
No. 18-1896

IN THE UNITED STATES COURT OF APPEALS
FOR THE SIXTH CIRCUIT

ADAM KANUSZEWSKI and ASHLEY KANUSZEWSKI, as parent-guardians and next friend to their minor children D.W.L., R.F.K., and C.K.K.; SHANNON LAPORTE as parent-guardian and next friend to her minor children, M.T.L. and E.M.O. and LYNNETTE WIEGAND as parent-guardian and next friend to her minor children, L.R.W., C.J.W., H.J.W. and M.L.W.

Plaintiffs – Appellants,

v.

MICHIGAN DEPARTMENT OF HEALTH AND HUMAN SERVICES; NICK LYONS, sued in his official and individual capacities; SANDIP SHAH, sued in his official and individual capacities; SARAH LYON-CALLO, sued in her official and individual capacities; MARY KLEYN, sued in her official and individual capacities; MICHIGAN NEONATAL BIOBANK, INCORPORATED, aka Michigan Neonatal Biorepository; ANTONIO YANCEY, sued in his official and individual capacities,

Defendants - Appellees

and

HARRY HAWKINS

Defendant

On Appeal from the United States District Court
for the Eastern District of Michigan – Northern Division
Honorable Thomas L. Ludington, District Judge

REPLY IN RESPONSE TO
BIOBANK DEFENDANTS' APPELLEE BRIEF

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INTRODUCTION

Sonia M. Suter, a law and bio-ethics professor at The George Washington University School of Law[1], defined the heart of this case—

> If you ask parents whether their child should undergo genetic testing or participate in research, most would probably say, consistent with legal norms in most areas of medicine, "only with my consent!" Yet the majority of parents do not realize that in every state, a small blood sample is collected from newborns to test for inborn errors of metabolism (many of which are inherited). Nor do they realize that, in many states, the dried blood spots (DBS) are retained for long periods or indefinitely, with few, if any, limits on third-party access to and uses of these samples. Indeed, evidence suggests that a great deal of research is being conducted on these stored blood spots by the state and other entities. All of this, from collection to retention of samples, often comes without parents' affirmative, let alone informed, consent.
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> I argue… developments in NBS should give pause to the presumption that parental consent is not necessary with respect to NBS. We already obtain much more information from NBS than we did in the past and we are on the cusp of being able to obtain substantially more information in the near future. Moreover, the nature of the information we will be able to glean will be of varied value, certainty, and complexity, raising issues not only about what diseases we should screen for, but whether parents should be

[1] https://www.law.gwu.edu/sonia-m-suter

> required to consent to some or all parts of the NBS process. In addition, the fact that newborn samples are increasingly used for research, and that anonymization of biospecimens is increasingly difficult, supports the need to rethink the role of consent in NBS, at least with respect to storage and research uses of DBS. As I will argue, the case for consent with respect to research also supports, in part, the notion of consent for NBS itself.

Sonia M. Suter, *Did You Give the Government Your Baby's DNA? Rethinking Consent in Newborn Screening*, 15 MINN. J.L. SCI. & TECH. 729, 730-731, 733-734 (2014), *available at* https://scholarship.law.umn.edu/mjlst/vol15/iss2/3. She "concludes by suggesting that requiring affirmative consent for NBS and for research on DBS best balances the values of protecting the newborn's well-being and promoting research, while also protecting autonomy and privacy as much as possible." *Id.,* at 734. Appellant-Plaintiffs wholeheartedly agree.

REPLY

The appellee brief of Michigan Neonatal Biobank, Inc and Dr. Antonio Yancey (in his official capacity) (hereafter collectively "the Biobank") is analytically muddled. It has intertwined, mixed, and

overlapped separate applicable doctrines, law, and jurisprudence. This reply brief is seeking to untangle and respond to the arguments. However, at its core (according to the "Statement of Issues") is whether there is standing and whether there is a plausible Fourth Amendment violation pled at this pre-answer stage of the case. **Appellee Br., Dk. #32, PageID #9.** The Biobank did not list its opposition to the Fourteenth Amendment matter in the Statement of Issues as required by FRAP 28(b)(2). ***Id.*** However, the Biobank did brief the issue and so it will be responded to herein.

Initially, the Biobank has briefed heavily to try to protect the initial ability of the State Defendants to seize newborn infants' blood for nonconsensual testing as to 50+ non-contagious genetic maladies so that those blood samples will continue to flow to the Biobank. However, the Biobank is admittedly not performing the initially blood extraction. Instead, their role is further downstream when the excess unused blood samples are shipped to the Biobank for indefinite storage and to

profitably sell the samples to business and researchers for medical tests. Their role is markedly different than that of the State Defendants, but are still part of the overt conspiratorial scheme to violate the Infants and Parents' respective Fourth and Fourteenth Amendment rights. After all, the Biobank concedes it "stores the [Dried Blood Spot cards] for MDHHS." **Appellee Br., Dk. #32, PageID #15.** It also sells them for revenue. **First Am. Compl., RE 26, PageID #321, ¶80.**

BACKGROUND

Without any parental consent, the State causes the nonconsensual extraction and appropriation of blood containing deeply-private medical, genetic and biological information. The State then extracts that information by highly scientific processes. Once it is done, the next party to this program takes over—the Michigan Neonatal Biobank, Inc (the "Biobank"). The Biobank indefinitely stores the remaining samples, **Appellee Br., Dk. #32, PageID #15,** and then, when a buyer is found, sells punches of newborns' samples to businesses and researchers to

conduct further medical tests upon the newborns' blood samples. **Punches Sizes and Prices, RE 26-15, PageID #377-379.** The State and Biobank conduct a variety of tests covering everything from public health studies to laboratory machinery calibration. This non-governmental entity has never sought or obtained permission to use, store, or sell any Infant blood as part of the NSP. Plaintiffs have sued the Biobank claiming that their storage and testing practices, as part of the NSP and in conspiratorial agreement with the State officials, was done in violation of the constitutional limits existing under the Fourth and Fourteenth Amendments. **First Am. Compl., RE 26, Counts II, IV, and V.**

ARGUMENT

I. The Biobank incorrectly frames the actual issues.

A. Plaintiffs are suffering current and imminent future harm.

As an initial matter, the Biobank is focused on the wrong harm having been inflicted upon the Infants and Parents. The wrong that has

occurred is the *nonconsensual* seizure, use, storage, and highly-likely sale of Infants' blood at the time of their birth through today. Those actions themselves make up the injury caused to Infants and their Parents. The Biobank instead focuses its arguments only on "the fear"—although legitimate itself—these Parents have for the imminent future and unauthorized uses being actively undertaken by the Biobank's sale of infant blood samples. See *In re Zappos.com, Inc.*, 888 F.3d 1020, 1024 (9th Cir. 2018) (a plaintiff has standing when threatened with future injury if "there is a *substantial risk* that the harm will occur"). The harm being sued about is in two parts. First, the Biobank is *currently* unlawfully possessing (storing), testing, and selling these blood samples via a nonconsensual process in concert with the State. Second, the lawsuit seeks to prevent the additional harm of the Biobank selling the Infants' personal and deeply-private medical, genetic and biological information to the highest public bidder. The sale is primed, **Punches Sizes and Prices, RE 26-15, PageID #377-379,** imminent, **Dr.**

Yancey's Bulk Bloodspot Sale Email, RE 26-19, PageID #428, and there are no "legal protections on who may access, use, or utilize the private medical and genetic information of the Infants which is obtainable through blood and blood-based testing, **First Am. Compl., RE 26, PageID #317, ¶64**. This lawsuit is seeking to remedy the past and current violations and halt the imminent harms of unauthorized use because consent was never first obtained. The overall wrong, however, is the lack of obtained consent.

B. The proposed destruction option does not remedy the constitutional actions of the Biobank.

As a second initial matter, the Biobank also asserts that a blood sample destruction option is available that will, if requested, cause the destruction of the Infants' DBS cards currently held by the Biobank and all is resolved. That alleged right-of-destruction appears nowhere in the newborn screening law. MCL 333.5431. A policy statement is not law. E.g. *U.S. 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." *U.S. v. Stevens*, 559 U.S. 460, 480 (2010). 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*" to self-correct unconstitutional laws by operation of bureaucratic promises and fiat. *Id.* Thusly, such a made-up post-violation 'option' does not resolve the constitutional violations *already* undertaken by the Biobank thus far in this case.[2] This lawsuit is

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[2] The veiled argument seems to be backhandedly invoking an exhaustion-of-state-remedies argument. It has been long established state-level remedy exhaustion is *not* required prior to bringing a § 1983 claim. *Felder v. Casey*, 487 U.S. 131, 147 (1988); *Patsy v. Bd. of Regents for Florida*, 457 U.S. 496, 500-501, 516 (1982). "The federal remedy is supplementary to the state remedy and the latter need not be first sought and refused before the federal one is invoked." *Monroe v. Pape*, 365 U.S. 167, 183 (1971). Exhaustion is only required when Congress requires it;

challenging the process how the Biobank even *first* came into unauthorized possession or control of the Infants' blood and medical data. No Parent or Infant has *ever* authorized the Biobank to become the possessor, owner, or salesperson of the Infants' blood spots as part of the search and seizure process, or by the medical treatment/testing process. Moreover, the Biobank is undertaking, facilitating, and authorizing medical testing to be done on the Infants' blood (and the embedded personal and deeply-private medical, genetic and biological information therein) without prior parental consent. This is unlawful.

C. Compliance with MCL 333.5431 does not resolve the constitutionality of the statute.

The Biobank also oddly asserts that there is no allegation that the blood spots were extracted from the Infants' body "inconsistent with MCL 333.5431" and because of such *statutory* compliance, the Biobank claims

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it has not done so for the § 1983 claims raised in this case. *McCarthy v. Madigan*, 503 U.S. 140, 144 (1991).

its actions pass *constitutional* muster. **Appellee Br., Dk. #32, PageID #35.** That misses the mark. Plaintiffs allege that the law itself and the Biobank's use of or benefit from the same is unconstitutional. Promised or actual compliance with an unconstitutional statute is *still* a violation of the Constitution. *Stevens*, supra, at 480. 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 the newborns' blood, together with its personal and deeply-private medical, genetic and biological information therein, should have never been in the custody, control, or for the beneficial use of the Biobank in the first place without proper prior-obtained consent; the blood spots should have never reached the Biobank in such an unauthorized manner via its conspiratorial agreement 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 Michigan Newborn Screening Program is missing the key element of consent—as required under the Fourth and Fourteenth Amendments.

D. State legislatures cannot override constitutional protections.

On a final initial note, the Biobank argues that Michigan has and can waive informed consent. **Appellee Br., Dk. #32, PageID #48-50.** However, informed consent as to this case is a constitutional underpinning from *Cruzan*.[3] The Michigan "Legislature is bound by the federal and state constitutions" and a state "statute cannot offend or amend the constitution" "regardless of the common-law theory being modified by statute. *City of Kentwood v. Sommerdyke Estate*, 458 Mich. 642, 682 (1998).

[3] *Cruzan v. Dir., Missouri Dep't. of Health*, 497 U.S. 261 (1990)

II. The Biobank needs to understand the nature of the claims being made.

It is important first to look at the nature of the claims being asserted against the Biobank. There are three counts being asserted the Biobank in the First Amended Complaint, Counts II, IV, and V. The problems with the newborn screening programs is well-outlined and discussed in a law review article written by Sonia M. Suter, a professor of law at The George Washington University School of Law. Her 2014 article in the Minnesota Journal of Law, Science & Technology is a must read for this case. Sonia M. Suter, *Did You Give the Government Your Baby's DNA? Rethinking Consent in Newborn Screening*, 15 MINN. J.L. SCI. & TECH. 729 (2014), *available at* https://scholarship.law.umn.edu/mjlst/vol15/iss2/3. This Court should and is asked to afford her presented

arguments and analysis, for purposes of this case, with great weight in resolving whether this lawsuit should, at least, go forward.[4]

A. Count II – Substantive Due Process

Count II alleges that the Biobank, as a state actor, improperly used non-existing or incomplete informed consent to conduct medical tests and/or medical procedures on the Infants' blood in violation of due process. **First Am. Compl., RE 26, PageID #323, ¶92.** "A competent person has a constitutionally protected liberty interest in refusing unwanted medical treatment. *Cruzan, supra*, at 278. Competent parents speak for their children in matters of medical decisions. *Parham v. J.R.*, 442 U.S. 584, 603 (1979); see also *Pierce v. Society of Sisters*, 268 U.S.

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[4] Appellants take exception to one assertion by Professor Suter in her article. She asserts that "Michigan… created a specific repository for future search that would require affirmative, informed consent from the parents." Suter, *supra*, at 759; see also *id*., at 779. That is not actually happening in Michigan; informed consent was waived or not provided; it is not legally mandated or actually obtained. MCL 333.5431(2); MCL 333.17520(1); e.g. **First Am. Compl., RE 26, PageID #304, ¶15.**

510, 535 (1925) and *In re Rosebush*, 195 Mich. App. 675, 682 (1992). "The liberty interest in refusing medical treatment flows from decisions involving the State's invasions into the body." *Cruzan, supra*, at 287 (O'CONNORS, J., concurring). "Because our notions of liberty are inextricably entwined with our idea of physical freedom and self-determination, the Court has often deemed state incursions into the body repugnant to the interests protected by the Due Process Clause." *Id.* The "notion of bodily integrity has been embodied in the requirement that informed consent is generally required for medical treatment." *Id.,* at 270. Consent obtained by stealth or subterfuge is no consent at all. *Gouled v. United States*, 255 U.S. 298, 305-306 (1921). Neither is acquiescence to a claim of lawful authority which does not exist.[5] *Bumper v. North Carolina*, 391 U.S. 543, 549-550 (1968). Plaintiffs alleged that

[5] An unconstitutional law, though having the form and name of law, is in reality no law at all. *Dascola, supra*, at 742.

the Biobank's actions of storage and use of blood samples for medical testing violates the substantive due process rights of the Infants and their parents. These actions deprived both the Infants and their Parents from exercising their constitutionally protected rights of medical decision-making under *Cruzan* and as an impingement on the rights of Parents as to the care, custody, and control of their child under *Troxel v. Granville*, 530 U.S. 57, 65-66 (2000).

B. Count IV and V – Search and Seizures

Counts IV and V are premised on the Fourth Amendment including liability via a civil conspiracy theory. "The Amendment guarantees the privacy, dignity, and security of persons against certain arbitrary and invasive acts by officers of the Government *or those acting at their direction.*" *Skinner v. Railway Labor Executives' Ass'n.*, 486 U.S. 602, 613-614 (1989) (emphasis added). While the Biobank is not the one initially obtaining the blood by piercing the skin of the Infant and extracting their blood, the U.S. Supreme Court has explained that those

using blood samples and its embedded information—post-extraction—at the direction of the government are still conducting a Fourth Amendment search. *Skinner, supra*, at 616 (explaining how extraction, use, and testing are separate and distinct searches or seizures). Additionally, in *Chandler*, the Supreme Court held that the testing of bodily fluids, wholly separate from the material extraction from a person's body, still constitutes a search subject to the demands of the Fourth Amendment. *Chandler v. Miller*, 520 U.S. 305, 313 (1997).[6] Using the extracted blood for testing *is* a Fourth Amendment search. *McNeely v. Missouri*, 569 U.S. 141, 148 (2013).

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[6] The Biobank has not asserted that the "individualized suspicion of wrongdoing" theory applies in this case because it simply cannot logically do so. The blood testing being done on newborns is not premised on any particular individualized suspicious of criminal activity or the suspicion of having contracted a non-contagious disease by specific infants. They try other tests which are addressed further in this brief.

III. The Infants and Parents all have standing against the Biobank.

The Biobank Defendants, like State Defendants, claim Plaintiffs lack of standing to challenge the wrongful impingements on their constitutional rights. The argument is incorrect and was passed over by the District Court. **Opinion, RE 50, PageID #828**. To have standing to sue, a plaintiff must show injury-in-fact, causation, and redressability. *Steel Co. v. Citizens for a Better Env't*, 523 U.S. 83, 103 (1998). All three are easily present here. However, the majority of the Biobank's arguments are based on the merits, while falsely claiming to be within a standing analysis. This is improper.

A. Standing has nothing to do with the merits.

As explained in the State Defendants' reply brief, "the 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). Courts "assume that on the merits the plaintiffs would be successful in their claims." *Parker v. Dist. of Columbia*, 478 F.3d 370, 377

(DC Cir. 2007) (citing *Warth v. Seldin*, 422 U.S. 490, 502 (1975). Fuller briefing was done in the reply in response to the State Defendants' brief. That briefing is adopted by reference. See FRAP 28(i).

B. Standing exists for these Plaintiffs.

i. Injury-in-fact.

Injury-in-fact requires "a showing of 'an invasion of a legally protected interest.'" *Spokeo, Inc. v. Robins*, 578 U.S. __; 136 S. Ct. 1540, 1548 (2016). The injury must be concrete and non-abstract. *Id.*

Plaintiffs have a constitutional right to be free from nonconsensual searches and seizures of their blood currently being held and stored by the Biobank. Continued testing post-extraction is also a search (or perhaps a continuing search or seizure). *Skinner, supra*, at 616; *Chandler, supra*, at 313. The Biobank has the blood via an unauthorized, nonconsensual manner. **Appellee Br., Dk. #32, PageID #15.** This is a concrete injury to warrant injury-in-fact. See *Beleno v. Lakey*, 306 F. Supp. 3d 930, 943 (W.D. Texas 2009) (plausible injury when parents and

infants claim a right to be free from unlawful search and seizure and continue to do so from the storage of their blood). Moreover, Plaintiffs also have a concrete injury in the form of an invasion of their interest to be free from nonconsensual medical testing and treatment on their blood samples being held by the Biobank. *Cruzan, supra*, at 278 (recognizing a constitutionally protected liberty interest in refusing unwanted medical treatment); see *Beleno, supra*, at 942 ("plaintiffs allege the storage of the infants' blood samples… has occurred and continues to occur, and there is reasonable fear of the potential for misuse because of the continued storage"). This injury is concrete and nonspeculative because that Biobank admits it is *currently* happening. **Appellee Br., Dk. #32, PageID #15**. Because the Biobank's part of the NSP scheme infringes on Plaintiffs' legally protected constitutional interests and the Biobank is actually storing and selling blood spot punches for medical testing (and we must assume that on the merits the plaintiffs would be successful in their claims, *Parker, supra,* at 377), injury-in-fact is met.

The Biobank suggests that because it has not yet *sold* the Infants' blood samples, the fear of further future misuse of the Infants' blood and medical data is speculative. That argument fails because the harm being challenged here—first and foremost—is the *current* illegal indefinite storage and undertaking of medical testing (by sale) by the Biobank without consent. That is harm that has already happened. There is nothing speculative about that. But even if we also look to future harm upon sale, the harm is not speculative. Sharing of blood spots containing deeply private medical and genetic information is being used for law enforcement purposes in Michigan via the Biobank, **First Am. Compl., RE 26, PageID #318, ¶70**, and has recently in the wrongful arrests of persons who were not guilty of any crime., ***id.*, PageID #321, ¶79**. The Biobank "has begun a process mass selling samples to commercial research outfits around the country." ***Id.*, ¶81.** And problematically there is no legal protections from invasion or use by courts, law enforcement, state actors, for-profit business, and/or private actors who gaining access

to the blood spot collections and DBS cards. ***Id.*, ¶82.** Thusly, once that information is distributed upon sale by the Biobank, there is no getting it back. So, in addition to the past and current harms, there is clear "substantial risk" of injury in the immediate future due to the nonconsensual sale of blood samples and medical information to third parties for unauthorized use.

A substantial risk of injury for unauthorized use is sufficient for standing purposes. In *Zappos*, hackers breached the computerized customer records of an online shoe retailer. The retailer challenged the standing of customer-plaintiffs who had their information stolen but their personal data had not been used to conduct subsequent financial transactions by the hackers. Following the retailer's dismissal argument, the district court dismissed for lack of standing. The Ninth Circuit reversed concluding that the data breach put the customers at risk of identity theft and their injury-in-fact existed due to there being a "substantial risk" of injury as a result of unauthorized access. The *Zappos*

plaintiffs had an injury-in-fact when alleging a credible threat of real and immediate harm stemming from the theft of a laptop containing their unencrypted personal data. *Zappos, supra*, at 1029. Citing *Susan B. Anthony List v. Driehaus*, 573 U.S. __, 134 S.Ct. 2334 (2014), a substantial risk of injury is enough. In *Susan B. Anthony List,* the Supreme Court explained that "[a]n allegation of future injury may suffice if the threatened injury is 'certainly impending,' or there is a 'substantial risk that the harm will occur.'" *Id.* at 2341. This is because where likely action is concerned, we do not require a plaintiff to expose himself before bringing suit to challenge the basis for the threat. *MedImmune, Inc. v. Genentech, Inc.*, 549 U.S. 118, 128-129 (2007).

To claim a lack of any injury-in-fact, the Biobank cites *Higgins v. Texas Dep't. of Health Servs.*, 801 F. Supp. 2d 541 (W.D. Texas 2011) and *Doe v. Adams*, 53 N.E.3d 483 (Ind. 2016)—two cases not binding on this Court. Both are also distinguishable.

In *Higgins*, plaintiffs claim violations of their rights based on the distribution of the newborn screening blood samples to private research companies, government agencies, and other third parties without knowledge or consent. Following *Beleno*, Texas passed a highly revised NSP law requiring express informed consent of parents. *Higgins, supra*, at 545. Texas also required a new parental disclosure statement that the State may retain genetic material used to conduct the newborn screening tests and provided actual notice of how the material is managed and used. *Id.* The law further prohibit retention the genetic material for any purpose other than the conduct of newborn screening tests. *Id.* In other words, it mostly (but not completely, see Suter, *supra*) fixed the problems currently existing in Michigan's NSP. The *Higgins* plaintiffs did not sue under a *Cruzan*-style theory but rather only a Fourth Amendment storage theory. The Court concluded because there was no evidence that the parties' newborn samples were actually used or distributed for

research in light of the post-*Beleno* NSP amendments, the District Court dismissed the case on mootness grounds.

In this case, we have proof and concessions of actual research uses of the Biobank-held blood spots of infants; Plaintiffs have pled it. Moreover, the Biobank has conceded that "dried blood spot samples have been used to detect a number of other conditions and substances." **Biobank Brochure, RE 26-16, PageID #381.** This distinguishes this case's facts from *Higgins*. The Biobank is actively selling the samples, at set sizes and prices, for current and active uses. **Punches Sizes and Prices, RE 26-15, PageID #377-379.** In short, the Michigan NSP's status is similar to *Beleno*, not *Higgins,* the latter of which is not helpful or relevant given these differences between Michigan's and Texas' NSPs.

As for *Doe*, it was simply wrongly decided and is also distinguishable. *Higgins*, for example, explained plaintiffs "may have suffered a past injury in fact if their children's blood samples were retained after the newborn screening was completed." *Higgins, supra*, at

552. Indiana failed to recognized that the unauthorized keeping of a person's illegally extracted blood is an injury-in-fact—it is an unconstitutional search and involves the impingement of the "most personal and deep-rooted expectations of privacy." *McNeely, supra*, at 148. The Indiana Supreme Court justices committed the same error as done by the most astute litigators—it wrongfully combined the standing inquiry with the merits inquiry. As noted above, standing analysis requires the courts to assume that on the merits the plaintiffs would be successful in their claims. The Indiana Supreme Court did not do that. It concluded, after assuming a constitutionally-protected privacy interest in the continued storage of her lawfully-obtained DBS sample, the *Doe* plaintiff must show she has suffered, or is in immediate danger of suffering, some direct injury in order to have standing. *Doe, supra*, at 497. Citing the state's website for a hearsay assertion that DBS samples of babies born before June 1, 2013 have not been made available for medical research, the Indiana Supreme Court essentially found no

tangible harm in the storage—only nonuse—of the Indiana infants' blood. *Id.*, at 488. That was in error; storage is a constitutional injury because Congress may identify intangible harms and authorize litigants to seek their redress in court. Violations of constitutional rights are authorized by Congress to be redressed in courts. 42 U.S.C. § 1983.[7] In this Circuit, violations of constitutional rights are redressed with, at minimum, nominal damage awards. *Midwest Media Property, L.L.C. v. Symmes Twp.*, 503 F.3d 456, 481 (6th Cir. 2007) ("where a deprivation of [constitutional] rights has occurred, nominal damages must be awarded"). But *Doe* can be more easily distinguished from the instant case on other grounds. The Biobank (i.e. Michigan's NSP) actively and currently is selling and making available blood samples for sale. E.g. **Dr.**

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[7] The *Doe* opinion does not explain if § 1983 was invoked. It simply noted claims of "violations of the United States and Indiana constitutions and state law" were asserted. *Doe, supra*, at 485.

Yancey's Bulk Bloodspot Sale Email, RE 26-19, PageID #428; **Biobank Brochure, RE 26-16, PageID #381**; **Punches Sizes and Prices, RE 26-15, PageID #377-379.** Indiana is not. *Doe, supra*, at 498 (no sale of post-2013 DBS samples). There is tangible harm here.

1. Future harm qualifies for proper standing.

Even if fear is concluded to be the only harm (which cannot possibly be true as briefed herein), standing is still met. When a party's allegations of injury rest on future harm, standing arises if "there is a 'substantial risk' that the harm will occur." *Susan B. Anthony List, supra,* at 2342. Again, the Biobank has been actively seeking to mass-sell samples to commercial research outfits around the country (**First Am. Compl., RE 26, PageID #321, ¶81**; see also **Dr Yancey's Bulk Bloodspot Sale Email, RE 26-19, PageID #428** (email from Dr. Yancey seeking to mass-sell blood samples to Trans-Hit Bio). "There are no statutory legal protections on who may access, use, or utilize the private medical and genetic information of the Infants which is obtainable

through blood and blood-based testing." **First Am. Compl., RE 26, PageID #317, ¶64.** Thusly, we have that certainly impending harm or a substantial risk of harm with the impending mass sale of newborn blood samples to Trans Hit Bio, a company providing direct interaction between biobank members in [Trans Hit Bio] network and industrial partners for Research & Development programs in in vitro diagnostics (IVD), biomarker validation, drug discovery and development. Once the medical data is public, there is no going back—the genie is out of the bottle. See National Human Genome Research Institute, < https://www.genome.gov/27561246/privacy-in-genomics/ >; see also Susan Scutti, *You Might Not Be Anonymous, Thanks to Genealogy Databases*, CNN, Oct. 11, 2018 *available at* https://www.cnn.com/2018/10/11/health/genetic-privacy-study/index.html.

ii. **Causation.**

Causation is "a fairly traceable connection between the plaintiff's injury and the complained-of conduct of the defendant." *Steel Co., supra*,

at 103. The defendant here is the Biobank—named both directly and via Dr. Yancey in his official capacity. The Biobank concedes it "stores the [Dried Blood Spot cards] for MDHHS" which has been alleged be done nonconsentually **Appellee Br., Dk. #32, PageID #15.** The Biobank also sells them for more medical testing. **Biobank Brochure, RE 26-16, PageID #381.** Causation clearly exists.

iii. **Redressability.**

Redressability is "a likelihood that the requested relief will redress the alleged injury." *Steel Co., supra*, at 103. A plaintiff, however, need not show that a favorable decision will relieve his every injury. *Larson v. Valente*, 456 U.S. 228, 244 fn.15 (1982). Money damages, injunctive and declaratory relief, and nominal damages provide a remedy to these unconstitutional actions. As such, these § 1983 claims are redressable.

IV. Plaintiffs have pled plausible claims against the Biobank.

A. The Fourth Amendment was violated.

The Biobank is correct—a cause of action under § 1983 for an unlawful search under the Fourth Amendment exists where a plaintiff can allege facts that tend to show a state actor exceeded the bound of the Fourth Amendment. **Appellee Br., Dk. #32, PageID #35.** That is exactly what Plaintiffs have pled. The First Amended Complaint asserts that the State Defendants caused "a needle or other skin-piercing device to breach the outside skin of the newborn Infants to extract five or six samples of blood, known as blood spots." **First Am. Compl. RE 26, PageID #309, ¶35.** "At no point were the Parents ever presented with the option to simply opt-out of the blood draw *before* their Infants' blood draw occurred, the seizure of blood spots occurred via the DBS cards, the medical testing was undertaken on the Infants, or otherwise." ***Id.*, PageID #312, ¶35.** The Supreme Court has been clear—"our cases

establish that the taking of a blood sample… is a search."[8] *Birchfield v. North Dakota*, 579 U.S. __; 136 S. Ct. 2160, 2173 (2016).

i. A *Chandler/Skinner* search is still a search.

Relevant to the Biobank, the continued use and testing of those samples—separate from the original extraction requirement—is also a search. *Chandler, supra*, at 313. *Skinner* confirms the same—

> the Fourth Amendment may be relevant at several levels.... A compelled intrusion into the body for blood... must be deemed a Fourth Amendment search…. The ensuing chemical analysis of the

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[8] The Biobank tries to argue that no search has occurred here citing the Ninth Circuit's decision in *U.S. v. Attson*, 900 F.2d 1427 (9th Cir. 1990). **Appellee Br., Dk. #32, PageID #38.** *Dubbs* rejected that argument in full by distinguishing *Attson* on its facts. *Dubbs v. Head Start, Inc.*, 336 F.3d 1194, 1205-1206 (10th Cir. 2003). The District Court also similarly rejected *Attson* stating "it is clear enough from the line of cases cited in *Dubbs*… that the conduct at issue here, a government mandated blood test that involves a non-consensual invasion of bodily integrity, constitutes a search even if the information derived from that search is not used for law enforcement purposes." **Opinion, RE 50, PageID #851.** The Biobank has not explained how the District Court was in error. Therefore, the argument is waived.

> sample to obtain physiological data *is a further invasion* of the tested employee's privacy interests.

Skinner, supra, at 616 (citations omitted). Remember, a search done without a warrant in this case is "*per se* unreasonable under the Fourth Amendment" unless a "specifically established and well-delineated exception" applies. *Coolidge v. New Hampshire*, 403 U.S. 443, 454-455 (1971). Here, the Biobank has offered no exception establishing—as a matter of law—that a particular exception to a blood search is applicable. The Biobank offers no discussion or suggestion of any applicable warrant exception. It just simply concludes—

> the search in question is a blood draw from a newborn, preformed by a medical professional within the first 24-26 hours of the child's life, for the purpose of screening for serious conditions. This is not unreasonable as a matter of law.

Appellee Br., Dk. #32, PageID #42. By not offering an applicable exception, the Biobank is completely wrong and the opposite is true under *Birchfield, Chandler,* and *Coolidge*—a warrantless blood draw and the suspicionless testing of the bodily material is *per se* unreasonable on its

face. This Court is one of law, not only of governmental fiat. For the Biobank to blankly assert it is reasonable merely because 'it says so' is a direct affront to both the rule of law and Fourth Amendment jurisprudence.[9]

ii. Police power for vaccinations is not an exception to the Fourth Amendment.

Rather than raise an exception, the Biobank confusingly tries to argue that a search that is a non-consensual invasion of a person's body is acceptable under the State's general police powers, citing *Jacobson v. Commonwealth of Massachusetts*, 197 U.S. 11 (1905). In other words, the Biobank appears to be conflating the Fourth Amendment and Fourteenth

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[9] The Biobank also attempts to suggest there is no expectation of privacy in blood draws and the private medical information extracted from within blood. **Appellee Br., Dk. #32, PageID #42-44.** The Supreme Court has *expressly* rejected that assertion. Invasively piercing the skin and extract blood without consent or a warrant involves the "most personal and deep-rooted expectations of privacy." *McNeely, supra*, at 148.

Amendment jurisprudence, i.e. that the police power of the State can override the constitutional prohibitions on unreasonable warrantless search. This is clearly incorrect. *Jacobson* is not an exception to the warrant requirement for Fourth Amendment analysis; *Jacobson* was not even a Fourth Amendment case.[10]

B. The Fourteenth Amendment claim meets the plausibility standard.

The Fourteenth Amendment claim, on the other hand, is premised on two theories: that competent parents have a constitutionally protected liberty interest in refusing unwanted medical treatment for their children as an extension under *Cruzan* and there is a fundamental constitutional right of parents as to their care, custody, and control of their minor children which "is perhaps the oldest of the *fundamental*

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[10] Plaintiffs have previously explained how *Jacobson* and *Cruzan* can be read together in proper harmony under substantive due process analysis. **Appellants Br., Dk. #25, pp. 38-40.**

liberty interests recognized by" the Supreme Court under *Troxel* and related progeny. At this stage, the question is plausibility. *Bell Atlantic Corp. v. Twombly*, 550 U.S. 544, 555, 570 (2007).

In response, the Biobank asserts that a "committee of ten" under MCL 333.5430 exists and can make these medical decisions in lieu of parents when the latter has the constitutionally-protected right to do so. However, there is no fundamental right in favor of this government committee to have or exercise care, custody, and control over children in Michigan. A minor child is *not* a "mere creature of the State." *Parham, supra*, at 602. Because both of these constitutional rights involved are fundamental, governmental impingements on the same are subject to strict scrutiny. *Seal v. Morgan*, 229 F.3d 567, 574 (6th Cir. 2000). Therefore, the Biobank's assertion that there is a governmental interest in conducting these medical research tests, it fails the legal challenge. Judicial review requires 1.) a compelling governmental interest 2.) that

is narrowly tailored. The Biobank has not argued for or supported either prong of this test.

Here, Plaintiffs are asserting that the strict scrutiny test must be applied, and alternatively the acts fail to pass any other applicable test. The District Court applied a rational basis test. **Opinion, RE 50, PageID #831.** The federal trial judge in *Dubbs* used shocks-the-conscious test, which was later reversed by the Tenth Circuit. *Dubbs*, *supra*, at 1202. The Biobank concedes, for purposes of this appeal, that liberty interest has been demonstrated. **Appellee Br., Dk. #32, PageID #47.** That is appreciated, but it is only half the equation. It continues by asserting that "the court must then determine whether a person's constitutional rights have been violated by balancing the liberty interest against the relevant state interest." ***Id.*, PageID #47-48.** But against what judicial standard? The Biobank never provides an answer to this Court. Instead, it cites what it claims is *this Court's* decision in *Cincinnati Radiation*, but is actually a lower district court case from the Southern

District of Ohio. Compare **Appellee Br., Dk. #32, PageID #47** with *In re Cincinnati Radiation Litigation*, 874 F. Supp. 796 (S.D. Ohio 1995). *Cincinnati Radiation* is not applicable as it is a case involving the government using unwitting cancer patients for radiation experiments. The *Cincinnati Radiation* district court, when denying dismissal of a substantive due process claim premised on bodily integrity, explained that "that the government's burden was to provide more than minimal justification for its action." *Id.*, at 813. So, at minimum under *Cincinnati Radiation*, this means the test is something greater than mere rational basis (as utilized by the District Court in this case) but is unclear what test is being or should be used for a claim substantive due process challenge as to bodily integrity theory. Fortunately, *Cincinnati Radiation* is not troubling or hand-tying precedent upon this Court as it is a trial level decision involving a liberty interest not at play in this case (bodily integrity versus medical decision-making and the care, custody, and control of one's child), and the liberty interest (now conceded in this case)

has been expressly deemed to be "the oldest" fundamental one. *Troxel, supra,* at 65-66. Governmental action interfering with *fundamental* rights is subject to strict scrutiny. *Seal*, *supra*, at 574. *Cincinnati Radiation* is not inconsistent but conveniently is otherwise not directly applicable to the instant case.

So, yes, the Biobank is correct that the Michigan Legislature can "pass suitable laws for the protection and promotion of the public health," Const. 1963, art. IV, § 51, but those "suitable laws" and their use by entities like the Biobank (as a state actor) must pass constitutional muster. Here, the Biobank's actions of storing samples, and conducting and facilitating medical testing on the newborns' blood samples, and allowing the immediate future use of their deeply-private medical, genetic and biological information—all three without parental consent—violates a fundamental right which is not overcome by a compelling governmental interest having been narrowly tailored. A plausible Fourteenth Amendment claim has been pled.

RELIEF REQUESTED

This Court is requested to reverse the dismissal of this action pursuant to FRCP 12(b)(6), and then remand this matter for further proceedings.

Date: November 15, 2018

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CERTIFICATE OF COMPLIANCE

Pursuant to Sixth Circuit Rule 32(a)(7)(C) and Sixth Circuit Rule 32(a), the undersigned certifies that this brief complies with the type-volume limitations of the Sixth Circuit Rule 32(a)(7)(B).

This brief has been prepared in proportional typeface using TeXGyreSchola 14-point font. The principal portion of the reply brief, including headers and footnotes, contains 6,499 words according to the Word Count feature in the Microsoft Word program, being less than 6,500 words.

The undersigned understands that a material misrepresentation in completing this certificate or circumvention of the type-volume limitations may result in the Court's striking the brief and imposing sanctions against the person signing the brief.

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CERTIFICATE OF SERVICE

I hereby certify that on the date stated below, I electronically filed the foregoing with the Clerk of the Court using the CM/ECF System, which will send notice of and a copy of such filing to counsel of record at their email address(es) of record.

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DESIGNATION OF RELEVANT DISTRICT COURT DOCUMENTS

RE.	PageID Range	Description of the Document
26	#300-453	First Amended Complaint (Exhibits A-R)
50	#825-846	Opinion