UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF MICHIGAN

ADAM KANUSZEWSKI, et al,
Plaintiffs,

v.

MICHIGAN DEPARTMENT OF HEALTH AND HUMAN SERVICES, et al,
Defendants
_____/

Case No.: 18-cv-10472

Hon. Thomas L. Ludington,
District Court Judge

Hon. Patricia T. Morris,
Magistrate Judge

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PLAINTIFFS' RESPONSE TO
BIOBANK/YANCEY DEFENDANTS' MOTION TO DISMISS

NOW COME Plaintiffs, by counsel, and fully oppose the motion to dismiss filed by the Michigan Neonatal Biobank and Dr. Antonio Yancey in his official capacity[1] under Rule 12(b)(6). **ECF No. 33.** They assert that "[o]ne of the most valuable health tools developed over the past fifty years has been newborn screening, which allows doctors to detect the presence of rare disorders in newborns, allowing them to receive necessary treatment as early as possible." **ECF No. 33, PageID#594.** That may very well be true,[2] but the system they developed and operated in—for which the Michigan Neonatal Biobank and Dr. Antonio Yancey are in conspiratorial agreement—forgot to include a major legal and constitutional obligation—***consent***. No consent was obtained before or after the Biobank and Yancey became part of a system that illegally seizes, utilizes, and stores/sells newborn blood without consent. Dismissal should be denied.

Date: July 6, 2018

RESPECTFULLY SUBMITTED:

/s/ Philip L. Ellison

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[1] For purposes of this response and briefing, these parties are collectively referred to as the Biobank.

[2] Technically, the "doctors" are not "detecting" anything. The State laboratory technicians are performing medical services for patients.

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BRIEF REGARDING PLAINTIFFS' RESPONSE TO BIOBANK/YANCEY DEFENDANTS' MOTION TO DISMISS

QUESTIONS PRESENTED

I.
Do Plaintiffs have standing?

Answer: Yes

II.
Have Plaintiffs pled plausible Fourth and Fourteenth Amendment claims against the Biobank?

Answer: Yes

MOST RELEVANT AUTHORITY

Standing

Lujan v. Defenders of Wildlife, 504 U.S. 555 (1992)

Campbell v. Minneapolis Pub. Hous. Auth., 168 F.3d 1069 (8th Cir. 1999)

Flast v. Cohen, 392 U.S. 83 (1968)

G.C. v. Owensboro Pub. Schs., 711 F.3d 623 (6th Cir. 2013)

Fourth Amendment

U.S. Const. amend. IV

Birchfield v. North Dakota, 579 U.S. __; 136 S. Ct. 2160 (2016)

Missouri v McNeely, 569 U.S. __; 133 S.Ct. 1552 (2013)

Dubbs v. Head Start, Inc. 336 F.3d 1194 (10th Cir. 2003)

Fourteenth Amendment

U.S. Const. amend. XIV

Cruzan v. Director, Missouri Dep't of Health, 497 U.S. 261 (1990)

Dubbs v. Head Start, Inc. 336 F.3d 1194 (10th Cir. 2003)

OPPOSITION BRIEF

This lawsuit is about a non-consensual infant blood collection and seizure program that reads as if it is from George Orwell's book, *Nineteen Eighty-Four*. Since 1984 (ironically enough), the Michigan Department of Health and Human Services (MDHHS) and its officials, and later with the Michigan Neonatal Biobank and its officials, have been quietly seizing, collecting, indefinitely storing, and utilizing/selling excess blood samples of newborn Michiganders taken, without consent, within 24 to 48 hours after birth. MDHHS never sought or obtained any consent from parents *before* invasively piercing the skin of the newborn and taking its blood, and since approximately 2010 has only sought consent to use already-seized blood for vague "research" purposes which has been improperly exceeded. The Biobank, itself, has never sought or obtained permission to use any Infant blood.

In truth, the Biobank has been selling 'stolen' blood samples to medical researchers for a fee. To keep this blood supply pool (and earnings) up, MDHHS and the Biobank purposely seizes more blood than necessary extracted to conduct non-consensual medical tests by State laboratory technicians and then divvies up the remaining blood to *indefinitely* keep one sample in a MDHHS warehouse and transferring the remainder to the

Michigan Neonatal Biobank. The Biobank, in turn, sells the blood samples to researchers who conduct a variety of tests covering everything from public health studies to laboratory machinery calibration. This lawsuit now follows.

FACTS

To support this brief, Plaintiffs rely on and incorporate the detailed facts pled in their First Amended Complaint. **ECF No. 26.** Plaintiffs generally accept the Biobank's statement of facts recapping paragraphs 1 through 83 of the First Amended Complaint, **ECF No. 26**, with three qualifications.

First, Footnote 1 states that "Plaintiffs were, apparently, aware of the existence of the statute allowing health care professionals to draw blood for screening for chronic diseases." Plaintiffs were not. See **ECF No. 26, ¶¶48-49**.

Second, the Biobank argues there are several statutes that protect the blood spots, including the *Health Insurance Portability and Accountability Act* or the *Genetic Information Nondiscrimination Act of 2008*. The Biobank did not brief these laws, so to comment would be inappropriate. E.g. *Berkowski v. Comm'ner*, 652 F.Supp.2d 846, 861 (E.D. Mich. 2009)("issue is not properly before the Court due to [a party's] failure to brief it.").

Lastly, the Biobank forgot to mention the biggest concern of all—it is selling the newborns' blood spots for revenue. **ECF No. 26, ¶¶10, 80.**

Plaintiffs have obtained preliminary evidence that the Biobank "has begun a process mass selling samples to commercial research outfits around the country." ***Id.*, ¶81.** Plaintiffs allege that any consent believed to have been obtained from the Parents has been far exceeded when it comes to the public sale of the Infants' samples. ***Id.*, ¶¶97-99.**

ARGUMENT

The Biobank's brief has improperly intertwined, mixed, and overlooked key portions of the applicable law and has arrived at a deluded conclusion. This case is, in fact, far simpler than presented by the Biobank.

"Our notions of liberty are inextricably entwined with our idea of physical freedom and self-determination." *Cruzan v. Director, Missouri Dep't of Health*, 497 U.S. 261, 287 (1990)(O'CONNOR, J., concurring). Three United States Supreme Court cases are key to this case and are not at all addressed or even cited by the Biobank. The first is *Birchfield v. North Dakota*, which held that nonconsensual drawing of blood of a citizen—even when it is to protect the health, safety, and welfare of others (i.e. motorists), *is a search* and requires a warrant. 579 U.S. __; 136 S. Ct. 2160 (2016). The second is *Missouri v. McNeely* which confirmed that an invasion to extract blood from a citizen "implicates an individual's 'most personal and deep-rooted expectations of privacy.'" 569 U.S. __; 133 S.Ct. 1552, 1558 (2013). Failure

to obtain such a warrant when seizing blood and private information is a Fourth Amendment violation. The third case is *Cruzan v. Director, Missouri Dep't of Health*, which held that an individual has a constitutional right to refuse any medical testing or treatment, absent exceptional circumstances, as a protected liberty interest under due process. 497 U.S. 261, 278 (1990). After all, "the sanctity, and individual privacy, of the human body is obviously fundamental to liberty" and "every violation of a person's bodily integrity is an invasion of his or her liberty." *Id.* at 342 (O'CONNOR, J., concurring). As will be explained in this brief, the Biobank is missing the main point of this lawsuit—none of these blood extractions (and the uses thereafter) should have occurred unless and until consent was first obtained from Parents of the Infants to satisfy constitutional limitations on government action.

STANDARD OF REVIEW

The Biobank's motion is premised on Rule 12(b)(6), not Rule 56, at this pre-answer procedural posture. "A complaint need not set down in detail all the particularities of a plaintiff's claim." *Decorative Panels v. Intern. Ass'n of Machinists*, 996 F.Supp.2d 559, 568 (E.D. Mich. 2014)(LUDINGTON, J.). "Complaints initiate the litigation but need not cover everything necessary for the plaintiff to win; factual details and legal arguments come later." *Id.* (quoting *Doe v. Smith*, 429 F.3d 706, 708 (7th Cir. 2005)). In considering a

Rule 12(b)(6) motion, the Court construes the pleading in the non-movant's favor and accepts the allegations of facts therein as true (*even if doubtful in fact*). *Bell Atlantic Corp. v. Twombly*, 550 U.S. 544, 555 (2007); see also *In re Duramax Diesel Litigation*, 2018 U.S. Dist. LEXIS 26543, at *16 (E.D. Mich. 2018)(LUDINGTON, J.)(same). Only a "short and plain statement of the claim showing that the pleader is entitled to relief." Fed.R.Civ.P. 8(a)(2). The pleader need not provide "detailed factual allegations" to survive dismissal, but the pleading "must contain sufficient factual matter, accepted as true, to state a claim to relief that is plausible on its face." *Ashcroft v. Iqbal*, 556 U.S. 662, 678-679 (2009); *Twombly, supra*, at 555. "Plaintiff need only plead sufficient factual matter, which we must accept as true, to 'state a claim to relief that is plausible on its face' meaning that we can draw the reasonable inference that the defendant is liable for the misconduct alleged." *Currier v. First Resolution Inv. Corp.*, 762 F.3d 529, 533 (6th Cir. 2014).

I. STANDING

The Biobank, surprisingly, argues the Infants lack standing to challenge the legality of *their own* blood being taken without prior consent and when the blood is currently being used and/or indefinitely stored by the

Biobank as a third party alleged to be in a civil conspiracy with the State Defendants. This absurd argument fails.[3]

A. The Infants Have Standing About Their Own Blood

"[T]he standing inquiry requires careful judicial examination of a complaint's allegations to ascertain whether the particular plaintiff is entitled to an adjudication of the particular claims asserted." *Allen v. Wright*, 468 U.S. 737, 752 (1984).

> Whether a party has a sufficient stake in an otherwise justiciable controversy to obtain judicial resolution of that controversy is what has traditionally been referred to as the question of standing to sue. Where the party does not rely on any specific statute authorizing invocation of the judicial process, the question of standing depends upon whether the party has alleged such a personal stake in the outcome of the controversy, as to ensure that the dispute sought to be adjudicated will be presented in an adversary context and in a form historically viewed as capable of judicial resolution.

Sierra Club v. Morton, 405 U.S. 727, 731-732 (1972). "For Article III standing purposes, then, the plaintiff must allege personal injury fairly traceable to the defendant's allegedly unlawful conduct and likely to be redressed by the requested relief." *Allen, supra*, at 751. All three are met easily.

[3] Standing is appropriately challenged under Rule 12(b)(*1*), not Rule 12(b)(*6*) as done by the Biobank. However, the Biobank did not attach any exhibits to the motion. Thus, the Biobank's challenge will be treated as a *facial* attack to the Court's subject matter jurisdiction. See *Cartwright v. Garner*, 751 F.3d 752, 759 (6th Cir. 2014). On a motion raising a facial attack, "the court must take the material allegations of the petition as true and construed in the light most favorable to the nonmoving party," i.e. the same standard via Rule 12(b)(6). *United States v. Ritchie*, 15 F.3d 592, 598 (6th Cir. 1994).

B. Standing Does Not Go To The Merits

Standing gets confused with success on the merits, even by seasoned litigators. *In re Certification of Questions of Law*, No. 18-01 (FISCR 2018) (*available at* https://bit.ly/2MQ41nG), at *10-15. We all know the established standard for standing: a suffered "injury in fact" via a "concrete and particularized" invasion of a legally protected interest; a "causal connection between the injury and the conduct complained of;" and redressability. *Lujan v. Defenders of Wildlife*, 504 U.S. 555, 561 (1992). Yet, it is crucial not to conflate Article III's requirement of standing with a plaintiff's potential causes of action. "[T]he ultimate merits of the case have no bearing on the threshold question of standing." *Campbell v. Minneapolis Pub. Hous. Auth.*, 168 F.3d 1069, 1074 (8th Cir. 1999). Instead, "standing is generally an inquiry about the plaintiff: is this the right person to bring this claim?" *Davis v. Wells Fargo*, 824 F.3d 333, 348 (3d Cir. 2016). The fundamental aspect of standing is that it focuses on the party seeking to get his complaint before a federal court and not on the issues he wishes to have adjudicated. *Flast v. Cohen*, 392 U.S. 83, 99 (1968); see also *Gregory v. CitiMortgage, Inc.*, 890 F. Supp. 2d 791, 797-798 (E.D. Mich. 2012)("'[H]aving standing to bring a claim does not mean you have a valid claim on the merits.'").

C. Subject Matter Jurisdiction Is Established

As an initial matter, the Biobank does not challenge this Court's subject matter jurisdiction to decide claims on constitutional violations. How can it? See 42 U.S.C. § 1983; 28 U.S.C. §§ 1331, 1343. Instead, they challenge on standing grounds. Plaintiffs have alleged—and the Biobank does not dispute for purposes of this motion—that they are in possession of and indefinitely storing the Infants' blood taken as part of an ongoing constitutional conspiracy with the State Defendants. **ECF No. 33, Page ID# 325**.[4] They are also selling the Infants blood obtained without consent of the parents. **ECF No. 26, ¶¶41, 43.** The Infant Plaintiffs and their Parents want the 'stolen' blood (and the data extracted from the blood spots) back. They further want the state law allowing the Biobank to obtain and indefinitely keep these blood spots deemed unconstitutional. While there are three elements standing, the Biobank challenges on the injury-in-fact element only.

C. Injury in Fact

The Biobank argues that the blood draw was undertaken for a valid public health reason and is a routine medical procedure, and thus this Court lacks jurisdiction to decide the matter. **ECF No. 33, PageID# 601.** This

[4] "The Biobank and its Director, Dr. Antonio Yancey, indefinitely store the Infants' blood in a temperature and humidity-controlled facility in an area in or near Wayne State University known as Tech Town."

argument goes to the merits and cannot be a basis to challenge standing. See *Campbell, supra*. Instead, "[t]o establish injury in fact, a plaintiff must show that he or she suffered 'an invasion of a legally protected interest.'" *Spokeo, Inc. v. Robins*, 578 U.S. __; 136 S. Ct. 1540, 1548 (2016). Infants and their parents have alleged a legally protected interest in being free from unreasonable searches and seizures, as well as a liberty interest in making their own medical decisions, *Birchfield, supra*; *McNeely, supra*, and *Cruzan, supra*, and Defendants are invading the same. Violating constitutional rights fulfills injury-in-fact, *G.C. v. Owensboro Pub. Schs.*, 711 F.3d 623, 634 (6th Cir. 2013), including Fourth Amendment violations, e.g. *Slicker v. Jackson*, 215 F.3d 1225, 1231 (11th Cir. 2000); *Briggs v. Marshall*, 93 F.3d 355, 360 (7th Cir. 1996) (recognizing nominal damages are available for Fourth Amendment claims). An invasion to extract blood from a citizen "implicates an individual's 'most personal and deep-rooted expectations of privacy.'" *McNeely, supra*, at 1558. These legally-competent Parents, and not the State,[5] are empowered to make decisions regarding medical procedures on behalf of their Infant children. *Dubbs v. Head Start, Inc*. 336

[5] For this same reason, the State does not *ipso facto* assume *parens patriae* status over every child in Michigan. The Supreme Court has long (and expressly) rejected that a minor child is "the mere creature of the State." *Parham, supra, at 602.* And surely a private non-profit, like the Biobank, cannot be granted *parens patriae* status in the face of loving competent parents.

F.3d 1194, 1202-1204 (10th Cir. 2003) *cert. denied*, 540 U.S. 1179 (2004); see also *Pierce v. Society of Sisters,* 268 U.S. 510, 535 (1925). By interfering with that fundamental and natural rights of parentage vis-à-vis invasively piercing the skin of the newborn child and extracting a part of the baby's body, i.e. six blood spots, for medical testing and storage of highly personal medical information *without consent*, the Infants and their Parents have clearly suffered an injury in fact for standing purposes. Additionally, the government's unlawful seizure of something (i.e. blood and medical data extracted therefrom) is also an injury in fact when the Infants and their Parents also have a colorable interest in seized property that can be redressed by returning the same. See *U.S. v. $515,060 in US Currency*, 152 F.3d 491, 497-498 (6th Cir. 1998). The Infants and their Parents are asserting a constitutional injury in the violations of their rights to be free from such actions in the absence of expressly-provided consent (or warrant) under the Fourth and Fourteenth Amendments. The injury being caused by the Biobank is its being part of an unconstitutional scheme.[6] In other words,

[6] A person can be liable under § 1983 if acting in a civil conspiracy with a state actor. "If a private party has conspired with state officials to violate constitutional rights, then that party qualifies as a state actor and may be held liable pursuant to § 1983...." *Cooper v. Parrish*, 203 F.3d 937, 952 fn.2 (6th Cir. 2000). A civil conspiracy under § 1983 is "an agreement between two or more persons to injure another by unlawful action." *Bazzi v. City of Dearborn*, 658 F.3d 598, 602 (6th Cir. 2011). The Sixth Circuit has held that "plaintiffs ha[ve] successfully pled a § 1983 conspiracy by alleging that (1) a single plan existed, (2) the conspirators shared a conspiratorial objective to deprive the plaintiffs

legal injury-in-fact is fulfilled with alleged injury to the Infants' and Parents' rights, not the amount of physical pain a blood draw causes.

D. Particularized and Concrete Injury

Next, the Biobank claims the injury is not particularized and concrete enough. For an injury to be particularized, it "must affect the plaintiff in a personal and individual way." *Spokeo, supra*, at 1548. A concrete injury must "actually exist." *Id.* Both are easily fulfilled here. The Biobank is alleged to have the Infants' own blood and that it is not legally permitted to have (or continue to have) such or use such in the face of the lack of consent from obtaining via the blood draw in conspiracy with the State.[7] The Biobank also concedes to currently have the Infants' blood spots. Thus, the injury is particularized and concrete.

E. Actual or Imminent Harm

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of their constitutional rights, and (3) an overt act was committed." *Revis v. Meldrum*, 489 F.3d 273, 290 (6th Cir. 2007). "Express agreement among all the conspirators is not necessary to find the existence of a civil conspiracy..." *Bazzi, supra*, at 602. This makes sense because "rarely in a conspiracy case will there be direct evidence of an express agreement among all the conspirators to conspire." *Weberg v. Franks*, 229 F.3d 514, 528 (6th Cir. 2000). Thusly, a plaintiff may rely on circumstantial evidence to establish an agreement among the conspirators. *Id.*; see also *Hensley v. Gassman*, 693 F.3d 681, 695 (6th Cir. 2012)(same). Moreover, each conspirator need not have known all of the details of the illegal plan or all of the participants involved to still be part of an illegal conspiracy. *Bazzi, supra*, at 602.

[7] Despite claims of consent, there is no evidence in any record *the Biobank* ever asked for or obtained permission or consent. Perhaps, at best, the State *arguendo* might have been given consent. The Biobank never has been.

The Biobank lastly argues there is no actual or imminent harm because "the damages claimed – that the specimens *might* be used for research – are speculative and hypothetical." The Biobank, again, misunderstands the case and claimed injury. The case is not about testing per se. The wrong being challenged is the lack of obtained consent. The challenge here is that the State (and those in conspiracy with it) must get consent beforehand, and not after; the consent they do obtain must be full and meaningful. Acquiescence to a claim of lawful authority which does not exist is no consent at all. *Bumper v. North Carolina*, 391 U.S. 543, 549-550 (1968). Nor is consent lawfully obtained by stealth or subterfuge. *Gouled v. United States*, 255 U.S. 298, 305-306 (1921). But even more to the point (and missed by the Biobank), consent has never been given *to the Biobank*, ever, to conduct any of these acts (like storage, medical research, or sale of specimens).

Again, the harm in this case is not about pain of a needle prick; it is about interference with legal rights in requiring consent. But for Defendants' illegal acts, the Biobank should not have had any blood samples and data therefrom in the first place given the lack of consent. In other words, the harm

is that the Biobank has the blood samples in the first place in the ongoing absence of consent.[8] Harm is thusly actual and currently ongoing. *Id.*

In addition, the Parents also are asserting the additional harm of fear about the potential for misuse of that information and fear the possibility of discrimination against their Infants and perhaps even relatives through the use of such blood samples and research activity thereon, and that "Michigan statutory law provides no legal protections from invasion or use by courts, law enforcement, state actors, or private actors who gain access to the blood spot collections and DBS cards held by" the Biobank. **ECF No. 26, ¶78-82.** That fear is today well founded. See *Privacy Concerns After Public Genealogy Database Used To ID "Golden State Killer" Suspect*, CBS NEWS, April 27, 2018, *available at* https://cbsn.ws/2jghjx2 (biodata "was his team's biggest tool").

F. Conclusion

The legal conclusion is clear. Plaintiffs have standing.

II. FOURTH AMENDMENT

[8] Repeatedly, the Biobank Defendants suggest that all ills can be cured by the Parents asking the State—via post-seizure and testing—to destroy the Infants' blood samples the Biobank currently holds. However, this case is not about destroying the blood spots post-seizure. It about the *ab initio* illegality of the seizing, testing, and indefinite storage of blood samples before fully informed consent was secured. See **ECF No. 45, PageID# 716-717 fn.11**.

The Biobank next seeks dismissal claiming there is no possible Fourth Amendment violation. Under the Fourth Amendment, anytime the government (or its agent) seeks to conduct a search, it needs a warrant (or consent[9] which Plaintiffs allege was not sought or received) unless search is deemed reasonable by one of the narrow exemptions provided by Supreme Court precedence. *Katz v. United States*, 389 U.S. 347, 357 (1967). This is because the general rule dictates that "searches conducted outside the judicial process, without prior approval by judge or magistrate, *are per se* unreasonable under the Fourth Amendment—subject only to a few specifically established and well-delineated exceptions." *Coolidge v. New Hampshire*, 403 U.S. 443, 454-455 (1971). In other words, "a warrantless search is reasonable *only if* it falls within a *recognized* exception." *McNeely*, *supra*, at 1558. The burden of proving an exception to the warrant requirement rests with the Biobank—an alleged state actor. *U.S. v. Jeffers*, 342 U.S. 48, 51 (1951). Despite making a slew of complicated and circular legal arguments, the issue for purposes of this portion of the case is whether the nonconsensual drawing and the later nonconsensual indefinite storage and use/sale of newborns' blood—a clear search under *Birchfield*—has an

[9] This case presents a unique question as to what level of consent is required. In the medical context, *informed* consent is required. See *Cruzan, supra.* The Biobank does not directly raise this question so it will be saved for another time.

exception to the warrant (or consent) protections of the Fourth Amendment. If not, it is unconstitutional. *Birchfield* provided no governmental blood draw exception to the warrant requirement, thus "securing a warrant before a search is the rule of reasonableness." *Birchfield, supra*, at 2188. The Biobank has produced no such warrant against the Infants. Thusly, this Court needs to resolve whether there is, as a matter of law, any "specifically established and well-delineated" exception which renders the Biobank's retention of the fruits of an alleged illegal search and seizure as lawful. The Biobank has provided no such precedence. Have Plaintiffs, on the other hand, pled facts to plausibility warrant that the taking of blood and storing the same indefinitely is part of an illegal search and seizure scheme in violation of the Fourth Amendment? The standard at this stage, now at pre-discovery, is merely plausibility, *Twombly, supra*, at 570, and the answer is yes.

A. Statutory Compliance Is Irrelevant

As an initial matter, the Biobank asserts that "there is no allegation that the blood draw is undertaken in a manner that does not comply with MCL 333.5431", but "once the initial screening is done, *the law* permits the DBS cards to be to be used for medical research…." **ECF No. 33, PageID#605-606**. Because of statutory compliance, the Biobank thinks its actions pass constitutional muster. *That's the whole point of the lawsuit.* Plaintiffs allege

that the law *itself* (or at least aspects of MCL 333.5431) and the Biobank's use of the same is unconstitutional. Promised compliance with an unconstitutional statute is *still* a violation of the Constitution. See *United States v. Stevens*, 559 U.S. 460, 480 (2010). An unconstitutional statute, though having the form and name of law, is in reality no law "but is wholly void and ineffective for any purpose." *Dascola v. City of Ann Arbor*, 22 F. Supp. 3d 736, 742 (E.D. Mich. 2014). Plaintiffs are asserting newborns' blood should have never been taken *without consent in the first place* and thus the blood spots should have never reached the Biobank without consent (for retention or otherwise) because it was the result of an unconstitutional search and seizure without the express consent of the Infants and/or the Infants' Parents. The entire Newborn Screening Program is missing the key element of consent—as required under the Fourth (and Fourteenth, see *infra*) Amendment.

B. Opt Out Is Not A 'Cop Out'

The Biobank also charges that "the Parents in this matter have not elected to opt out of testing, and they have not requested the DBS cards be destroyed."[10] **ECF No. 33, PageID# 606.** The Biobank misses the point.

[10] Contrary to its assertion, Michigan's newborn screening law, MCL 333.5431, has not listed, provided, or afforded any destruction or blood spot repatriation process to destroy or return seized blood samples to parents. Moreover, Parents are never given the option to opt-out in the first instance because they are not given informed consent—i.e.

Again, the point of this lawsuit is that such blood draws and testing never should have been taken *in the first place* due to the absence of consent (or a judicial warrant). The question is not whether the blood draw was authorized by a state statute; it is whether a state statute and self-made scheme allowing these acts, in the first instance, by government officials and those in concert with the government is constitutional in the face of lack of consent. Plaintiffs plainly allege the same is not constitutional. A promise to do something—i.e. destroy blood on request—depends on these Defendants' "*noblesse oblige*" to adhere to a policy without the force of law—and such a dependence cannot correct an unconstitutional law into a lawful one on the promise to act in a certain way. *Stevens, supra*, at 480.

C. No Public Health Exception

The Fourth Amendment provides that "[t]he right of the people to be secure *in their persons*, houses, papers, and effects, against unreasonable searches and seizures, shall not be violated…" U.S. Const. amend. IV.

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knowledge of the blood draw and testing—before heel-prick tests are administered. MCL 333.5431(2)(statute purporting to waive Infants' right of informed consent); see also MCL 333.17520(1)(requiring informed consent for all genetic tests undertaken except for newborn screening tests). A policy statement is not law. See e.g. *US v. Flemmi*, 225 F.3d 78, 88 (1st Cir. 2000) (a government manual or policy book "merely provides guidance… and does not have the force of law."). Courts may "not uphold an unconstitutional statute merely because the Government promise[s in policy statements] to use it responsibly." *Stevens, supra*, at 480. Trying to 'correct' an unconstitutional statute by construing it for only permissible purposes does not fix the constitutional violations. Courts may not rely on "the mercy of *noblesse oblige*" of the government to self-correct unconstitutional laws by operation of bureaucratic fiat. *Id.*

Claiming the drawing of blood of newborns without the consent is lawful under the Fourth Amendment, the Biobank raised the expected 'public health' justification. However, the Biobank never actually cites any binding precedence which dictates that the extraction of blood[11] for alleged public health reasons is an exception to the warrant or consent requirements. No exceptions have been authorized as an exception to the warrant (or parental consent) requirement. *Dubbs, supra*, at 1201-1204.[12] The Biobank's implicit argument is simple: what is good for the masses must be constitutional. This is wrong and not supported as a matter of law.

[11] The Biobank cites the Michigan Supreme Court decision of *People v Perlos*, 436 Mich. 305 (1990) in support of the alleged notion of the non-search status of a blood draw by the Department for medical testing. As an initial matter, *Perlos* is now on shaky grounds following *Birchfield*, and given the pled allegations that law enforcement is accessing these samples for criminal investigatory and prosecution purposes. See **ECF No. 26-13.** However, in *Perlos*, each defendant had *already voluntarily provided* a blood sample to a private actor; the state had not seized or forced the seizure of the blood in the first stance. This case is different. Here, the Infants' blood draw was not voluntarily undertaken and consent never obtained, and the blood draw done at the express direction and knowledge of the state via is conscripted agents. *Perlos*, even as non-binding extraterritorial law to this Court, is unhelpful and easily distinguishable. The Biobank also cites *Schmerber*. It too is no longer good law for these circumstances and seemingly has been overruled or highly narrowed by *McNeely* and *Birchfield*.

[12] The Biobank cites *United States v. Attson*, 900 F.2d 1427, 1431 (9th Cir. 1990) recounting that "the issue of whether the fourth amendment applies to an instance of non-law enforcement governmental conduct requires us to decide whether that conduct was intended as a search or a seizure, be it in the context of a criminal investigation or an administrative inspection." This holding has been rejected. *Dubbs, supra*, at 1205 (the "contention that the Fourth Amendment does not apply in the 'noncriminal' and 'noninvestigatory' context is without foundation"). Nevertheless, *Attson* is distinguishable. In *Attson*, the medical procedure was consensual; the real issue was the legality of providing the results to police. Here (as was the same in *Dubbs*), Plaintiffs contend that the blood draw was performed without consent.

The primary argument fronted by the Biobank is from *Jacobson v. Massachusetts*, 197 U.S. 11 (1905), which held that in a public health emergency a local board of health could require vaccinations, over objections, when it was necessary for the public health or the public safety. Plaintiffs do not dispute the same. However, nearly 85 years later, the Supreme Court explained a "competent person[13] has a constitutionally protected liberty interest in refusing unwanted medical treatment." *Cruzan, supra*, at 278.[14] At first blush, there appears to a direct conflict and Plaintiffs would simplistically propose the *Cruzan* as impliedly overruled *Jacobson*. See Mariner, W. K., Annas, G. J., & Glantz, L. H., *Jacobson v Massachusetts: It's Not Your Great-Great-Grandfather's Public Health Law*, AM. J. OF PUB. HEALTH, Volume 95(4), *available at* http://doi.org/10.2105/AJPH.2004.055160. However, the Biobank fails to cite or discuss *Cruzan* (which is astonishing). But on more careful review, the question in *Jacobson* was about police power, while the question in *Cruzan* was liberty due process rights. Reading the cases together, a proper distinction emerges. Laws that are intended to prevent a person from harming *others*

[13] Both state and federal law recognize that parents speak for their minor children in matters of medical treatment. E.g. *Parham v. J.R.*, 442 U.S. 584 (1979); *Zoski v Gaines*, 271 Mich. 1 (1935); *Bakker v Welsh*, 144 Mich. 632 (1906)).

[14] "The [constitutional] principle that a competent person has a constitutionally protected liberty interest in refusing unwanted medical treatment may be inferred from our prior decisions." *Cruzan, supra*, at 278.

by disease contagion can be justified as an exercise of police power under *Jacobson*, but laws that are intended to affect only the health and well-being of *an individual* are subject to challenge as unjustified violations of liberty rights under *Cruzan*. This newborn blood case falls in the latter theory because "[n]one of the maladies, disorders, or diseases sought to be detected [by newborn screenings] are contagious or can spread by communitive human contact." **ECF No. 26, ¶57**. In other words, an Infant might have one of these diseases by operation of their heredity only and cannot involuntarily spread the same to third parties, like the flu. ***Id.*** As a case involving the right to decide (i.e. grant or withhold consent) about one's *own* body and health with no effect on the general health of the populace by contagion, the *Cruzan* framework applies. In other words, this case is not about the State forcing someone undertaking required medical procedures for the protection of the "general health, safety, and welfare" of *the populace*; instead, these blood tests are the extraction of parts and seizing the information deriving therefrom for medical testing and treatment of *a person*. Because *Jacobson* is not applicable in this case, it fails to be any possible exception to the Fourth Amendment warrant requirement especially given *Birchfield* and *McNeely*. To seize the blood of newborns and to then utilize that blood for purposes beyond newborn disease screening, the State (and

the Biobank) must either get consent or a warrant—as there is not a "specifically established and well-delineated exception" in this case otherwise. *Coolidge, supra,* at 454-455. The Fourth Amendment protects those extractions as a form of search-and-seizure from "their persons" without consent or warrant; this includes blood draws. See *Birchfield, supra*. Therefore, this case does not fit within the general police power analysis in *Jacobson*, but rather under the more specific Fourth Amendment jurisprudence to be free from unreasonable search and seizures of their persons—as dictated by the clear text and jurisprudence of the Fourth Amendment.

D. Fourth Amendment Curtails Police Power.

The most controlling US Supreme Court case on blood extraction from a citizen is *Birchfield v. North Dakota*, 579 U.S. __; 136 S. Ct. 2160 (2016). Again, suprisingly, the Biobank does not cite or discuss it. Looking to *Birchfield*, the Supreme Court was blunt: "blood tests are a different matter." *Id.* at 2178. A blood test places in the hands of government a bodily sample that can be preserved and from which it is possible to extract information beyond its original purpose. *Id.* The process itself is a compelled physical intrusion beneath skin after piercing and extracting a part of the subject's body. *Id.* For newborn testing (as an even more extreme use than for BAC

testing), the government takes the blood to its facilities where it withdraws, by scientific extraction, highly personal information about a person's core genetic makeup, i.e. the essence of their person, and their deeply personal medical information. It then keeps that expropriated information in government files and databases. The excess blood spots not used up in the Newborn Screening Program are then sent on to the Biobank (even though no Parent has approved this transfer to such a private third-party non-profit) where it is then indefinitely stored for uses *other than newborn screening*. Our highest court recognized that even if the government "is precluded from testing the blood for any purpose other than [its original purpose], the potential remains and may result in anxiety for the person tested." *Id.* Thus, according to the Supreme Court, a warrant is needed for the government to extract blood when consent is not first obtained.

As such and at this stage, if the extraction of blood samples is protected by the Fourth Amendment from searches without a warrant for individuals who are overtly drunk (contrary to the public's health, safety, and welfare), there can be little question about needing a warrant to extract the blood of newborn citizens who are not even suspected of committing any

wrong. [15] As such, this process must be covered by the protections of the Fourth Amendment. As *Birchfield* notes that the government has "paramount interest" in preserving the safety of the public as to blood draws and yet ***still*** the Supreme Court required government blood testing to be had only warrant or proper consent is first obtained. Moreover, the Biobank failed to note that the Supreme Court has also explained (as discussed later in this brief) that an individual has a right to refuse any medical testing or treatment, absent exceptional circumstances, via a liberty interest under due process. *Cruzan, supra,* at 278. After all, "the sanctity, and individual privacy, of the human body is obviously fundamental to liberty" and "every violation of a person's bodily integrity is an invasion of his or her liberty." *Id.* at 342 (O'Connor, J., concurring).

E. The Biobank is Part of the Conspiracy

The problem involving the Biobank is that while the entity, itself, does not draw the blood, it is part of a scheme whereby the blood spot extractions are seemingly done without consent to create a blood supply pool from which third parties can use the highly personal health data extracted from blood samples, and law enforcement can use the same to investigate and

[15] Unlike the State Defendants, the Biobank does not try to raise the special needs exception, which has been rejected. *Dubbs, supra*, at 1214.

prosecute crimes. After the screenings (i.e. testing) are done, the purpose of the blood's extraction immediately morphs from the protection of individual to proposed unspecified research and sale of samples. Plaintiffs have alleged that the Parents are never asked to give consent to 1.) transfer the blood samples from the Department to a private non-profit, the Biobank, who then sells the same, and 2.) indefinitely store the Infants' blood with the Department or at the Biobank. Under Michigan's claimed procedures, even if a parent opts not to allow medical research, the Biobank—as the downstream agent of the Government—still indefinitely stores the excess blood spots of newborns in its warehouse facility. **ECF No. 26-3**. Plaintiffs have pled that they did not provide this consent, but if they did they had an insufficient understanding of the form they were forced to sign under a claim of lawful authority. See **ECF No. 26, ¶48.** And even if consent was given, it has been far exceeded. ***Id*., ¶83.** Acquiescence to a claim of lawful authority which does not exist is no consent at all. *Bumper v. North Carolina*, 391 U.S. 543, 549-550 (1968). Nor is consent obtained by stealth or subterfuge. *Gouled v. United States*, 255 U.S. 298, 305-306 (1921). The government acting in this way without consent (even if done pursuant to an invalid statute) is unconstitutional. Plaintiffs' claims meet the *Twombly* plausibility pleading

standard. The Parents' choice must be via actual consent, and not a false consent by omission.[16] Violation of the same is actionable.

F. Conclusion

In summary, the Supreme Court has held that the drawing of blood *is a search*. *Birchfield, supra*, at 2173. And there is nothing provided, as a matter of law, that exempts the Fourth Amendment protections from this type of search-and-seizure. Consent or a warrant is constitutionally required before seizing a newborn's blood sample; the Biobank has obtained neither. Dismissal is unwarranted and should be denied.

III. FOURTEENTH AMENDMENT

The Biobank has conceded for purposes of the motion that Plaintiffs can demonstrate a liberty interest protected by the Fourteenth Amendment. However, it goes on to suggest that it is "a valid exercise of the public health authority, done with regularity, and minimal invasiveness." Again, the Biobank failed to discuss or factor in *Cruzan*'s constitutional principle that citizens have the right to refuse any medical testing or treatment as a protected liberty right. *Cruzan, supra*, at 278. There has been no allegation

[16] The Biobank also suggests that "a committee of ten (10) individuals" oversees this process, **ECF No. 26, PageID# 609**, and *that* somehow makes this blood extraction, retention, and sale scheme constitutionally adequate in place of consent. A government committee cannot take away the decision of consent from a competent parent and give it to a committee of ten, twenty, or a hundred. The decision of consent belongs to the Infants and their Parents, not the government or its self-appointed representatives.

or suggestion that these parents are incompetent or unable to act in the best interests of their newborns. The autonomy to refuse in the medical testing program operated by the Biobank with the State is a right of the Parents—even if claimed only to be minimal invasive.[17] Here, the Biobank's actions thus far have exceeded any possible consent given by the Parents. **ECF No. 26, ¶83.** As noted above, laws and regulations that are intended to prevent a person from harming the public can be justified as an exercise of police power under *Jacobson*, but laws that are intended to protect only the health and well-being of particular individuals are subject to challenge as unjustified violations of liberty rights under *Cruzan*. Plaintiffs here have pled—which must be deemed true for purposes of this motion—that the Biobank

- Improper[ly] used incomplete informed consent which inadequately, vaguely, unclearly, ambiguously and/or imprecisely failed to provide all pertinent information under the doctrine of informed parental consent in an intentional attempt to claim obtainment of consent needed to conduct medical test and/or medical procedure on the Infants.

- deprived the Infants their liberty interest in their guardians self-making informed personal and private medical procedure decisions without due process of law.

ECF No. 26, ¶¶97, 99. "When transferring the blood samples… to the [Biobank], who then sells the samples to third-party businesses, or third-

[17] The doctrine [of informed consent] applies equally to invasive, as well as noninvasive, procedures. *Allen v. Harrison*, 374 P.3d 812, 817 (Okla. 2016).

party bio-sample brokers… for use by for profit companies, any consent alleged to have been obtained has been far exceeded than any alleged consent received by these Defendants." ***Id.*****, ¶¶83, 98.** Thus, a valid Fourteenth Amendment liberty due process claim has been pled.

However, the existence of a liberty right is not the be-all, end-all of this claim. As the Supreme Court has explained, "determining that a person has a 'liberty interest' under the Due Process Clause does not end the inquiry" but "balancing [the person's] liberty interests against the relevant state interests" is needed to resolve "whether respondent's constitutional rights have been violated." *Cruzan, supra*, at 279. Because the interests involved here are fundamental, the review is via strict scrutiny. See **ECF No. 45, PageID# 725-726.** The Biobank's argument is hard to follow as to suggested valid governmental interests. It argues the "newborn screening is explicitly exempt from informed consent laws" and thus "is a valid use of the state police power to protect public health – a power the fourteenth amendment does not restrict." **ECF No. 33, PageID# 616**. This makes no sense and is, in fact, the precise constitutional problem with the newborn screening program raised by this case. Plaintiffs have alleged that under the liberty due process rights, the government and its conspiratorial actors cannot exempt themselves from the constitutional requirement of informed consent absent

compelling governmental interests. The only way the State may do so is if its interest in waiving such—on balance—overcomes the heady presumptive right to refuse medical testing and procedures (i.e. refuse consent). For example, in *Cruzan,* the Supreme Court held a state may establish a procedural safeguard delaying the withholding of medical treatment to assure that the actions of a surrogate conform as closely as possible to the expressed wishes of a formerly-competent patient. Conversely, however, a mentally ill prisoner possessed significant liberty interest in avoiding unwanted administration of antipsychotic drugs. *Washington v. Harper*, 494 U.S. 210, 221-222, 229 (1990). In *Rochin v. California*, 342 U.S. 165, 166-168 (1952), the Supreme Court also held that the need to find evidence of a crime did not outweigh the suspect's right to bodily autonomy. The Biobank has failed to point to a specific or collective overriding governmental interest, especially when the general public health by the spread of contiguous diseases is not implicated under *Jacobson*. See **ECF No. 26, ¶57**. Fortunately, the exact balance cannot and need not be resolved on a Rule 12(b)(6) motion. "[A]t this stage, [Plaintiffs are] not required to prove that [their] constitutional rights have in fact been violated" under a liberty due process claim. *Teasel v. Laskowski*, 2017 U.S. Dist. LEXIS 206174, at *15 (E.D. Mich. 2017)(LUDINGTON, J.) They are "simply required to allege, via

well-pleaded factual allegations, that a legally protected interest… has been invaded." *Id.* Plaintiffs have done that here. **ECF No. 26, ¶¶97-99**. Because of the lack of case law directly on-point, the Biobank cannot show, as a matter of law, that it is impossible for Plaintiffs not to prevail on this claim and thus the motion to dismiss at this pre-answer stage must be denied. *Dubay v. Wells*, 506 F.3d 422, 427 (6th Cir. 2007)(a motion to dismiss "should not be granted unless it appears beyond doubt that the plaintiff can prove no set of facts which would entitle him to relief."). It does not meet the burden of having an overcoming state interest on balance when the Biobank suggests the Michigan Legislature may choose to simply do away with the consent requirement by *ipse dixit*.[18] Plaintiff can plausibly show, at this stage, that the State's lack of relevant interests in nonconsensual blood tests (i.e. precluding informed consent) does not outweigh a person's constitutional fundamental right to personal autonomy as a liberty right under *Cruzan*. See also *Dubbs, supra*, at 1204-1204. Outright dismissal is inappropriate and should be denied.

[18] Additionally, the Biobank asserts that the newborns' blood "is not taken for use in criminal proceedings." **ECF No. 33, PageID# 618**. That is simply not completely true. E.g. **ECF No. 26-13** (list of a few criminal subpoenas using newborn blood in criminal cases).

CONCLUSION

The idea—early testing for newborns—is a noble public policy idea but the method by which Michigan has opted to implement the program—and then morph the objectives into more—violates the United States Constitution. **ECF No. 26, ¶2**. The State and its officials and the Biobank and its officials need to obtain proper consent. **ECF No. 26, ¶15.** This case is all about the lack of needed consent. Consent has not been obtained regarding the extraction of the blood of Michigan's most precious citizens or otherwise asked for permission from their unwitting parents during the frenzy of child birth. In other words, a group of state actors has stolen the right of consent, and this Court is being asked to restore that legal right to the parents thenceforth. **ECF No. 26, ¶¶15, 118.**

RELIEF REQUESTED

WHEREFORE, the Biobank Defendants' motion to dismiss pursuant to Rule 12(b)(6) for the reasons raised should be denied.

Date: July 6, 2018

RESPECTFULLY SUBMITTED:

/s/ Philip L. Ellison
OUTSIDE LEGAL COUNSEL PLC
PHILIP L. ELLISON (P74117)
Counsel for Plaintiffs

CERTIFICATE OF SERVICE

I, the undersigned attorney of record, hereby certify that on the date stated below, I electronically filed the foregoing with the Clerk of the Court using the ECF system which will send notification of such filing to all counsel or parties of record.

Date: July 6, 2018

RESPECTFULLY SUBMITTED:

/s/ Philip L. Ellison

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