

**UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF OHIO
EASTERN DIVISION**

IN RE: NATIONAL PRESCRIPTION OPIATE LITIGATION)	MDL 2804
)	Case No. 1:17-md-2804
THIS DOCUMENT RELATES TO:)	
)	Judge Dan Aaron Polster
<i>Doyle v. Purdue Pharma L.P., et al.</i>)	
No. 1:18-op-46327)	<u>OPINION AND ORDER</u>
)	
<i>Artz v. Purdue Pharma L.P., et al.</i>)	
No. 1:19-op-45459)	
)	
<i>Salmons v. Purdue Pharma L.P., et al.</i>)	
No. 1:18-op-45268 ¹)	
)	

Before the Court is the NAS Guardians’ Motion for Class Certification (Doc. #: 3066). Defendants collectively filed a brief in opposition (Doc. #: 3536), and Assertio Therapeutics, Inc. filed a separate brief in opposition (Doc. #: 3534).² The NAS Guardians (also referred to below as “Plaintiffs”) filed a reply (Doc. #: 3555),³ and Defendants and Assertio filed sur-replies (Doc. #: 3567, 3570). During the course of briefing, the Court allowed the NAS Guardians numerous opportunities to amend their class definition, to identify and change the proposed class representatives, and to extend the time period for class-related discovery.⁴

¹ Plaintiffs include *Salmons* in the caption in their briefs, but no plaintiff in *Salmons* is a proposed class representative, so the Court will not consider whether to certify a class in that case. Plaintiffs also include *Flanagan v. Purdue Pharma L.P., et al.*, No. 18-op-45405, in the caption in their briefs, but that case was dismissed on February 11, 2020.

² The redacted versions of Defendants’ and Assertio’s briefs are at Doc. #: 3523 and Doc. #: 3522, respectively.

³ Sealed exhibits accompanying Plaintiffs’ reply are at Doc. #: 3557.

⁴ See, e.g., Doc. 1829 (setting August 23, 2019 for Plaintiffs to file a motion to certify four putative classes); Doc. 2030 (directing the parties to jointly propose a briefing schedule); Aug. 22, 2019 Marginal Order (granting requests to amend complaints); Sep. 17, 2019 Marginal Order (granting-in-part request to amend); Oct. 1, 2019 Marginal Order (granting an additional extension of time of not more than 4 months); Oct. 25, 2019 Marginal Order (granting NAS Baby Plaintiffs’ Motion for Extension of Time regarding a discovery dispute); Dec. 3, 2019 Marginal Order (granting NAS Plaintiffs’ Motion for Extension of Time until December 9, 2019 to Disclose one of its Expert Reports); Mar. 5,

The Court concludes below that: (1) the Guardians' proposed class definitions are not administratively feasible; (2) the proposed classes do not meet Rule 23(a)'s typicality requirement; (3) the proposed classes do not satisfy the implied requirement that class membership must be ascertainable. Also, indicative of the problems with the Guardians' proposed class definition, at most only one of the Guardians' three proposed class representatives actually belongs to one of the proposed classes. Accordingly, the Guardians' Motion is **DENIED**.

I. Introduction.

The Guardians' Motion pertains to two of the nearly three thousand cases that make up this multidistrict litigation. The cases in this MDL share common questions concerning, among other things, Defendants' conduct regarding alleged diversion and improper marketing of prescription opioids. *See JPML Transfer Order* (Doc. #: 1). Most of the cases are brought by cities and counties alleging Defendants' conduct caused harm to the greater public (that is, caused a public nuisance). In contrast, the Plaintiffs seeking class certification here are Guardians of individual children diagnosed at birth with Neonatal Abstinence Syndrome ("NAS"). These children are sometimes referred to colloquially as "NAS Babies." The Guardians allege Defendants were the ultimate cause of the harms their wards suffer associated with NAS, and the Guardians must now shoulder greater burdens of care for these children.

In support of their Motion, the Guardians repeatedly refer to this Court's earlier certification of a Negotiation Class for settlement purposes. Specifically, when addressing Federal Rule of Civil Procedure 23(a), the Guardians "discuss the legal requirements as briefly as possible" and instead simply adopt the Court's findings from its *Memorandum Opinion Certifying a Negotiation Class* (Doc. #: 2590). *See Mem. at 26* (Doc. #: 3066-1). While Plaintiffs' Motion was

2020 Marginal Order (granting Joint Motion for Extension of Time to designate experts (in favor of Defendants)); *see also n.7, infra*, regarding various changes to class representatives.

pending, the Sixth Circuit reversed this Court’s Negotiation Class certification, although it did not fully reach this Court’s conclusions regarding Rule 23(a). *In re Nat’l Prescription Opiate Litig.*, 976 F.3d 664 (6th Cir. 2020).

More significant than the Sixth Circuit’s reversal, however, is that the Guardians advance allegations, claims, and injuries meaningfully different from those of the government entities that sought certification of the Negotiation Class. The different legal theories of these dissimilar groups cannot be viewed equally under Rule 23(a), and the proposed *litigation* classes of Guardians are simply not analogous to the negotiation class that this Court certified for *settlement*. Accordingly, the Court will not apply or refer to the analysis it used in the Negotiation Class Opinion and Order.

II. Classes and Claims.

The Guardians propose two different nationwide classes, two different California statewide classes, and two different Ohio statewide classes.

Specifically, Plaintiffs first ask the Court to certify two nationwide classes—an expansive class and a narrower class—of Guardians of children diagnosed with NAS at birth. The class definitions, including alternative subclass definitions, are discussed below. The nationwide classes assert claims for violations of RICO against certain marketing and supply chain defendants. *Mot.* at 3–4.⁵ The nationwide classes request relief in the form of: medical monitoring; creation of a science panel; compensatory damages; punitive damages; and attorneys’ fees. *Id.* at 4.⁶

⁵ Plaintiffs list the Pharmacies as Defendants to the nationwide class claims, but simultaneously state their RICO claims are asserted only against certain “Marketing Defendants” and “Supply Chain Defendants,” which groups do not include the Pharmacies. *See Mot.* at 3–4. Unfortunately, this is only the first of numerous imprecisions and contradictions in the Guardians’ briefs.

⁶ In their reply brief, Plaintiffs claim they “seek only injunctive relief for the class,” *Reply* at 10, but elsewhere they defend their decision to alternatively plead for an award of compensatory damages and certification under Rule 23(b)(3), *Reply* at 35 n.35.

Plaintiffs also request certification of expansive and narrow statewide classes of legal guardians of Ohio and California residents. Mot. at 5–10. The statewide class claims are made against a broader set of Defendants. *Id.* at 5–7, 9. In addition to the same RICO claims made against the nationwide class, the Ohio statewide class claims include negligence, negligence *per se*, civil battery, and civil conspiracy. *Id.* at 7. The Ohio statewide class requests the same relief as the nationwide class. *Id.* Similarly, the California statewide class asserts RICO claims, negligence, negligence *per se*, and violations of the California Unfair Competition Law. *Id.* at 9. In addition to the relief sought by the nationwide and Ohio classes, the California class also seeks disgorgement and other relief pursuant to the Unfair Competition Law. *Id.* at 9–10.

III. Proposed Class Representatives.⁷

The proposed class representatives are Guardians of four children residing in Ohio and California. These Guardians are the proposed representatives for the nationwide classes and also the statewide classes in the state where they reside. The three families that comprise the representative Guardians and their children are summarized below. As will be discussed, the key characteristics of the mother and child are: (1) which opioids the mother ingested, and when; (2) whether the child was diagnosed with NAS at birth; and (3) whether the child was ever treated with opioids later in life.⁸

A. Guardians Jacqueline and Roman Ramirez.

Jacqueline and Roman Ramirez are the birth parents and guardians of R.R., who was born in [REDACTED]. They reside in California. [REDACTED]

⁷ The proposed representatives have changed during the pendency of the Motion. Stephanie Howell voluntarily dismissed her claims, *see Doyle v. Actavis*, 1:18-op-46327, Doc. #: 31. Plaintiffs withdrew the request of Ohioan Michelle Frost to be class representative, and Ashley Poe assumed representation of the Ohio class. *See Doyle*, 1:18-op-46327, Doc. #: 40 (order on motion to intervene).

⁸ An “opiate” is a “natural” narcotic analgesic derived from an opium poppy, while an “opioid” is a narcotic analgesic that is at least partly synthetic. For ease of reference, the Court refers to both in this order as “opioids.”

[REDACTED]

C. Guardian Ashley Poe.

Ashley Poe is the guardian of P.P., born in [REDACTED]. They reside in Ohio. Defs.’ App’x A. [REDACTED]

[REDACTED]

IV. Legal Standard for Class Certification.

Certification of a class is proper if Plaintiffs satisfy all four requirements of Federal Rule of Civil Procedure 23(a) and at least one subdivision of Rule 23(b). *Clemons v. Norton Healthcare Inc. Ret. Plan*, 890 F.3d 254, 278 (6th Cir. 2018). The requirements of Rule 23(a) are: “(1) the

¹⁰ [REDACTED]

class is so numerous that joinder of all members is impracticable; (2) there are questions of law or fact common to the class; (3) the claims or defenses of the representative parties are typical of the claims or defenses of the class; and (4) the representative parties will fairly and adequately protect the interests of the class.”

Plaintiffs seek certification under Rule 23(b)(2), which authorizes injunctive relief where “the party opposing the class has acted or refused to act on grounds that apply generally to the class.” Plaintiffs also seek certification under Rule 23(b)(3), which applies where “the questions of law or fact common to class members predominate over any questions affecting only individual members, and that a class action is superior to other available methods for fairly and efficiently adjudicating the controversy.” Rule 23(b)(3) classes must also be “ascertainable.” *Cole v. City of Memphis*, 839 F.3d 530, 541 (6th Cir. 2016).

Plaintiffs bear the burden of “affirmatively demonstrating” compliance with Rule 23. *Sandusky Wellness Ctr., LLC v. ASD Specialty Healthcare, Inc.*, 863 F.3d 460, 466–67 (6th Cir. 2017) (quoting *Wal-Mart Stores, Inc. v. Dukes*, 564 U.S. 338, 350 (2011)). “Plaintiffs ... must actually *prove*—not simply plead—that their proposed class satisfies each requirement of Rule 23.” *Halliburton Co. v. Erica P. John Fund, Inc.*, 573 U.S. 258, 275 (2014).

A district court “has broad discretion in deciding whether to certify a class, but that discretion must be exercised within the framework of Rule 23.” *In re Am. Med. Sys., Inc.*, 75 F.3d 1069, 1079 (6th Cir. 1996). A district court should only certify a class if it finds, “after a rigorous analysis, that the prerequisites of Rule 23(a) have been satisfied.” *Gen. Tel. Co. of Sw. v. Falcon*, 457 U.S. 147, 161 (1982). “Frequently, that ‘rigorous analysis’ will entail some overlap with the merits of the plaintiff’s underlying claim.” *Dukes*, 564 U.S. at 351. A district court may look past the pleadings to “understand the claims, defenses, relevant facts, and applicable law in order to

make a meaningful determination of the certification issues.” *In re Welding Fume Prods. Liab. Litig.*, 245 F.R.D. 279, 289 (N.D. Ohio 2007).

The Court need not address all requirements of Rule 23 if it determines that one element has not been met. *See Kondash v. Kia Motors Am., Inc.*, No. 1:15-CV-506, 2020 WL 5816228 at *11–12 (S.D. Ohio Sept. 30, 2020) (discussing only the predominance requirement, the failure of which defeated certification); *Corwin v. Lawyers Title Ins. Co.*, 276 F.R.D. 484, 490 (E.D. Mich. 2011) (denying certification based on plaintiff’s failure to satisfy the commonality requirement of Rule 23(a)(2), and also 23(b)(3)); *Horacek v. Caruso*, No. 1:08-CV-262, 2008 WL 4820483, at *4 (W.D. Mich. Oct. 30, 2008) (denying class certification because, even if Plaintiffs could show numerosity, typicality, and commonality, they could not demonstrate adequacy).¹¹

V. Class Definitions.

Before considering the requirements of Rule 23(a), the Court first evaluates the Guardian’s proposed class definitions.

Different courts categorize concerns over class definition and member identity differently within Rule 23’s framework. *See Sandusky Wellness*, 863 F.3d at 473 (summarizing different approaches). The Sixth Circuit has held that Rule 23(b)(3) classes must satisfy an implied requirement that class membership is ascertainable, but classes certified under Rule 23(b)(2) need not satisfy this requirement. *Cole*, 839 F.3d at 541.¹² Because Plaintiffs seek certification under both subsections (b)(2) and (b)(3), the Court will consider whether the classes are ascertainable.

¹¹ *See also Aug. v. Mich. Dep’t of Corr.*, No. 2:16-CV-11224, 2018 WL 4679597, at *4–5 (E.D. Mich. Sept. 29, 2018) (denying class certification based on a lack of commonality without analyzing the other Rule 23(a) requirements); *Wagner v. White Castle Sys., Inc.*, 309 F.R.D. 425, 432 (S.D. Ohio 2015) (same); *In re Countrywide Fin. Mortg. Lending Pracs. Litig.*, No. 08-MD-1974, 2011 WL 4862174, at *4 (W.D. Ky. Oct. 13, 2011) (same), *aff’d sub nom.*, 708 F.3d 704 (6th Cir. 2013).

¹² The holding in *Cole* rested largely on the proposition that, to carry out the specific injunctive remedy requested, the members of the 23(b)(2) injunctive class did not need to receive notice or even be identified. Conversely, here, each Guardian class member must be identified in order to obtain the requested injunctive relief of enrolling their child in a medical monitoring plan. Thus, ascertainability still appears necessary in this case even under Rule 23(b)(2).

Additionally, Rule 23(c)(1)(B) provides that an order certifying a class “must define the class.” As such, before determining whether a class satisfies Rule 23(a) and (b), the Court should ensure the class is defined clearly; and the Court has “broad discretion to modify class definitions.” *Powers v. Hamilton Cty. Pub. Def. Comm’n*, 501 F.3d 592, 619 (6th Cir. 2007). *Cf. Romberio v. Unumprovident Corp.*, 385 F. App’x 423, 431 (6th Cir. 2009) (noting problems with class definition can carry over into problems with typicality). Identifying a clear definition is especially important here, where Defendants argue Plaintiffs redefined the proposed classes in their reply brief. *See* Surreply at 2–4.

For a class to be ascertainable, the class definition must be “sufficiently definite so that it is administratively feasible for the court to determine whether an individual is a member of a proposed class.” *See Young v. Nationwide Mut. Ins. Co.*, 693 F.3d 532, 537–38 (6th Cir. 2012). “For a class to be sufficiently defined, the court must be able to resolve the question of whether class members are included or excluded from the class by reference to objective criteria.” *Id.* at 538 (quoting Moore’s Fed. Prac. § 23.21). It is administratively feasible for the Court to determine class membership if the class is defined by reference to objective criteria, and with reasonable accuracy. *See id.* at 538–39; *Rikos v. Procter & Gamble Co.*, 799 F.3d 497, 525 (6th Cir. 2015).

In their Motion, Memorandum, and Appendix A, the Guardians attempt to set out objective definitions for the nationwide and statewide classes.¹³ All three documents contain slight variations from the others that the Guardians do not explain. For example, in their Memorandum, the Guardians summarize the class definitions first by stating the “**two** primary objective and readily ascertainable criteria” of each class definition are: “(1) the birth mother of every NAS Child received a prescription for opioids prior to the birth of her child and (2) that child was medically

¹³ Plaintiffs’ Proposed Order replicates Appendix A, excluding the alternate subclasses. *See* Doc. 3066-3.

diagnosed with NAS.” Mem. at 6 (emphasis added). Then, elsewhere in their brief, the Guardians highlight “**three** objective criteria” of the class definitions: (1) legal guardian; (2) child medically diagnosed with NAS; and (3) birth mother received a prescription for opioids. *Id.* at 23 (emphasis added). Still later, in their reply brief, the Guardians assert the definition is sufficient because class membership is established on the basis of documentary evidence of: (a) guardianship of a ward; (b) diagnosis of NAS at birth; and (c) either (i) a prescription for opioids received by the birth mother any time before the birth; or (ii) a prescription for opioids received during pregnancy. Reply at 11. Elsewhere in the reply brief, Plaintiffs do not include “at or near birth” when referencing the NAS diagnosis.¹⁴ In addition to these confusingly inconsistent statements of the *affirmative* criteria of class membership, Plaintiffs omit from certain iterations of their definitions the *exclusionary* criteria that elsewhere they state apply to all classes. *See* Mem. at 5 (identifying “exclusions from all classes (including statewide classes)”).¹⁵

Plaintiffs’ differing definitions and summaries of the class are inconsistent and imprecise, yielding a moving target for Defendants and the Court. The Court must clarify and more accurately calibrate the definitions before it can determine whether *any* class is certifiable. Below, the Court identifies the criteria included in Plaintiffs’ various class definitions and clarifies those criteria to make them as objective and definite as possible, in order to maximize ascertainability. But even

¹⁴ Defendants argue this omission is Plaintiffs’ attempt to abandon this definitional limitation. Sur-reply at 3. Defendants add that, in defending the sufficiency of the class definitions in their reply brief, Plaintiffs do not restate: (i) the temporal scope; (ii) the requirement that opioids were manufactured, distributed, or filled by a Defendant or Purdue entity; or (iii) the exclusions for guardians that are political subdivisions or for children treated with opioids after birth, other than for pharmacological weaning. The Court will not read these limitations, which Plaintiffs did not expressly abandon or alter, out of the class definition. However, Defendants likely are correct that doing so would create even greater problems under Rule 23.

¹⁵ Examples of other inconsistencies in class definition include: (1) Plaintiffs’ Motion defines the subclasses to include guardians of United States, Ohio, and California residents, *see* Mot. at 10–12, but in their Memorandum and Appendix A they include only Ohio residents, *see* Mem. at 5–6, Pls.’ App’x A at 9–10; and (2) In the Motion and Appendix A, Plaintiffs use March 16, 2000 as the relevant birth date for the NAS children, *see* Mot. at 1–2; Pls.’ App’x A at 1, but in the Memorandum they use May 25, 2000, Mem. at 4–5. These inconsistencies are not merely sloppy – they made it substantially more difficult for the Court to assess the merits of the Guardians’ motion.

the Court's best attempt to enhance Plaintiffs' proposed criteria cannot cure fatal flaws in their proposed class definitions.

A. The Nationwide Class.

Upon reviewing the nationwide class definition, the Court identifies the following five inclusive and exclusive class-definition criteria proposed by Plaintiffs: (1) class members are legal guardians, other than governmental entities, of a child who is a United States resident and was born after March 16, 2000¹⁶; (2) the child was medically diagnosed with opioid-related NAS at or near birth; (3) the child's mother either (a) received a prescription for opioids prior to the child's birth, or (b) received or filled a prescription for opioids in the 10 months prior to the child's birth; (4) those opioids were manufactured, distributed, or filled by a Defendant or a Purdue entity; and (5) the child was not treated with opioids after birth, other than for pharmacological weaning. *See* Mot. at 1–2.

After carefully analyzing these five criteria, and even redefining them to make them as objective as possible, the Court concludes that no class proposed by the Guardians is reasonably ascertainable.

1. Legal guardian of a U.S. resident born after March 16, 2000.

Plaintiffs define “legal guardian” as “any natural person or entity who has the primary legal responsibility under law for an infant or child’s physical, mental, and emotional development.” Mot. at 1 n.2. This includes “natural and adoptive parents who have not otherwise lost legal custody of their children, legal custodians, legal caretakers, and court-appointed guardians.” *Id.* Plaintiffs’ definition excludes any guardians that are governmental entities. *Id.*

¹⁶ As previously stated, Plaintiffs define the temporal scope slightly narrower in their brief, using May 25, 2000 as the relevant birth date, but this discrepancy does not change whether the definition is objective.

Plaintiffs argue guardianship is established “simply and by reference to objective criteria,” such as: (i) an affidavit and a copy of the child’s birth certificate or adoption papers; or (ii) a birth certificate and a judicial order of appointment. Mem. at 24. Plaintiffs describe this inquiry as a fact question regarding legal status that does not require legal analysis.

Defendants do not dispute that guardianship can be established by reference to documentary evidence. But Defendants observe correctly that, “in many cases, it is no simple task to identify a child’s legal guardian under state law.” Opp. at 64 (citing *In re Carrie W.*, 110 Cal. App. 4th 746, 758–60 (2003)). As an example, Defendants cite a former proposed class representative who, they say, was not a class member at the time her complaint was filed because she did not have custody of her child; moreover, custody was and remains in dispute. Opp. at 64 (referring to proposed-but-then-withdrawn class representative Michelle Frost). In reply, Plaintiffs merely repeat that guardianship can be established on the basis of documentary evidence. Reply at 11.

Defendants’ argument, and the example of Michelle Frost, bring into tight focus the Court’s serious concern with a class of legal guardians in this case. Legal guardianship of a child is subject to change. An individual who is a guardian at the time the class is certified may no longer have guardianship over the child upon resolution of the case. Conversely, another individual may not be a legal guardian, and thus, not a class member, but may later become one during the pendency of the litigation. The Court’s concerns are especially acute here, where many of the guardians unfortunately suffer from opioid addiction, and so are at greater-than-average risk of potentially losing guardianship – leading to new guardians for their children. Although it is uncontested that legal guardianship can be objectively ascertained by documentary evidence, that alone cannot make a class ascertainable where class membership is even modestly in flux over a long period of

time. *See McElhaney v. Eli Lilly & Co.*, 93 F.R.D. 875, 878 (D.S.D. 1982) (denying class certification because, among other reasons, “the composition of the proposed class is constantly changing, as unknown persons move into and from South Dakota”).

The Court does not mean to state that a class of legal guardians in *any* case would suffer from lack of ascertainability. *See, e.g., Evans v. Buchanan*, 555 F.2d 373, 381 (3d Cir. 1977) (certifying a class of “all black and Hispanic children presently enrolled in the Wilmington, Delaware School system,” and noting the named plaintiffs could be represented by their “legal guardians”). In this case, however, the principal relief Guardians seek is a Court Order requiring “Defendants to provide for the benefit of the Plaintiff Legal Guardians and the Putative Class Members ongoing medical monitoring, testing, intervention, provision of caregiver training and information, and medical referral . . . and all future medical care reasonably necessary to treat these children.” Mot. at 4. This request implicates a shifting class membership for a period of many years, perhaps decades.

Ultimately, the Court is of the opinion that ascertaining over a period of years which individuals are the legal guardians of NAS Babies will present difficult and infeasible administrative hurdles. These hurdles translate to an insufficiently ascertainable composition of class membership.

As discussed further below, however, there are other problems with the Guardian’s definition of class membership besides the first criterion.

2. Medically diagnosed with opioid-related NAS at or near birth.

The second definitional criterion, “medically diagnosed with opioid-related NAS at or near birth,” is also deeply problematic. Unlike, for example, a broken leg, which is easy to define and diagnose, NAS is by definition a syndrome, meaning a constellation of medical signs and

symptoms. Even then, there is no checklist of symptoms that are *always* present and automatically lead to a diagnosis of NAS.

Accordingly, Plaintiffs define NAS to include not only “Neonatal Abstinence Syndrome,” but also “additional, but medically symptomatic identical, terminology and diagnostic criteria, including Neonatal Opioid Withdrawal Syndrome (NOWS) and other historically and regionally used medical and/or hospital diagnostic criteria for infants born addicted to opioids from *in utero* exposure.” Mot. at 2 n.3; Mem. at 24. Plaintiffs explain that some states have birth registries for children born with NAS, but others don’t, and in any event the keys to class membership are “objective medical criteria for such medical diagnosis [that] can also be found in a child’s medical records at birth.” Mem. at 24–25. According to Plaintiffs, there are “multiple and additional objective indicia of opioid exposure.” Reply at 16. These “objective medical criteria” *can* include, but do not *have to* include any of the following: (1) diagnosis of NAS or NOWS as documented in the child’s medical record; (2) NAS/NOWS score(s) after birth that meet certain diagnostic indicia set out by Plaintiffs’ expert;¹⁷ (3) postnatal weaning with opioid replacement drugs (morphine, methadone, buprenorphine, or other opioids); *or* (4) opioid-positive toxicology screening of either umbilical cord blood or the baby’s meconium. Anand Decl. at 2, ¶ 3 (Doc. #: 3067-5); Reply at 17 n.22 (citing Anand Dep. at 203:1–204:22) (clarifying that the criteria are alternative, not additive). Although the Guardians refer to these alternative bases for finding a medical diagnosis of NAS as “objective medical criteria,” the Court more accurately refers below to these alternatives as “diagnostic indicia.”

Defendants assert multiple reasons why class membership cannot be ascertained using this complex, multipartite definition. Defendants first observe that NAS may be related to opioids *or*

¹⁷ For example, “successive NAS-diagnostic Finnegan scores greater than ‘8.’” Reply at 6 n.8.

other drugs, such as antidepressants, barbiturates, benzodiazepines, methamphetamine, cocaine, and alcohol. Opp. at 5. Of course, whether a child’s NAS is “opioid-related” is central to the merits of Plaintiffs’ case, and Defendants insist it requires individualized assessment, including examination of each child’s medical records, many of which are very lengthy. *Id.* at 63 (arguing this problem is exemplified by the fact that not a single child of any proposed class representative was diagnosed with “*opioid-related* NAS” at or near birth). Thus, a “diagnosis of NAS . . . as documented in the child’s medical record,” without more, does not ensure a child suffered NAS due to opioids, and so does not ensure the child’s guardian is a class member.

Defendants further argue that Plaintiffs’ attempt to import into their class definition other “terminology and diagnostic criteria,” which are supposedly “medically symptomatic identical,” is legally untenable because the definition must operate without needing to refer to separate and sometimes inconsistent alternative yardsticks. *Id.* Defendants further assert the alternative diagnostic indicia are not objective and each again requires searching medical records. *Id.* at 63–64.

Plaintiffs say little to rebut Defendants’ arguments, other than re-asserting that this second class-definition criterion, like the others, may be established using documentary evidence. Reply at 11. The flaw with this criterion, however, is that it is not sufficiently definite. Indeed, it is even less definite than the first criterion of “legal guardian.” Plaintiffs expressly use open-ended language to define NAS. The Guardians write, “The term “NAS” (Neonatal Abstinence Syndrome) is defined to include additional, but medically symptomatic identical, terminology,” Mot. at 2 n.3, and that there are “multiple and additional objective indicia of opioid exposure.” Reply at 16. By their own definition then, the Guardians require this Court to, on a case-by-case basis, review each NAS Baby’s medical records, which may not contain a verbatim diagnosis of “opioid-related

NAS” (or even just “NAS”), and instead look for various combinations of indicia that are “medically symptomatic identical” to opioid-related NAS.

To their credit, the Guardians provide the Court with what amount to several *examples* of diagnostic indicia that their expert asserts are symptomatically identical to a diagnosis of NAS. However, this does not save the Guardians’ definition. If anything, it further illustrates the problem. The four diagnostic indicia provided by the Guardians demonstrate only four of the potentially limitless number of ways in which opioid-related NAS may be recorded as “diagnosed” in a medical record. These examples provide no guidance to the Court—or the Defendants—who ought to be included or excluded from the class without a medical expert on hand to identify other potentially relevant diagnostic indicia. Indeed, Plaintiffs’ expert, Dr. Anand, simply identifies NAS diagnosis as “present” in the records of three of the four children who are the wards of the proposed Class Representatives, but he does not identify what indicia purportedly appear in those records to establish the diagnosis. *See* Anand Supp. Decl. at 2 (Doc. #: 3557). Dr. Anand also testified infants can receive scores on a diagnostic scale that can lead to an NAS diagnosis without being exposed to opioids *in utero*. Ex. A to Sur-reply, Anand Dep. at 266:12–269:18 (Doc. #: 3567-2). And Dr. Anand admits that allowing for all of the alternative diagnostic indicia would lead to inclusion in the class—defined by “medical diagnosis of NAS at birth”—of guardians of infants that were not diagnosed with NAS at birth. Defs.’ Ex. 41, Anand Dep. at 309:15–20.

Of course, this Court is completely unqualified to determine whether diagnostic indications in a medical record are “symptomatically identical” to NAS, or whether those indications appear even though the infant was not exposed to opioids. Moreover, even if the Court, with enormous assistance, could undertake this task, it would take a document-by-document review of each child’s medical records to reach an individual determination, and require analysis of an unknowable

number of potential ways that a medical doctor might indicate a diagnosis of opioid-related NAS. Such a requirement would fit perfectly the definition of administrative infeasibility.

In sum, a definitional standard that requires combing through hundreds of pages of medical records to demonstrate satisfaction of one or more alternative criteria is not an administratively feasible way to measure “medical diagnosis of NAS at birth.” The second criterion of Plaintiffs’ class definition is not reasonably ascertainable and renders it unworkable.

3. Birth mother’s opioid prescriptions.

For completeness, the Court addresses the remaining three class-definition criteria. Plaintiffs offer a broad alternative and a narrow alternative for the third component regarding the birth mother’s opioid prescriptions: either the birth mother (a) received a prescription for opioids *at any time prior* to the birth, or (b) received and/or filled a prescription of opioids in *the 10 months prior* to the birth. Plaintiffs claim satisfaction of this component can be determined through pharmacy records. Defendants criticize both alternatives because “Plaintiffs offer the Court no reason to pick one over the other; nor do they identify in which of the two cases the chosen nationwide class would proceed.” Opp. at 61. In fact, the Court concludes the first alternative is virtually nonsensical.

The alternatives are meant by Plaintiffs to distinguish between: (a) *any* lifetime opioid use by the mother before or during pregnancy, and (b) opioid use specifically during pregnancy. Mem. at 4. However, Plaintiffs’ imprecise drafting establishes a second difference. The wording of the first, expansive, lifetime alternative pertains to opioid prescriptions “received” by the birth mother, while the wording of the narrower, pregnancy-related alternative pertains to prescriptions “received and/or *filled*.” Plaintiffs do not provide any rationale for, or clarification of, yet another

clumsy discrepancy in their definition.¹⁸ More pointedly, opioid-related NAS only occurs if the opioids ingested by the mother *during pregnancy* pass to the fetus in utero. Including in the class definition guardians of mothers who “received” opioid prescriptions “at any time prior to birth” would work to expand class membership needlessly.

The Court finds this component can be clarified and made objective by allowing only the second alternative, and rephrasing it to require that prescriptions be “filled” during the relevant time period. While neither “received” nor “filled” establishes that the opioids were actually ingested as prescribed, whether they were “filled” is more easily established by reference to documents – specifically, pharmacy records. And any prescription “filled” necessarily was “received,” so there is no reason to require class members to show both.

In sum, the Court rewrites this component to be: “the child’s mother filled a prescription for opioids in the 10 months prior to the child’s birth.”

4. Opioids were manufactured, distributed, or filled by a Defendant or Purdue entity.

Plaintiffs do not address how a class member can demonstrate the opioid medications prescribed to a birth mother were manufactured, distributed, or filled by a Defendant or Purdue entity. Defendants do not argue this component is not objective, but they do challenge Plaintiffs’ ability to identify the Defendants against which a particular guardian-plaintiff might have a claim. *See* Opp. at 9 n.6 (claiming Plaintiffs ignore the distinction between branded and generic products, which is significant because it affects which manufacturers a particular plaintiff might have a claim against); *id.* at 11 n.9 (noting that proposed representative Barnwell is factually incorrect in her recollection that she filled opioid prescriptions at CVS).

¹⁸ The numerous unexplained and unnecessary discrepancies in Plaintiffs’ class definitions are especially irksome given the importance of the matter and given that Plaintiffs received numerous extensions of time during briefing.

Though Plaintiffs include this requirement in their class definition, they claim Defendants' conspiracy to create a diversionary market "obviates the need for any individual Guardian to establish product identification (or the route of any opioid through the pharmaceutical supply chain) specific to an NAS child." Mem. at 39. The Court will address this assertion when considering whether the class representatives' claims are typical of the class. For now, the Court concludes this aspect of the class definition is sufficiently objective.

5. Child was not treated with opioids, other than for pharmacological weaning.

Defendants do not argue that whether the child was treated with opioids, other than for pharmacological weaning, is not objective.¹⁹ Accordingly, the Court deems this component objective such that it can be used to ascertain class membership.

B. The Statewide Class and the Alternative Subclasses.

1. Statewide Classes.

Plaintiffs' proposed Ohio and California classes are defined in substantially the same way as the nationwide class. *See* Mot. at 5, 8–9.²⁰ Accordingly, the analysis of the class definition above applies equally to the statewide classes.

2. Alternative Defendant-Specific Subclasses.

Plaintiffs propose six alternative subclasses that include substantially the same components as in their primary definition. In these subclasses, however, Plaintiffs (without explanation) narrow the temporal scope by nearly two months to children born after May 9, 2000 (rather than March

¹⁹ Defendants do argue, however, that some of the proposed representatives are not members of the class because they *did* use opioids other than for pharmacological weaning. Opp. at 23. This is discussed below.

²⁰ Plaintiffs appear to alternatively propose a California class that is not defined using the exclusions applicable to the other proposed classes, but elsewhere they say exclusions apply to all definitions, so the Court will not separately consider the additional definition at Section III.A.3 of their Motion. *See* Mot. at 8–9.

16, 2000).²¹ Further, each alternative subclass definition limits the scope to opioids manufactured or distributed by a particular defendant family. *See* Mot. at 10–12 (identifying alternative subclasses separately relating to: Cephalon Defendants, Endo Defendants, Mallinckrodt Defendants, Actavis Defendants, and “one or more Defendant or Purdue entity.”).²² This additional limitation is also objective. Accordingly, the above analysis of the nationwide class definition applies equally to these alternative subclasses.

VI. Class Membership.

Given Plaintiffs’ failure to offer a class definition that is sufficiently ascertainable and administratively feasible, the rest of the Court’s analysis below is not strictly necessary. Nonetheless, the Court’s observations below strengthen its ultimate conclusion that the Guardians’ motion for class certification must be denied.

“A class representative must be a part of the class and possess the same interest and suffer the same injury as the class members.” *Rutherford v. City of Cleveland*, 137 F.3d 905, 909 (6th Cir. 1998) (quoting *Amchem Prods., Inc. v. Windsor*, 521 U.S. 591, 625–26 (1997)). Courts may either analyze whether proposed representatives are members of the class under varying components of Rule 23(a), or consider this issue separately. Having refined the class definition to one that is more objective, the Court now considers separately whether the proposed representatives are members of the class.

Plaintiffs put forth scant evidence demonstrating the representatives’ class membership. *See* Reply at 6 (summarizing representatives’ class membership in three sentences with citations

²¹ Plaintiffs do not explain the use of two different dates for the alternate subclasses and the primary class definitions. Though the reason for this discrepancy is unclear, both dates are objective.

²² As previously stated, Plaintiffs include in the definition offered in their Motion the guardians of United States, Ohio, and California residents, *see* Mot. at 10–12, but they include in their Memorandum and Appendix A only Ohio residents, *see* Mem. at 5–6, Pls.’ App’x A at 9–10.

to depositions and expert reports). Much of the evidence bearing on this issue comes from Defendants, who do not have the burden of proof. *See Opp.* at 9–13, 22–24 (citing to documentary evidence in arguing that the representatives are not class members). Most notably, Plaintiffs do not put forth any evidence that each relevant birth mother received opioids that were manufactured, distributed, or filled by a Defendant or Purdue entity.²³ As discussed above, Plaintiffs insist the need to establish product identification, which they include in their class definition, is obviated by their conspiracy theory of liability. *Mem.* at 39.²⁴ If Plaintiffs are wrong, however, then they have failed to show the proposed representatives are class members. For now, the Court evaluates class membership without requiring this product identification.

Applying the remaining components of the class definition, the Court finds:

- Jacqueline and Roman Ramirez are not members of the class [REDACTED]
[REDACTED]
[REDACTED]
- Ashley Poe is not a member of the class [REDACTED]
[REDACTED]
[REDACTED]
- Melissa Barnwell is the only proposed representative that appears to possibly satisfy all class definition criteria. [REDACTED]
[REDACTED]

²³ Defendants assert the record is “bereft of *any* evidence that *any* of the mothers of the children of proposed class representatives received medications that any of the Distributor Defendants supplied.” *Opp.* at 33.

²⁴ It bears noting that, even if the Court accepted the argument that product identification is unnecessary, that would eviscerate Plaintiffs’ alternative class definitions, which are defendant-specific based on product identification.

²⁵ [REDACTED]

[REDACTED]

As Defendants note, Plaintiffs’ inability to demonstrate class membership of three of their four proposed guardian-representatives is especially significant “given that proposed class counsel represents more than 75 plaintiffs from which they could try to select a suitable representative.” Opp. at 24. Plaintiffs have added and removed multiple representatives and have come up with only one representative who *might* meet the class definition.²⁷ This highlights the flaws in their class definition and their attempt to satisfy Rule 23(a).²⁸

VII. Rule 23(a).

Even though Plaintiffs fail to offer a viable class definition, for the sake of completeness the Court also considers whether Plaintiffs meet the requirements of Rule 23(a). It turns out this consideration need not be lengthy. Because Plaintiffs clearly cannot demonstrate one of Rule 23(a)’s four requirements – typicality – the Court need not consider the remaining three. *See Corwin*, 276 F.R.D. at 490.

²⁶ [REDACTED]

²⁷ In their reply brief, perhaps sensing ongoing problems with their choice of class representatives, Plaintiffs “request the right to add an additional class representative if in (sic) the unlikely event that this Court requires a class representative that purchased each opioid manufacturer’s product.” Reply at 8 n.9. This request comes far too late, as the Court has given Plaintiffs multiple opportunities to find sufficient class representatives. *See, e.g.*, Case 18-op-46327, Doc. 40 (allowing class representative Poe to intervene). Indeed, in the Guardian’s various complaints, they at one time proposed all of the following class representatives: Doyle, Frost, Howell, Poe, Walker, Flanagan, Salmans, Artz, Barnwell, and Ramirez. Like Poe and the Ramirezes, it appears several of these individuals also would not have met the class definition, for various reasons.

²⁸ Ms. Barnwell is a proposed representative of the California and nationwide classes only. Plaintiffs do not identify *any* representative for their proposed alternative defendant-specific subclasses, nor indicate in which cases those alternative subclasses should be certified. And the Court cannot correct this defect for Plaintiffs even if it wanted to, because the subclasses all pertain to specific opioid manufacturers and distributors, and Plaintiffs do not make any showing as to which Defendant(s) manufactured or distributed opioids relevant to Ms. Barnwell or any other proposed representative. Even ignoring all other issues, without a representative class member, the Court cannot certify any of the alternative subclasses.

Rule 23(a)(3) requires the claims or defenses of the representative parties to be “typical of the claims or defenses of the class.” “Although the two prerequisites of commonality and typicality are sometimes examined together, their foci are distinct: ‘commonality focuses on similarities, while typicality focuses on differences.’” *In re Welding Fume*, 245 F.R.D. at 303 (citation omitted). Under the typicality prong, a court must ask whether, “despite the presence of common questions, each class member’s claim involves so many *distinct* factual or legal questions as to make class certification inappropriate.” *Id.* (quotation omitted). Typicality is not satisfied where a “named plaintiff who proved his own claim would not necessarily have proved anybody else’s claim.” *Sprague v. Gen. Motors Corp.*, 133 F.3d 388, 399 (6th Cir. 1998).

Plaintiffs assert all of the class representatives’ claims (including Ms. Barnwell’s) are typical of the class because they satisfy two factors in their class definition: (1) legal guardians, of (2) children diagnosed with NAS at or near birth. Mem. at 29.²⁹ Plaintiffs further claim typicality is shown by expert testimony opining that a uniform medical monitoring plan is required for the guardians to carry out their duties to care for the children. *Id.* at 29–30.

Defendants offer three reasons why Plaintiffs fail to demonstrate typicality: (1) the proposed class representatives are not even class members; (2) each Guardian-Plaintiff’s claim poses distinct factual and legal questions; and (3) Plaintiffs cannot establish typicality of Defendants’ conduct with respect to individual class members. Opp. at 20–34. In reply, Plaintiffs: (1) reiterate that the representatives meet the class definition if it does not require the NAS diagnosis to be “opioid-related”; (2) assert Defendants are seeking to defeat typicality by arguing the merits; and (3) contend Defendants sneak a predominance requirement into the analysis by arguing that individualized proof defeats typicality. Reply at 3.

²⁹ Of course, the Court found above that these two factors, in particular, are insufficiently objective criteria for definition of class membership.

The Court already addressed whether the proposed representatives are members of the class and determined only Ms. Barnwell *might* meet the class definition. Thus, Ms. Barnwell’s claims must be typical of the proposed classes she purports to represent. As to the Guardians’ argument that the uniform medical monitoring remedy sought by all Plaintiffs demonstrates typicality, the Guardians have failed entirely to show that seeking a uniform *remedy* establishes that one class member’s *claims* are typical of all others. Expert opinions that medical monitoring is necessary are virtually unrelated to a showing that any Defendant is liable for providing that remedy.

Furthermore, Ms. Barnwell’s—and any class member’s—claims involve too many distinct questions of law and fact to find that any one representative is typical of the class. [REDACTED]

[REDACTED]

Plaintiffs make the conclusory (and confusing) assertion that, “because of the nature of Defendants’ alleged underlying conspiracy, [] the birth mother’s history of drug usage (other than the prescribed opioid required by the definition) is irrelevant.” Mem. at 7. But the core of Plaintiffs’ theory of liability is that “[Defendants’] conspiracy to create the diversionary market and oversupply opioids to targeted, at-risk Americans, who should not have access to *addictive* quantities or *not have access to opioids at all (such as pregnant women ...)*, [produced] two generations and hundreds of thousands of NAS children in the United States.” Mem. at 7.

30 [REDACTED]

31 [REDACTED]

Plaintiffs cannot simply invoke the word “conspiracy” as a mechanism to avoid the typicality requirement. Further, even assuming all Defendants engaged in a single conspiracy that affected each class member – an enormous assumption – that conspiracy would not affect each class member in a “typical” way. For example, Plaintiffs offer no support for their assertion that pregnant women should “not have access to opioids at all.” To the contrary, Plaintiffs’ expert concedes physicians may appropriately treat pregnant women with opioid medications. Defs.’ Ex. 5, Howard Dep. at 261:7–11. Indeed, such treatment is not uncommon, as demonstrated by the fact that two of the proposed class representatives continued taking opioids during pregnancy in consultation with their physicians. [REDACTED]

[REDACTED] What this means is that, assuming Defendants have a duty to prevent *a particular* class member from properly taking *prescribed* opioids during pregnancy – a questionable proposition – that class member’s claims would not be typical of claims of other class members who, for example, obtained or used opioids illicitly.³² Thus, if Ms. Barnwell proved her individual claim, she would not necessarily prove anybody else’s. *See Sprague*, 133 F.3d at 399. Accordingly, Ms. Barnwell cannot be a typical class member; and due to the nature of Plaintiffs’ claims, there can be no typical member of the proposed classes.³³

³² In addition to the highlighted differences in the class members’ claims, courts have concluded that, where a subset of the proposed class may be subject to defenses particular to that subset alone, this may also preclude a finding of typicality. *See J.H. Cohn & Co. v. Am. Appraisal Assocs.*, 628 F.2d 994, 999 (7th Cir.1980); *Gary Plastic Packaging Corp. v. Merrill Lynch, Pierce, Fenner & Smith, Inc.*, 903 F.2d 176, 180 (2d Cir.1990). Here, the Defendants certainly may have viable defenses against a subset of the class that used *illicit* opioids, which would not apply against a separate subset that did not.

³³ Another problem with typicality is that the conduct of each Defendant toward each class-member varies across the class. For example, Assertio is named as a Manufacturer Defendant in the *Artz* complaint. But discovery records show neither Ms. Barnwell nor any other proposed class representative from that case ever took a prescription opioid manufactured by Assertio, which did not enter the opioids market until well after the children of those representatives were born. *See Opp.* at 42. Plaintiffs also ignore the distinction between branded and generic products, even though this distinction implicates the identity of the manufacturer-defendants against which an individual Plaintiff might have a claim. *Id.* at 9. Again, that Plaintiffs assert a conspiracy claim does not paper over these problems with typicality.

In sum, the Guardians bear the burden of “affirmatively demonstrating” compliance with all aspects of Rule 23, but they have not borne their burden of meeting the typicality requirement. *Wal-Mart Stores*, 564 U.S. at 350.

VIII. Rule 23(b).

Because the proposed classes so clearly do not satisfy the requirements of Rule 23(a), the Court need not determine whether they can be certified under either Rule 23(b)(2) or 23(b)(3).

IX. Other Issues.

A. Rule 23(c)(4) Issue Class.

In their reply brief, Plaintiffs alternatively ask the Court to certify “under a combination of Rule 23(c)(4) and Rule 23(b)(3)” an issue class on any of the “many issues” that can be resolved on the basis of common evidence, such as the existence of a RICO conspiracy. Reply at 40. Defendants argue this request should be denied because arguments made for the first time in a reply brief are waived. Sur-reply at 2 (citing *Hunt v. Big Lots Stores, Inc.*, 244 F.R.D. 394, 397 (N.D. Ohio 2007)). Defendants’ argument is well-taken.

Plaintiffs provide no explanation for why their alternative request is made for the first time in their reply brief, over ten months after they filed their Motion. Accordingly, Defendants are correct that Plaintiffs waived this argument. Even if the request were timely, the Court would not use Rule 23(c)(4) to cure Plaintiffs’ motion and grant certification on any issues. As the Court already has stated, it has the power and discretion to redefine the class in a way that allows maintenance of the class action. *See Powers*, 501 F.3d at 619. But other courts have warned that “a court must not ‘manufacture’ adherence to the requirements of Rule 23 ‘through the nimble use of subdivision (c)(4).’” *In re Welding Fume*, 245 F.R.D. at 312. Moreover, to support issue certification, Plaintiffs must prove the particular issue meets the Rule 23(a) requirements, which

Plaintiffs did not even try to do. Partial certification pursuant to Rule 23(c)(4) is not appropriate in this case.

B. PEC Representation.

Having concluded Plaintiffs cannot possibly show typicality, and also that most of the proposed class representatives are not actually class members, no further analysis is necessary. Still, the Court adds the following observation. Plaintiffs argue class certification is a practical and ethical imperative to ensure finite funds are allocated fairly among MDL Plaintiffs, because the MDL Plaintiffs Executive Committee (“PEC”) is ignoring the interests of the NAS Guardian Plaintiffs. The Guardians claim the lawyers appointed to the PEC have “devoted themselves solely to the pursuit of the cities’ and counties’ interests and have ignored the conflicting interests of non-clients, including the Guardians and the NAS children.” Mem. at 55–56. The Guardians suggest they will only be heard in MDL settlement negotiations if the Court recognizes the class-wide merit of their claims. *Id.* at 56. They highlight that the city and county plaintiffs can neither sue on behalf of the guardians or children, nor release their claims.

It almost need not even be said that ensuring the Guardians will receive a share of possible settlement funds from Defendants, and providing the Guardians leverage in settlement negotiations, are not valid bases for certifying a litigation class. These considerations have no place in the analysis of, and certainly do not obviate, the requirements of Rule 23. Moreover, as the Plaintiff Guardians acknowledge, the PEC and the Plaintiff cities and counties cannot release the Guardians’ claims. While the Guardians may prefer class status, they do not need to operate as a class in order to maintain their claims. And as long as their claims remain, the Guardians can pursue them as MDL Case Management Orders allow, and the Guardians can engage in settlement negotiations through or alongside the PEC. The same is true for all MDL Plaintiffs.

X. Conclusion

The Court does not harbor any doubt that, across the nation, many mothers and their newborn children have been injured by the opioid epidemic. In some cases, the harms these children suffered may be serious and lifelong, forcing the guardians of these children to shoulder a tremendous and continuing burden. For all of the reasons stated above, however, the law does not permit these guardians to pursue claims against the Defendants and seek relief as a class under Rule 23. Accordingly, the Guardians' Motion for Class Certification, Doc. #: 3066, is **DENIED**.

IT IS SO ORDERED.

/s/ Dan Aaron Polster February 1, 2021
DAN AARON POLSTER
UNITED STATES DISTRICT JUDGE