, they destroy society and families, today, tomorrow, and for generations to come. These costs far exceed the cost and burden of pregnancy tests and a second office visit.[67]

VIII. GRANTING THE INJUNCTION WILL NOT CAUSE SUBSTANTIAL HARM TO OTHERS

The I-Pledge (Accutane) program is evidence that institutional requirements, like those sought here, do protect babies from teratogenic injuries.[68] The costs associated with the proposal here are urine pregnancy tests and communications between the physician and the dispensing agent.[69] The manufacturers can require this communication of their distributors and dispensers. Communications between physicians and pharmacies can, in most cases, be accomplished electronically. Another opportunity for the patient to confer with a physician about pain and treatment options benefits both. Anyone recently filling a prescription will have encountered delays associated with insurance companies and the like, the proposal adds a slight burden to an already busy transaction.

[65] Ohio, for example passed several laws and its health department issued opioid guidelines. Though some progress was noted, Ohio health officials remain unsatisfied. UMB: 15
[66] FRE Rule 201
[67] UMF: 53, 55
[68] UMF: 60
[69] UMF: 53, 55

There will, of course, be exceptions to the preliminary injunction such as surgical patients or those with chronic diseases like sickle cell or lupus.[70] Working through these details will take some effort but nothing that outweighs the gains to be achieved by the preliminary injunction. Pain will and can be treated, and future babies will not be injured.[71] There are non-opioid pain medications available to potential patients like the plaintiffs.[72]

IX. RELIEF REQUESTED

Women, children, and families will be strengthened by this preliminary injunction as the incidence of in-utero opioid exposure will be substantially reduced. A natural consequence of strong and healthy families is a strong and healthy country. Medical, social, education, and countless other public expenses will be preserved for other uses including helping the NAS/OUD population that already exists. The costs associated with the injunction are negligible when compared to the costs associated with NAS and OUD.

The preliminary injunction should be granted.

Respectfully submitted,

/s/ Celeste Brustowicz
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[70] Exhibit 29: Anand Declaration
[71] UMF: 62
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CERTIFICATE OF SERVICE

The undersigned hereby certifies that on 28TH of March 2019, the foregoing document was served on all counsel of record by the CM/ECF system.

/s/ Celeste Brustowicz
Celeste Brustowicz

UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF OHIO
EASTERN DIVISION

IN RE: NATIONAL PRESCRIPTION OPIATE LITIGATION

MDL No. 2804

Master Docket No. 1:17-MD-02804-DAP

This document relates to:

Hon. Judge Dan A. Polster

AMANDA HANLON, INDIVIDUALLY AND ON BEHALF OF ALL OTHERS SIMILARLY SITUATED;

AMY GARDNER, INDIVIDUALLY AND ON BEHALF OF HER MINOR DAUGHTER A.L.D. AND ALL OTHERS SIMILARLY SITUATED,

Plaintiffs,

v.

PURDUE PHARMA L.P.;
PURDUE PHARMA, INC.;
THE PURDUE FREDERICK COMPANY, INC.;
TEVA PHARMACEUTICAL INDUSTRIES, LTD.;
TEVA PHARMACEUTICALS USA, INC.;
CEPHALON, INC.; JOHNSON & JOHNSON;
JANSSEN PHARMACEUTICALS, INC.;
ORTHO-MCNEIL-JANSSEN PHARMACEUTICALS, INC. n/k/a JANSSEN PHARMACEUTICALS, INC.;
JANSSEN PHARMACEUTICA INC. n/k/a JANSSEN PHARMACEUTICALS, INC.;
ENDO HEALTH SOLUTIONS INC.;
ENDO PHARMACEUTICALS, INC.;
ALLERGAN PLC f/k/a ACTAVIS PLC;
WATSON PHARMACEUTICALS, INC. n/k/a ACTAVIS, INC.;
WATSON LABORATORIES, INC.; ACTAVIS LLC; and
ACTAVIS PHARMA, INC. f/k/a WATSON PHARMA, INC.;

Defendants.

Case No. 1:19-op-45206

UNDISPUTED MATERIAL FACTS SUPPORTING MOTION FOR PRELIMINARY INJUNCTION

1. Except for ancient history, for which there is no evidence, mankind has used opium.[1] For centuries, mankind has understood the addictive nature of opium.[2]

2. Addiction is defined as a chronic, relapsing disorder characterized by compulsive drug seeking, continued use despite harmful consequences, and long-lasting changes in the brain. It is considered both a complex brain disorder and a mental illness. Addiction is the most severe form of a full spectrum of substance use disorders, and is a medical illness caused by repeated misuse of a substance or substances. An addicted person is willing to sacrifice themselves, their families, and society in general to gain access to a harmful substance.[3]

3. Addiction is a complex chronic psychiatric illness with a high relapse rate.[4] The costs associated with addiction include medical costs, police costs, jail and prison costs, work-related accidents, other accidents caused by impairment, to name a few.[5] In all users, long-term opioid use leads to decreased brain volume, for example, in the emotional centers of the brain (amygdala).[6]

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[1] **Exhibit 1**: Nencici P. The rules of drug taking wine and poppy derivatives in the Ancient World. IX. Conclusions. Subst Use Misuse 1997; 32 :2111-9.; **Exhibit 2:** Nencini P. The Rules of drug taking wine and poppy derivatives in the Ancient World. VIII. Lack of evidence of opium addiction. Subst Use Misuse 1997; 32:1581-6.; **Exhibit 3:** Nencini P. The rules of drug taking: wine and poppy derivatives in the ancient world. VII. A ritual use of poppy derivatives? Subst Use Misuse 1997; 32:1405-15.

[2] **Exhibit 4:** Kocherlakota, P. (2014). Neonatal Abstinence Syndrome. Pediatrics, 134(2). doi:10.1542/peds.2013-3524, Retrieved from https://pediatrics.aappublications.org/content/134/2/e547; **Exhibit 5:** Rosenblum, A., Marsch, L. A., Joseph, H., & Portenoy, R. K. (2008). Opioids and the treatment of chronic pain: Controversies, current status, and future directions. Experimental and Clinical Psychopharmacology, 16(5), 405-416. doi:` 10.1037/a0013628, Retrieved from https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2711509/; **Exhibit 6:** Brownstein, M. J. (1993). A brief history of opiates, opioid peptides, and opioid receptors. Proceedings of the National Academy of Sciences, 90(12), 5391-5393. doi:10.1073/pnas.90.12.5391, https://www.ncbi.nlm.nih.gov/pmc/articles/PMC46725/; **Exhibit 7:** Gomez-Pomar, E., & Finnegan, L. P. (2018). The Epidemic of Neonatal Abstinence Syndrome, Historical References of Its' Origins, Assessment, and Management. Frontiers in Pediatrics, 6. doi:10.3389/fped.2018.00033; retrieved from https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5827164/.

[3] **Exhibit 8**: Media Guide. *National Institute on Drug Abuse*, (2 Jul. 2018) Retrieved from https://www.drugabuse.gov/publications/media-guide.; **Exhibit 9:** Parekh, R. What is Addition. *American Psychiatric Association* (2017, January) Retrieved from https://www.psychiatry.org/patients-families/addiction/what-is-addiction.

[4] **Exhibit 8**

[5] **Exhibit 8**

[6] **Exhibit 10**: Upadhyay J, Maleki N, Potter J, et al. Alterations in brain structure and functional connectivity in prescription opioid-dependent patients. Brain 2010; 133:2098-114.

4. Short of addiction, drug abuse, impacts critical brain regions resulting in reward – seeking and crediting, drug dependence, withdrawal, and alterations in both anxiety, learning, and memory.[7]

5. In December 1995, the FDA approved the manufacturing and dispensing of time-released synthetic opioids, namely Oxycontin.[8] Others soon followed.

6. The American Pain Society was sponsored by the opioid manufacturers. In 1996 it trademarked the slogan "Pain: The Fifth Vital Sign". In 1998, the Veterans Health Administration and the Joint Commission for Accreditation of Healthcare Organizations made pain the fifth vital sign.[9]

7. The Federation of State Medical Boards in 1998 released a recommended policy reassuring physicians they would not face regulatory action for prescribing large amounts of narcotics (opioids).[10]

8. In 2001, the JCAHO issued new standards requiring hospital to ask patients about pain and to make treating pain a priority. It also published a Purdue Pharma sponsored guide that stated that some physicians exaggerated concerns about addiction, tolerance, and risk of death. It stated there was no evidence that addiction was a significant issue when persons are given opioids for pain control.[11]

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[7] **Exhibit 11**: Sinha, Rajita. "Chronic stress, drug use, and vulnerability to addiction" *Annals of the New York Academy of Sciences* vol. 1141 92008): 105-30.

[8] **Exhibit 12**: FDA. "Timeline of Selected FDA Activities and Significant Events Addressing Opioid Misuse and Abuse." Federal Drug Administration. 13 Feb. 2019. https://www.fda.gov/Drugs/DrugSafety/InformationbyDrugClass/ucm338566.htm

[9] **EXHIBIT 13:** Retrieved from: Terplan, M. (2017). Women and the opioid crisis: Historical context and public health solutions. Fertility and Sterility, 108(2), 195-199. doi :10.1016/j.fertnstert.2017.06.007.

[10] **EXHIBIT 14:** Kolodny, A. (2013, March 29). [Letter to State Medical Board]. Physicians for Responsible Opioid Prescribing, Brooklyn, NY, Retrieved from: https://www.supportprop.org/wp-content/uploads/2014/12/PA_3_29_13_FSMB.pdf.

[11] **EXHIBIT 15:** Silverman, E. (2019, January 19). Drug maker payments to doctors linked to higher opioid overdose deaths. Retrieved from https://www.statnews.com/pharmalot/2019/01/18/opioids-payments-doctors-overdose-deaths/

9. The need for pain medication for chronic or acute pain needs did not increase from 1995 to present. Stated another way, major increases in opioid prescriptions cannot be explained by the underlying health-related trends for the U.S. population, although some studies point to the past prevalence of untreated pain.[12]

10. Recent studies published in JAMA concluded that physicians were greatly influenced to write more opioid prescriptions when they were the beneficiary/recipient of industry "freebies", such as meals. According to the study, physicians who had greater interactions with industry marketing efforts were more likely to write opioid prescriptions.[13]

11. In 2007, Purdue Pharma and three of its executives pleaded guilty to "misbranding" opioids as less addictive and less subject to abuse than other pain medications. The fine was $635 million. Purdue agreed that these facts were true, even though the individual defendants did not agree they had knowledge of their salesforce saying these things to physicians:[14]

> The information in this case charges, among other things, that
>
> [b]eginning on or about December 12, 1995, and continuing until on or about June 30, 2001, certain PURDUE supervisors and employees, with the intent to defraud or mislead, marketed and promoted OxyContin as less addictive, less subject to abuse and diversion, and less likely to cause tolerance and withdrawal than other pain medications as follows:
>
> a. Trained PURDUE sales representatives and told some health care providers that it was more difficult to extract the oxycodone from an OxyContin tablet for the purpose of intravenous abuse, although PURDUE's own study showed that a drug abuser could extract approximately 68% of the oxycodone from a single 10mg OxyContin tablet by crushing the tablet, stirring it in water, and drawing the solution through cotton into a syringe;

[12] **EXHIBIT 16:** Dowell D, Haegerich TM, Chou R. CDC Guideline for Prescribing Opioids for Chronic Pain – United States, 2016. MMWR Recomm Rep 2016;65(No. RR-1):1-49. DOI: http://dx.doi.org/10.15585/mmwr.rr6501e1; **EXHIBIT 17:** Portenoy RK. Cancer pain. Epidemiology and syndromes. Cancer 1989;63;2298-307.; Pain in nursing-home cancer patients often goes untreated. Am J Health Syst Pharm 1998:55;1544, 8.

[13] **EXHIBIT 15**

[14] **EXHIBIT 18:** *USA v The Purdue Frederick Company,* 1:07-cr-00029, pp. 2-3

b. Told PURDUE sales representatives they could tell health care providers that OxyContin potentially creates less chance for addiction than immediate-release opioids;
c. Sponsored training that taught PURDUE sales supervisors that OxyContin had fewer "peak and trough" blood level effects than immediate-release opioids resulting in less euphoria and less potential for abuse than short-acting opioids;
d. Told certain health care providers that patients could stop therapy abruptly without experiencing withdrawal symptoms and that patients who took OxyContin would not develop tolerance to the drug; and
e. Told certain health care providers that OxyContin did not cause a "buzz" or euphoria, caused less euphoria, had less addiction potential, had less abuse potential, was less likely to be diverted than immediate-release opioids, and could be used to "weed out" addicts and drug seekers.

12. Synthetic opioids, like natural opioids, are highly addictive.[15]

13. "Prescription drug abuse is rampant in all areas of our country, particularly among young people, causing untold misery and harm. The White House Drug Policy Office estimates that such abuse rose seventeen percent from 2001 to 2005. That office reports that currently there are more new abusers of prescription drugs than new users of any illicit drug…. Young people mistakenly believe prescription drugs are safer than street drugs…. There are more than 6.4 million prescription drug abusers in the United States.[16]

14. Since 1996, the incidence of opioid-based addiction in the United States of America has risen to the point of a national epidemic.[17]

15. In the late 1990s and early 2000s, a correlation was found between escalating crime and opioid addiction. The problem was traced to the increased use of time-released opioids like Oxycontin. At that time, the issue was prevalent in only a handful of states; those states had high

[15] **EXHIBIT 12**
[16] **EXHIBIT 18**
[17] **EXHIBITS 12, 18** and **EXHIBIT 20:** Ending America's Opioid Crisis. (n.d.). Retrieved from https://www.whitehouse.gov/opioids/

populations of chronic pain sufferers and higher rates of work-related accidents.[18] Criminals seized on the money-making potential and the illicit-drug market dramatically increased. Addicts were committing crimes and disrupting their families and communities. Both the House and Senate held hearings and programs were initiated to reverse the course of addiction resulting from Oxycontin and drugs like it. In addition to the federal government, states and professional organizations also participated in identifying the causes and plans to resolve the increasing addiction rates. Notwithstanding those efforts, the opioid epidemic spread to where it is now a national problem, crossing every population, rich poor, coastal interior, industrial rural, every race, every religion. In sum, any person is subject to potential injury by the opioid epidemic.[19]

16. Dispensing of synthetic opioids requires a written prescription under federal and state laws.[20]

17. In 2012, the number of opioid prescriptions written in the U.S. was 259 million resulting in sales of more than $9 billion.[21]

18. Several of the defendants have made settlements with government agencies related to opioids.[22]

19. Women are more likely than men to be prescribed opioids for conditions such as headache.[23]

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[18] **EXHIBIT 19:** 2002 Hearing before a subcommittee on appropriations; **EXHIBIT 20:** U.S. Senate, Committee on the Health, Education, Labor, And Pensions. (2002). Oxycontin: Balancing Risks and Benefits [S. Rept. from 107th Cong., Second sess.]. Washington, DC: US Government Printing Office.

[19] **EXHIBIT 21**

[20] 21 CFR §1306.11 2010.;

[21] **EXHIBIT 22:** Schirle, L., & McCabe, B. E. (2016). State Variation in Opioid and Benzodiazepine Prescriptions between Independent and Non-Independent APRN Prescribing States. Nursing Outlook, 64(1), 86-93. Retrieved from https://www.nursingoutlook.org/article/S0029-6554(15)00277-8/pdf.; **EXHIBIT 23:**To require the Food and drug Administration to Revoke the Approval of One Opioid Pain Medication for Each New Pain Medication Approved, S. 419, 116th Cong. (2019).

[22] F.R.E. Rule 201. The Court may take judicial notice of other judicial proceedings.

[23] **EXHIBIT 24:** Darnall, Beth D and Brett R Stacey. "Sex differences in long-term opioid use: cautionary notes for prescribing in women" Archives of internal medicine vol. 172,5 (2012): 431-2.

20. Female subjects, on average, have plasma of oxycodone concentrations up to 25% higher than males on a body weight adjusted basis. The reason for this difference is unknown.[24]

21. It is estimated that one third of all opioid users are female and that two thirds of these women are of childbearing age; Almost 40% of women aged 15-44 years report receiving at least one opioid prescription in 2015.[25]

22. Among women in the U.S. who use opioids, an estimated 86% of their pregnancies are unintended.[26] Many women do not realize that they are pregnant.

23. Opiate drugs easily transfer cross the placenta to the fetus.[27] The placenta is an organ created by the embryo that allows the transfer of nutrients and oxygenated blood from the mother to the baby. Waste from the fetus transfers via the placenta to the mother. This is a symbiotic relationship that allows fetal growth and development.[28] Anything the mother ingests, or inhales is eligible to cross the placenta to the fetus.[29] Opioids are lipid (fat) based and easily transfer from mother to the baby. The developing fetal brain has a high lipid content and easily combines with the opioids circulating in blood.[30]

24. The transmission of opioids across the placenta is increased as gestation increases.[31]

25. Synthetic opioids cross the placenta more easily compared with semi-synthetic opiates.[32]

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[24] **EXHIBIT 25:** OXYCONTIN. Purdue Pharma LP; 2018, Http://app.purduepharma.com/xmlpublishing/pi.aspx?id=o

[25] **EXHIBIT 26:** Terplan, Mishka. "Women and the Opioid Crisis: Historical Context and Public Health Solutions." Fertility and Sterility, Volume 108, Issue 2, 195 – 199. https://www.fertstert.org/article/S0015-0282(17)30431-4/fulltext?rss=yes. 05 Mar. 2019.

[26] **EXHIBIT 27:** Ko, J. Y., Wolicki, S., & Barfield, W. (2017, March 10). Morbidity and Mortality Weekly Report (MMWR) 66(9); 242-245. Retrieved from https://www.cdc.gov/mmwr/volumes/66/wr/mm6609a2.htm.

[27] **EXHIBIT 28:** Kocherlakota, P. (2014). Neonatal Abstinence Syndrome. Pediatrics, 134(2). doi:10.1542/peds.2013-3524

[28] **EXHIBIT 29 -** Anand Declaration

[29] **EXHIBIT 29**

[30] **EXHIBIT 28**

[31] **EXHIBIT 28**

[32] **EXHIBIT 28**

26. The ease with which synthetic opioids can cross the blood-brain barrier of the fetus and the prolonged half-life of these drugs in the fetus may increase the risks of abnormal brain development[33] and worsen opioid withdrawal in infants after birth (NAS).[34]

27. The addictive nature of synthetic opioids can transmit to a fetus in utero during gestation. [35]

28. Prescription opioid use in pregnancy is strongly associated with neonatal complications.[36]

29. Opioid use can disrupt fetal brain development at any stage during pregnancy, except the first 10-14 days after conception.[37]

30. The prevalence of opioid abuse or dependence among pregnant women in the United States has increased from 1.7 per 1000 delivery admissions in 1998 to 3.9 per 100 delivery admissions in 2011.[38]

31. Recent figures demonstrated almost a 40-fold increase in the number of infants presenting with opioid withdrawal or neonatal abstinence syndrome (NAS) at birth.[39]

32. Neonatal abstinence syndrome is a constellation of symptoms suffered by newborn infants exposed to opioids in utero. Clinically significant NAS most commonly results from prolonged exposure to opioids, but symptoms of neonatal withdrawal have also been noted after short-term therapy.[40]

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[33] **EXHIBIT 30:** Hu S, Sheng WS, Lokensgard JR, Peterson PK. Morphine Induces Apoptosis of Human Microglia and Neurons. *Neuropharmacology* 2002; 42:829-36.
[34] **EXHIBIT 29**
[35] **EXHIBIT 29**
[36] **EXHIBIT 29**
[37] **EXHIBIT 29**
[38] **EXHIBIT 27**
[39] **EXHIBIT 31:** Yuan, Q., Rubic, M., Seah, J., Rae, C., Wright, I. M., Kaltenbach, K., Oei, J. L. (2014). Do Maternal Opioids Reduce Neonatal Regional Brain Volumes? A Pilot Study. *Journal of Perinatology*, 34(12), 909-913. doi:10.1038/jp.2014.111
[40] **EXHIBIT 32:** Hill, Timothy B. CMS. Neonatal Abstinence Syndrome: A Critical Role for Medicaid in the Care of Infants. Jun. 11, 2018. https://www.medicaid.gov/federal-policy-guidance/downloads/cib060818.pdf

33. By 2012, on average, one NAS-affected infant was born every 25 minutes in the United States.[41] In 2019, one NAS-affected baby is born every 15 minutes.[42]

34. Opioid-exposed infants are typically born with small head circumference, low birth weight, respiratory and feeding difficulties, seizures, neural tube defects, cleft palate, and visual disturbances which, are recognized as a complication of gestational opioid exposure.[43] Long-term outcomes beyond the initial NAS diagnosis are concerning. A substantial number of these children demonstrated neurodevelopmental, behavioral, and attention problems.[44]

35. Both long-term and short-term in utero exposure to opioids presents dangers to the developing child.[45]

36. NAS and OUD can occur with both long-term and short-term use of opioid use by the mother. Brain damage resulting from human opioid exposure[46] (duration and dose) is not well known. This means that a high dose short-term course could be more harmful than a long-term low dose opioid course. Science is unlikely to resolve this issue without required fetal testing. This is why preventing in utero exposure is the key to abatement.[47]

37. Prenatal exposure to opioids may decrease full brain and basal ganglia volumes in otherwise healthy newborn infants.[48]

38. Risks of sudden infant death syndrome (SIDS) in preterm infants with prenatal opioid exposure are increased because of the changes in normal infant sleeping patterns, depressed respiration or responses to hypoxia (low oxygen levels).[49]

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[41] **EXHIBIT 33:** GAO. Newborn Health: Federal Action Needed to Address Neonatal Abstinence Syndrome. GAO-18-32. Oct. 2017.
[42] National Institute on Drug Abuse. (2019, January 22). Dramatic Increases in Maternal Opioid Use and Neonatal Abstinence Syndrome. Retrieved from https://www.drugabuse.gov/related-topics/trends-statistics/infographics/dramatic-increases-in-maternal-opioid-use-neonatal-abstinence-syndrome
[43] **EXHIBIT 31**
[44] *Id.*
[45] **EXHIBIT 29**
[46] **EXHIBIT 30**
[47] **EXHIBIT 29**
[48] **EXHIBIT 31**

39. Preschool aged children, exposed to opiates, are known to the experience one or more of the following symptoms: mental and motor deficits, cognitive delays, hyperactivity, impulsivity, attention deficit disorder, behavior disorder, aggressiveness, poor social engagement, failure to thrive (socially), and short stature.[50]

40. School-age children exposed to opiates may experience one or more of the following cognitive/behavioral deficits: verbal impaired performance, impaired reading and arithmetic skills, for mental and motor development, memory and perception problems, attention deficit hyperactivity disorder, developmental delays, speech problems, language disorders, impaired self – regulation, school absence, reduced executive functions and behavioral regulation, for responses to stressful stimulations situations, poorly developed confidence or efficacy, impaired task performance, depressive disorder, and substance abuse disorder.[51]

41. Compared with nonexposed children, the children of drug-using parents are more than twice as likely to develop an alcohol and/or drug abuse disorders themselves as an adult.[52]

42. There is a continuous negative effect on infants/children related to prenatal-opioid exposure over time.[53]

43. Methadone has become the standard of care for pregnant women with opioid addiction.[54]

44. Methadone treatment is related to the increase incidence of NAS.[55]

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[49] **EXHIBIT 34:** Ratliff, Brittany V., "Prevalence of Communication Disorders in Children with Neonatal Abstinence Syndrome on School Speech-Language Pathology Caseloads: A National Survey" (2017). *Electronic Theses and Dissertations.* Paper 3204. http://dc.etsu.edu/etd/3204.
[50] **EXHIBIT 34**
[51] **EXHIBIT 34**
[52] **EXHIBIT 34**
[53] **EXHIBIT 35:** Nygaard, E., Moe, V., Slinning, K., & Walhovd, K. B. (2015). Longitudinal cognitive development of children born to mothers with opioid and polysubstance use. Pediatric Research, 78(3), 330-335. doi:10.1038/pr.2015.95
[54] **EXHIBIT 29**
[55] **EXHIBIT 29**

45. Gaps in medical knowledge still exists with NAS, including a lack of clarity and consistency in how the syndrome is defined, measured, and managed.[56]

46. NAS and OUD remain poorly understood.[57]

47. In the United States of America, between 2000 and 2012, NICU admissions increased more than fivefold, resulting in annual costs from $61 million and 67,869 hospital days (2003) to nearly $316 million and 291,168 hospital days (2012).[58] According to the CDC, once discharged from the NICU, first year Medicaid costs of opioid exposed babies in utero in 2015, ranged from $159,000 to $238,000.[59]

48. A recent study concluded that the opioid exposure to a developing animal brain may cause epigenetic modifications that makes addiction in that individual more likely. This modification, no matter the sex of the exposed fetus, is thought to pass on in their genetic material to their offspring.[60]

49. The number of NAS/OUD children in the U.S. is estimated by the CDC to be hundreds of thousands.[61] But when mothers stop taking opioids during pregnancy the fetus may go through in utero withdrawal, so those babies cannot be counted.[62] Only 28 states report NAS/OUD births.[63]

50. It is thought that in utero opioid exposures occurring between 3 weeks and 12 weeks after conception carry the highest risks for congenital defects.[64] The long-term risks of opioid

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[56] **EXHIBIT 29**
[57] **EXHIBIT 36:** Newborn Health Federal Action Needed to Address Neonatal Abstinence Syndrome. USGAO. Oct. 2017
[58] **EXHIBIT 32**
[59] **EXHIBIT 37:** Mihali, R. Medical Costs of Addicted Newborns: Neonatal Abstinence Syndrome." NC Drug Court. http://www.ncdrugtreatmentcourts.com/NAS.html
[60] **EXHIBIT 38:** Yohn, N. L., Bartolomei, M. S., & Blendy, J. A. (2015). Multigenerational and transgenerational inheritance of drug exposure: The effects of alcohol, opiates, cocaine, marijuana, and nicotine. Progress in Biophysics and Molecular Biology, 118(1-2), 21-33. doi: 10.1016/j.pbiomolbio.2015.03.002
[61] **EXHIBIT 39:** Ko JY, Patrick SW, Tong VT, Patel R, Lind JN, Barfield WD. Incidence of Neonatal Abstinence Syndrome — 28 States, 1999–2013. MMWR Morb Mortal Wkly Rep 2016; 65:799–802. DOI: http://dx.doi.org/10.15585/mmwr.mm6531a2
[62] **EXHIBIT 39**
[63] **EXHIBIT 39**

exposure during the 14-day period following conception are currently unknown, although the limited data available suggests that opioid will not result in fetal injury from in utero opioid exposure.[65]

51. Urine pregnancy tests are reliable and relatively inexpensive.[66] They provide an immediate test result. Blood pregnancy tests are more expensive and require lab analysis, and the test results are not immediately available.[67]

52. The closer a pregnancy test is taken from the completion of the menstrual cycle, the less likely it is to be accurate.[68]

53. If a woman has a negative urine pregnancy test and she is in fact pregnant, it is reasonable to conclude the pregnancy is very early, less than a few days. By limiting the opioid prescription to seven days, putative risks to such a fetus would be minimal. If the woman needs more opioids, she would return to her physician for a pain discussion and a second pregnancy test. If negative, it can be safely concluded the woman is not pregnant. If pregnant, a medication change to non- opioid analgesics can be made to deal with the pain issue.[69]

54. The standard of care for prescribing opioids changed as a result of the defendant manufacturers marketing campaigns which promoted pain resolution and created pain as a 5th vital

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[64] **EXHIBIT 30, EXHIBIT 40:** Broussard CS, Rasmussen SA, Reefhuis J, et al. Maternal treatment with opioid analgesics and risk for birth defects. *Am J Obstet Gynecol* 2011; 204:314 e1-11.; **EXHIBIT 41:** Rayburn WF, Brennan MC. Periconception warnings about prescribing opioids. *Am J Obstet Gynecol* 2011; 204:281-2.; **EXHIBIT 42:** Kallen B, Reis M. Use of tramadol in early pregnancy and congenital malformation risk. *Reprod Toxicol* 2015; 58:246-51.; **EXHIBIT 43:** Interrante JD, Ailes EC, Lind JN, et al. Risk comparison for prenatal use of analgesics and selected birth defects, National Birth Defects Prevention Study 1997-2011. *Ann Epidemiol* 2017; 27:645-53 e2.; **EXHIBIT 44:** Lind JN, Interrante JD, Ailes EC, et al. Maternal Use of Opioids During Pregnancy and Congenital Malformations: A Systematic Review. Pediatrics 2017; 139;

[65] **EXHIBIT 45:** Gallego MJ, Porayette P, Kaltcheva MM, Meethal SV, Atwood CS. Opioid and progesterone signaling is obligatory for early human embryogenesis. Stem Cells Dev 2009; 18:737-40.; **EXHIBIT 46:** Brennan MC, Rayburn WF. Counseling about risks of congenital anomalies from prescription opioids. Birth Defects Res A Clin Mol Teratol 2012; 94:620-5.; **EXHIBIT 47:** Dehghani L, Sahraei H, Meamar R, Kazemi M. Time-dependent effect of oral morphine consumption on the development of cytotrophoblast and syncytiotrophoblast cells of the placental layers during the three different periods of pregnancy in Wistar rats. *Clin Dev Immunol* 2013; 2013:974205.

[66] **EXHIBIT 48:** Werntz Declaration

[67] **EXHIBIT 48**

[68] **EXHIBIT 48**;

[69] **EXHIBIT 29**

sign. The marketing campaigns were successful in the sense that prescriptions for opioids increased tremendously and prescriptions were given for conditions not typically requiring opioids.[70]

55. The CDC has also issued guidelines to limit/control prescribing opioids for chronic pain.[71]

56. Professional medical societies devoted to the healthcare of women and children have recently issued guidelines on prescribing opioids to women and children.[72]

57. A teratogen is an agent that can disturb the development of the embryo or fetus. Teratogens halt the pregnancy or produce a congenital malformation (a birth defect). Classes of teratogens include radiation, maternal infections, chemicals, and drugs.[73]

58. The iPledge Program was established in Oct. 2010 and closely monitors women prescribed isoretinoin (Accutane) because of its teratogenic effects.[74] It was developed by the isoretinoin pharmaceutical manufacturers group under the guidance of the FDA.[75] It protects women from causing fetal injuries when taking this prescription medication. It is an established and successful program.[76]

59. The 2013 National Drug Control strategy focuses on four main pillars, each designed to intervene at a critical juncture in the process of diversion and abuse: education for prescribers,

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[70] **EXHIBIT 49:** Dept. of Veterans Affairs. *Pain as the 5th Vital Sign Toolkit*. Oct. 2000.
[71] **EXHIBIT 50:** Dowell D, Haegerich TM, Chou R. CDC Guideline for Prescribing Opioids for Chronic Pain — United States, 2016. MMWR Recomm Rep 2016;65(No. RR-1):1–49. DOI: http://dx.doi.org/10.15585/mmwr.rr6501e1
[72] **EXHIBIT 51:** Patrick, S. W., & Schiff, D. M. (2017). A Public Health Response to Opioid Use in Pregnancy. Pediatrics, 139(3). doi:10.1542/peds.2016-4070. Retrieved from https://pediatrics.aappublications.org/content/139/3/e20164070; **EXHIBIT 52:** The American College of Obstetricians and Gynecologists. (2017). Opioid Use and Opioid Use Disorder in Pregnancy. ASAM. Number 711. Aug. 2017.
[73] **EXHIBIT 53:** *(2005). Stedman's medical dictionary for the health professions and nursing. Philadelphia :Lippincott Williams & Wilkins,*
[74]Risk evaluation and Mitigation Strategy (REMS). The iPledge Program. https://www.fda.gov/downloads/drugs/drugsafety/postmarketdrugsafetyinformationforpatientsandproviders/ucm234639.pdf; **EXHIBIT 54:** iPledge Patient Introductory Brochure. Nov. 2016.
[75] **EXHIBIT 54**
[76] **EXHIBIT 54**

patients, and parents; prescription drug monitoring programs; proper medication disposal; and effective enforcement.[77]

60. There are many pain-relieving medications other than opioids.[78]

Respectfully submitted,

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[77] **EXHIBIT 55:** Kerlikowske, R. Gill. (Jun. 2013). Committee on Energy and Commerce. Examining the Federal Government's Response to the Prescription Drug Abuse Crisis. Washington, D.C.: U.S. H.O.R. https://docs.house.gov/Committee/Calendar/ByEvent.aspx?EventID=100984

[78] **EXHIBIT 56:** FDA. A Guide to Safe Use of Pain Medicine. Feb. 23, 2009. Last Updated Dec. 20, 2018. https://www.fda.gov/ForConsumers/ConsumerUpdates/ucm095673.htm

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CERTIFICATE OF SERVICE

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UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF OHIO
EASTERN DIVISION

IN RE: NATIONAL PRESCRIPTION OPIATE LITIGATION

MDL No. 2804

Master Docket No. 1:17-MD-02804-DAP

This document relates to:

Hon. Judge Dan A. Polster

AMANDA HANLON, INDIVIDUALLY AND ON BEHALF OF ALL OTHERS SIMILARLY SITUATED;

AMY GARDNER, INDIVIDUALLY AND ON BEHALF OF HER MINOR DAUGHTER A.L.D. AND ALL OTHERS SIMILARLY SITUATED,

Plaintiffs,

v.

PURDUE PHARMA L.P.;
PURDUE PHARMA, INC.;
THE PURDUE FREDERICK COMPANY, INC.;
TEVA PHARMACEUTICAL INDUSTRIES, LTD.;
TEVA PHARMACEUTICALS USA, INC.;
CEPHALON, INC.; JOHNSON & JOHNSON;
JANSSEN PHARMACEUTICALS, INC.;
ORTHO-MCNEIL-JANSSEN PHARMACEUTICALS, INC. n/k/a JANSSEN PHARMACEUTICALS, INC.;
JANSSEN PHARMACEUTICA INC. n/k/a JANSSEN PHARMACEUTICALS, INC.;
ENDO HEALTH SOLUTIONS INC.;
ENDO PHARMACEUTICALS, INC.;
ALLERGAN PLC f/k/a ACTAVIS PLC;
WATSON PHARMACEUTICALS, INC. n/k/a ACTAVIS, INC.;
WATSON LABORATORIES, INC.; ACTAVIS LLC; and
ACTAVIS PHARMA, INC. f/k/a WATSON PHARMA, INC.;

Defendants.

Case No. 1:19-op-45206

EXHIBIT LIST FOR
STATEMENT OF UNDISPUTED FACTS

NOW INTO COURT, through undersigned counsel, come plaintiffs, who respectfully submit the following List of Exhibits to their Statement of Undisputed Facts:

Nencici P. The rules of drug taking wine and poppy derivatives in the Ancient World. IX. Conclusions. Subst Use Misuse 1997; 32 :2111-9 .....Exhibit 1

Nencini P. The Rules of drug taking wine and poppy derivatives in the Ancient World. VIII. Lack of evidence of opium addiction. Subst Use Misuse 1997; 32:1581-6 .....Exhibit 2

Nencini P. The rules of drug taking: wine and poppy derivatives in the ancient World. VII. A ritual use of poppy derivatives? Subst Use Misuse 1997;32:1405-15. .....Exhibit 3

Kocherlakota, P. (2014). Neonatal Abstinence Syndrome. Pediatrics, 134(2). doi:10. 1542/peds.2013-3524, Retrieved from https://pediatrics.aappublications.org/content/134/2/e547 .....Exhibit 4

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Brownstein, M. J. (1993). A brief history of opiates, opioid peptides, and opioid receptors. Proceedings of the National Academy of Sciences, 90(12), 5391-5393. doi:10.1073/pnas.90.12.5391, https://www.ncbi.nlm.nih.gov/pmc/articles/PMC46725/ .....Exhibit 6

Gomez-Pomar, E., & Finnegan, L. P. (2018). The Epidemic of Neonatal Abstinence Syndrome, Historical References of Its' Origins, Assessment, and Management. Frontiers in Pediatrics, 6. doi:10.3389/fped.2018.00033; retrieved from https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5827164/. .....Exhibit 7

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Parekh, R. What is Addition. *American Psychiatric Association* (2017, January) Retrieved from https://www.psychiatry.org/patients-families/addiction/what-is-addiction. .....Exhibit 9

Upadhyay J, Maleki N, Potter J, et al. Alterations in brain structure

and functional connectivity in prescription opioid-dependent patients.
Brain 2010; 133:2098-114. ..... Exhibit 10

Sinha Rajita. "Chronic stress, drug use, and vulnerability to addiction"
Annals of the New York Academy of Sciences vol. 1141 92008): 105-30. .....Exhibit 11

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Opioid Misuse and Abuse." Federal Drug Administration. 13 Feb. 2019
https://www.fda.gov/Drugs/DrugSafety/InformationbyDrugClass/ucm338566.htm.....Exhibit 12

Retrieved from: Terplan, M. (2017). Women and the opioid crisis: Historical context
and public health solutions. Fertility and Sterility, 108(2), 195-199. doi :10.1016/
j.fertnstert.2017.06.007 .....Exhibit 13

Kolodny, A. (2013, March 29). [Letter to State Medical Board]. Physicians for
Responsible Opioid Prescribing, Brooklyn, NY, Retrieved from:
https://www.supportprop.org/wp-content/uploads/2014/12/PA_3_29_13_FSMB.pdf. ...Exhibit 14

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overdose deaths. Retrieved from
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Pain – United States, 2016. MMWR Recomm Rep 2016;65(No. RR-1):1-49. DOI:
http://dx.doi.org/10.15585/mmwr.rr6501e1 .....Exhibit 16

Portenoy RK. Cancer pain. Epidemiology and syndromes. Cancer 1989;63;2298-307.;
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USA v The Purdue Frederick Company, 1:07-cr-00029, pp. 2-3 .....Exhibit 18

2002 Hearing before a subcommittee on appropriations .....Exhibit 19

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Benzodiazepine Prescriptions between Independent and Non-Independent
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To require the Food and drug Administration to Revoke the Approval of

cognitive development of children born to mothers with opioid and polysubstance use. Pediatric Research, 78(3), 330-335. doi:10.1038/pr.2015.95.....Exhibit 35

Newborn Health Federal Action Needed to Address Neonatal Abstinence Syndrome. USGAO. Oct. 2017 Exhibit 36

Mihali, R. Medical Costs of Addicted Newborns: Neonatal Abstinence Syndrome." NC Drug Court. http://www.ncdrugtreatmentcourts.com/NAS.html.....Exhibit 37

Yohn, N. L., Bartolomei, M. S., & Blendy, J. A. (2015). Multigenerational and transgenerational inheritance of drug exposure: The effects of alcohol, opiates, cocaine, marijuana, and nicotine. Progress in Biophysics and Molecular Biology, 118(1-2), 21-33. doi: 10.1016/j.pbiomolbio.2015.03.002 .....Exhibit 38

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Rayburn WF, Brennan MC. Periconception warnings about prescribing opioids. *Am J Obstet Gynecol* 2011; 204:281-2. .....Exhibit 41

Kallen B, Reis M. Use of tramadol in early pregnancy and congenital malformation risk. *Reprod Toxicol* 2015; 58:246-51. .....Exhibit 42

Interrante JD, Ailes EC, Lind JN, et al. Risk comparison for prenatal use of Analgesics and selected birth defects, National Birth Defects Prevention Study 1997-2011. *Ann Epidemiol* 2017; 27:645-53 e2.; .....Exhibit 43

Lind JN, Interrante JD, Ailes EC, et al. Maternal Use of Opioids During Pregnancy and Congenital Malformations: A Systematic Review. Pediatrics 2017; 139; .....Exhibit 44

Gallego MJ, Porayette P, Kaltcheva MM, Meethal SV, Atwood CS. Opioid and progesterone signaling is obligatory for early human embryogenesis. Stem Cells Dev 2009; 18:737-40. .....Exhibit 45

Brennan MC, Rayburn WF. Counseling about risks of congenital anomalies from prescription opioids. Birth Defects Res A Clin Mol Teratol 2012; 94:620-5.....Exhibit 46

Dehghani L, Sahraei H, Meamar R, Kazemi M. Time-dependent effect of oral morphine consumption on the development of cytotrophoblast and syncytiotrophoblast cells of the placental layers during the three different periods of pregnancy in Wistar rats. *Clin Dev Immunol* 2013; 2013:974205. .....Exhibit 47

Werntz Declaration .....Exhibit 48

Dept. of Veterans Affairs. *Pain as the 5th Vital Sign Toolkit*. Oct. 2000.....Exhibit 49

Dowell D, Haegerich TM, Chou R. CDC Guideline for Prescribing Opioids for Chronic Pain — United States, 2016. MMWR Recomm Rep 2016;65(No. RR-1): 1–49. DOI: http://dx.doi.org/10.15585/mmwr.rr6501e1 .....Exhibit 50

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The American College of Obstetricians and Gynecologists. (2017). Opioid Use and Opioid Use Disorder in Pregnancy. ASAM. Number 711. Aug. 2017. .....Exhibit 52

(2005). Stedman's medical dictionary for the health professions and nursing. Philadelphia :Lippincott Williams & Wilkins,.....Exhibit 53

iPledge Patient Introductory Brochure. Nov. 2016.....Exhibit 54

Kerlikowske, R. Gill. (Jun. 2013). Committee on Energy and Commerce. Examining the Federal Government's Response to the Prescription Drug Abuse Crisis. Washington, D.C.: U.S. H.O.R. https://docs.house.gov/Committee/Calendar/ByEvent.aspx?EventID=100984 .....Exhibit 55

FDA. A Guide to Safe Use of Pain Medicine. Feb. 23, 2009. Last Updated Dec. 20, 2018. https://www.fda.gov/ForConsumers/ConsumerUpdates/ucm095673.htm .....Exhibit 56

Amanda Hanlon Declaration.....Exhibit 57

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Service of the foregoing was accomplished through the Court's Electronic Filing System this 28th day of March, 2019,

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