No. 18-1896

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.

BRIEF OF APPELLEE MICHIGAN NEONATAL BIOBANK, INCORPORATED

ORAL ARGUMENT REQUESTED

Jeremy C. Kennedy
Jerold Lax
PEAR SPERLING EGGAN & DANIELS, P.C.
24 Frank Lloyd Wright Drive, Ste. D2000
Ann Arbor, Michigan 48105
Telephone: 734-665-4441
E-mail: jkennedy@psedlaw.com
Counsel for Michigan Neonatal BioBank, Inc. and Dr. Antonio Yancey in his capacity as director of the Michigan Neonatal Biobank, Inc. Only

TABLE OF CONTENTS

INDEX OF AUTHORIEITES

Page

U.S. Constitutional Provisions

Federal Rules

Federal Cases

Michigan Constitutional Provisions

Michigan Statutes

Michigan Cases

JURISDISTIONAL STATEMENT

BioBank Defendants concurs with the Appellants Jurisdictional Statement.

SUMMARY OF ISSUES AND RELIEF SOUGHT

Issue I:

Did the Trial Court properly determine that Appellants lacked Article III standing to bring their claim when they have failed to allege an injury that is (a) concrete and particularized and (b) actual or imminent, not conjectural or hypothetical?

Defendants Michigan Neonatal BioBank, Inc. and Cr. Antonio Yancey in his capacity as Director of the Michigan Neonatal BioBank, Inc. Answer: *Yes*

The Trial Court Answered: *Yes*

This Court Should Answer: *Yes*

Issue II:

Did the Trial Court properly determine that the drawing of blood from a newborn for the purpose of medical screening is not, as a matter of law, an illegal search or seizure prohibited by the fourth amendment?

Defendants Michigan Neonatal BioBank, Inc. and Dr. Antonio Yancey in his capacity as Director of the Michigan Neonatal BioBank, Inc. Answer: *Yes*

The Trial Court Answered: *Yes*

This Court Should Answer: *Yes*

REQUEST FOR ORAL ARGUMENT

This case raises questions that have not been decided at the Court of Appeals level by any Circuit Court in the United States. The District Court decided this matter without oral argument, but as this is a matter of first impression in this, oral argument should be permitted to allow the parties to address any questions that the Court has after briefs are submitted. This could help provide clarity for the Court when making its decision.

INTRODUCTION

Plaintiff-Appellants Adam Kanuszewski, Ashley Kanuszewski, Shannon LaPorte and Lynette Wiegand (collectively referred to as "the Parents")[1] are each the parents-guardians of one or more children born in the State of Michigan, and brought this action on behalf of their minor children (herein collectively referred to as "the Infants"), seeking to undo decades of positive public health efforts at the state level. The policy challenged is Michigan's law requiring screening of all newborns for over 50 different chronic and congenital genetic disorders to allow for early intervention and treatment. The process requires a small amount of blood to be taken from a baby's heel within the first 24-36 hours of life, and if one of the diseases is detected, the child's parents can then decide the course of action to take. (RE 26, ¶36). The Parents claimed that at the District Court this valuable medical tool was a violation of the Infants' fourth and fourteenth amendment rights. The District Court disagreed and dismissed their claims. (RE 50, 51). The Parents now claim, incorrectly, that the District Court erred when it weighed their claims of constitutional violations and found them wanting.

The Parents' claims were and are lacking basis in fact and are not supported by the existing law. The Parents note, correctly, that this issue is one of first

[1] This brief refers to the claims brought by the Parents for ease of writing. As next friends, Parents brought the Complaint on behalf of their minor children, the Infants.

impression in this Circuit, and at the Circuit Court level nationwide perhaps, but it is not an issue of first impression in this various lower courts and state courts around the nation. The issue of newborn screening has been considered in multiple courts across the country, and the screening programs have been consistently upheld in courts of all persuasions. Furthermore, as the District Court correctly noted regarding the Michigan Neonatal Biobank, Inc. and its Director, Dr. Antonio Yancey (herein collectively the "Biobank Defendants"), the Parents filed to demonstrate standing to bring a claim, as they did not allege a concrete, non-speculative harm that they or the Infants suffered at the hands of the Biobank Defendants. The Parents failed to state a claim as a matter of law despite correcting and/or amending their Complaint twice[2]; the District Court's decision to grant the Motions to Dismiss was correct, and this Court should Affirm that decision.

[2] The Appellants filed their original Complaint, and shortly after filed what they title a "Corrected Complaint," though it apparently added new paragraphs. After all the defendants filed Motions to Dismiss, the Appellants filed their First Amended Complaint, which was the version of the Complaint before the District Court when it granted the Motions to Dismiss.

STATEMENT OF CASE

A. Factual Allegations

Plaintiff-Appellants Adam Kanuskewski, Ashley Kanuszewski, Shannon LaPorte and Lynette Wiegand (collectively referred to as "the Parents") are each the parents-guardians of one or more children born in the State of Michigan, and brought this action on behalf of their minor children (herein collectively referred to as "the Infants"). (RE 26, p. 304-305, ¶¶16-18). Since at least 1987, and most likely earlier than that, as the statute in question was adopted in the 1960s, one or more of the Defendants-Appellees – which ones specifically are not specified – have, individually or collectively collected blood samples from nearly all newborn babies in Michigan at the time of birth and stored those samples. The dried blood spots are stored indefinitely, and by statute may be used for testing or later research. (RE 26, p. 309, ¶33).

Relevant to this case, the Parents allege that at the time the birth of each Infant, a health professional drew five or six samples of blood, known as blood spots, in the hospital, after the Infants' birth. The Parents acknowledge that the extent of the taking of blood from newborns is limited to taking these five or six drops by pricking the heel while the infant is in the hospital or under the care of a midwife. (RE 26, p. 322, ¶87). The Infants' blood spots were then transferred within 24-48 hours of birth to a filter paper collection device created for use by MDHHS and known as a Dried

Blood Spot ("DBS") card. (RE 26, p. 310, ¶37). The blood sample from each infant was then used to screen for dozens of diseases and/or disorders.

The Parents claim that they were unaware that the "health professional was taking their child's blood for the purpose of providing the blood spots to the state government when the statute only requires certain 'health professional[s]' to 'administered [*sic*] to the infant a test' for certain diseases, see MCL 333.5431(1)."[3] (RE 26, p. 310-311, ¶40). The First Amended Complaint contends that the parents of the Infants did not reasonably understand, were not reasonably told, or did not give expressed informed consent to the health professionals to take their respective Infants' blood for the purpose of providing the blood spots to the government. (RE 26, p. 311, ¶42). The First Amended Complaint also alleges that parents can be charged a fee for the cost of MDHHS undertaking the seizing, storage, and testing of the blood spots of their respective Infants. The Parents do not, however, allege

[3] Based on a plain reading of the First Amended Complaint, Plaintiffs were, apparently, aware of the existence of the statute allowing health care professionals to draw blood for screening for chronic diseases. If they were aware of the statute, however, they also were aware of subsection 7(b), which states the MDHHS can "(b) Allow the blood specimens to be used for medical research during the retention period established under subdivision (a), as long as the medical research is conducted in a manner that preserves the confidentiality of the test subjects and is consistent to protect human subjects from research risks under subpart A of part 46 of subchapter A of title 45 of the code of federal regulations." MCL 333.5431). They were further aware that their common law right of informed consent was statutorily waived by the law.

they specifically were charged such a fee, and in fact, the Parents cannot remember being charged the fee.

Per the First Amended Complaint, the DBS cards are sent to MDHHS and placed in the possession of the MDHHS Bureau of Laboratories. The dried blood spots are at that time under the custody and control of Dr. Sandip Shah, Dr. Sarah Lyon-Callo, and/or Mary Kleyn. Dr. Shah, Dr. Lyon-Callo, Ms. Kleyn, MDHHS and Nick Lyons, are collectively herein referred to as the "State Defendants." At that point, tests are conducted to detect and learn of any maladies, disorders, or diseases. At present, 56 different disorders are tested for, including cystic fibrosis, sickle cell anemia, critical congenital heart disease, and fifty-three other disorders.[4] (RE 26-2). Per the Parents' contentions, no defendant and no laboratory technician at MDHHS provided reasonable notice or explanation to the Infants or their Parents to seek informed consent to conduct these tests. (RE 26, p. 316, ¶59). Regardless of whether those blood spots tested positive for any of the 50+ maladies, disorders, or diseases, MDHHS retained the remaining blood spots indefinitely. (RE 26, p. 316, ¶61). The Michigan Neonatal Biobank, Inc., a nonprofit corporation that receives all or nearly all its funding from the State of Michigan, stores the DBS for MDHHS. The Parents allege that this funding is provided to indefinitely store the Infants' blood and to

[4] The First Amended Complaint seems somewhat uncertain as to when, exactly, the screening tests are performed.

conduct tests on the Infants' blood, including for medical studies, laboratory equipment calibration, and other uses. (RE 26, p. 320, ¶75). The Parents contend that this testing is not provided for by State law and is not done with the consent of the Infants or their Parents.

The Parents admit that they might have been presented with a card giving them an option to donate their infants' blood to medical research, admit they may have signed the document, but claim not to have understood what they were signing. (RE 26, ¶48-49). The Parents contend that they were never presented with the option to simply opt out of: the drawing of the blood entirely, the use of the blood spots to create the DBS cards, the testing of the Infants blood for the 56 conditions tested for, or anything else related to the newborn screening program.

The Parents allege that in addition to the blood spot samples, Defendants, individually or collectively, require the submission of certain data about the blood spots and also other private personal information, including the Infants' names, genders, weight, gestation time, and whether transfused with red blood cells and whether part of a single or multiple-newborn birth (i.e., twins, triplets).

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. (RE 26, p. 320, ¶75). The DBS cards

containing the dried blood spots are stored in archival boxes and are under the custody and control of the Biobank and/or MDHHS. (RE 26, p. 320, ¶76).

The Parents' allege that since the blood spots contain deeply private medical and genetic information, "the Parents are concerned and 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." (RE 26, p. 320, ¶78). The First Amended Complaint does not allege that the Infants' DBS Cards have been misused, nor does it allege actual discrimination against the Infants. The Parents, per the First Amended Complaint, were further "concerned and fear that Michigan statutory law provides no legal protections from invasion or use by the courts, law enforcement, state actors, or private actors who gaining [*sic*] access to the blood spot collections and DBS cards held by [the BioBank]." (RE 26, p. 321, ¶82). The Parents claim that it is easily possible to request and break the confidentiality protections, causing the private medical and genetic information of the Infants to be revealed. (RE 26, p. 317, ¶63). They cite no evidence to support this allegation, nor did they claim that the DBS cards of the Infants have actually had their private medical and genetic information revealed. The Parents finally claimed that there are no current 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. (RE 26, p. 317, ¶64). Aside from being wrong, as several statutes protect private health and genetic information, such as the Health Insurance Portability and Accountability Act or the Genetic Information Nondiscrimination Act of 2008, no support is made to back this allegation in the First Amended Complaint; it is purely speculative.

As Exhibits B and J of The Parents' First Amended Complaint makes clear, for blood samples drawn prior to 2010, "Parents, legal guardians of, and/or persons from whom the specimen was collected after reaching the age of majority, ***may request that their specimen not be used for any research,*** by contacting DCH by telephone or mail." (RE 26-3, p. 336-337). After 2010 the MDHHS policy on newborn screening was changed to require parents to "Opt-In," meaning they had to affirmatively permit their children's DBS to be used for research purposes. (RE 26-3). Further, as The Parents' First Amended Complaint clearly shows, "You may ask for your spots to be destroyed. You may also ask that your spots remain stored, but not used in research. Please call MDHHS for more details (Toll-free 1-866-673-9939)." (RE 26-11).[5]

[5] Coincidentally, while Plaintiffs include on MDHHS pamphlet discussing use of DBS, they do not address one previously filed with this Court as the State Defendants' Exhibit 2 to their Motion to Dismiss Plaintiffs' Corrected Complaint. This pamphlet states in relevant part: "Forms are available if you want your child's blood spots destroyed after newborn screening is complete. Please call 1-866-673-9939 for more information or visit www.michigan.gov/newbornscreening." Should

Parents, in their capacity as Next Friends for the minors, have not asserted that they attempted to have the Infants DBS cards destroyed, nor have they attempted to restrict the use of the DBS cards. They have therefore consented to the use of the DBS cards by MDHHS, and the storage of same at the Biobank. Further, the Parents have not alleged that the Infants' DBS cards have been used contrary to their authorization. As stated in their Exhibit J, "Stored blood spots collected after April 2010 can only be used for research if a parent or legal representative returns a signed consent form allowing it." (RE 26-11). The Parents have not alleged that the DBS cards of any of the Infants have been used contrary to the express authorization(s) of the Parents. At best, they have raised speculative allegations that the DBS cards ***might*** be used in the future. Absent evidence that the DBS cards have been used in a way contrary to the specific consent given by the Parents, there is no allegation of actual harm.

B. Procedural History

The Parents filed the First Amended Complaint on April 30, 2018. (RE 26). On May 29, 2018, Michigan Neonatal Biobank, Inc. and Dr. Antonio Yancey, in his capacity as Director of the Michigan Neonatal Biobank filed a motion to dismiss the first amended complaint. (RE 33). That same day, the State Defendants filed their

---

it choose to do so, the Court may take judicial notice of this fact pursuant to FRE 201(b), or disregard as inappropriate to consider at this time.

own Motion to Dismiss (RE 32), as did Dr. Antonio Yancey in his personal capacity. (RE 34). All of the Motions to Dismiss argued that Defendants had failed to state a claim as a matter of law. The Biobank Defendants additionally argued that the Parents lacked standing to bring a claim for the storage of the DBS cards, as the Parents had not requested the destruction of same and did not allege any misuse of the Infants' DBS cards.

The District Court agreed with the various Defendants and granted their motions to dismiss on August 8, 2018. (RE 50). The District Court granted the motions to dismiss on the grounds that the Parents had not pled facts sufficient to show that the newborn blood screening violated the fourth or fourteen amendment rights of the Parents or the Infants. (RE 50). The District Court further held that the Parents had not demonstrated standing to contest to storage of the DBS cards. (RE 50). Judgement dismissing the First Amended Complaint with prejudice was entered that same day. (RE 51). Less than one hour after the District Court entered its judgment dismissing the case, Notice of Appeal was filed by the Parents, on August 8, 2018.

SUMMARY OF ARGUMENT

The District Court properly granted the Biobank Defendants' motion to dismiss. This decision was correct for two reasons: first, the plaintiffs lacked standing to contest the storage of the DBS cards, and second, the blood draws are not unreasonable searches and seizures prohibited by the fourth or fourteenth amendments.

The First Amended Complaint alleges merely that the Parents "are concerned and fear about the misuse of [their private medical and genetic 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." (RE 50, p. 845). This is not a concrete, particularized, non-speculative injury. For that reason alone, the dismissal of the claims regarding the storage of the DBS cards was warranted and should be upheld.

Even if the Parents had standing, their claim that the newborn screening program is a violation of the Infants' fourth and fourteenth amendment rights falls flat. The blood draws in the newborn blood screening program are not unconstitutional, as the District Court correctly concluded. The draws are done in a medical environment, by a medical professional, in accordance with a neutral, universally applied law for the purpose of determining whether an infant has one of 56 chronic and/or congenital diseases. This is a legitimate use of the state's police

power to protect the public health and welfare of its residents. To the extent the taking of the blood is a search, it is not an unreasonable one, and none of the fourth amendments protections are violated. The blood draw also does not run afoul of the Parents or Infants due process rights and does not violate the fourteenth amendment. The District Court correctly dismissed the First Amended Complaint, and this Court should Affirm that decision.

STANDARD OF REVIEW

The Court of Appeals reviews *de novo* the grant of a motion to dismiss for failure to state a claim. *Casias v. Wal-Mart Stores, Inc.*, 695 F.3d 428, 435 (6th Cir. 2012). The Sixth Circuit stated the standard for reviewing a motion to dismiss under Rule 12(b)(6) in *Assn. of Cleveland Fire Fighters v. Cleveland*, 502 F.3d 545 (6th Cir.2007) as follows: "a plaintiff's obligation to provide the grounds of his entitlement to relief requires more than labels and conclusions, and a formulaic recitation of the elements of a cause of action will not do." *Id.* at 548, *citing Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 127 S. Ct. 1955, 167 L.Ed.2d 929 (2007).

To survive a motion to dismiss, plaintiffs must plead "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, 129 S. Ct. 1937, 173 L. Ed. 2d 868 (2009) (quoting *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 570, 127 S. Ct. 1955, 167 L. Ed. 2d 929 (2007)). Under this standard, a plaintiff must plead "factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." *Id.* While a complaint need not contain "detailed" factual allegations, its "[f]actual allegations must be enough to raise a right to relief above the speculative level on the assumption that all the allegations in the complaint are true." *Id.*) (internal citation and quotation marks omitted). In evaluating a motion brought pursuant to Rule 12(b)(6) , "[c]ourts must construe the complaint in the light

most favorable to plaintiff, accept all well-pled factual allegations as true, and determine whether the complaint states a plausible claim for relief." *Albrecht v. Treon*, 617 F.3d 890, 893 (6th Cir. 2010). The court must "accept all factual allegations as true," construing the complaint "in the light most favorable to the plaintiff." *Laborers' Local 265 Pension Fund v. iShares Trust*, 769 F.3d 399, 403 (6th Cir. 2014).

A decision regarding a plaintiff's Article III standing is also reviewed *de novo*. *Schultz v. United States*, 529 F.3d 343, 349 (6th Cir. 2008). "The 'well established' law of Article III standing requires a plaintiff to 'allege personal injury fairly traceable to the defendant's allegedly unlawful conduct and likely to be redressed by the requested relief.'" *Murray v. U.S. Dep't of Treasury*, 681 F.3d 744, 748 (6th Cir. 2012)(quoting *Hein v. Freedom From Religion Found., Inc.*, 551 U.S. 587, 598, 127 S. Ct. 2553, 168 L. Ed. 2d 424 (2007)). "We look to the complaint and any accompanying materials in deciding standing questions." *Id.*

ARGUMENT

I. THE TRIAL COURT PROPERLY DISMISSED THE CLAIMS REGARDING STORAGE OF THE OF THE DRIED BLOOD SPOT CARDS FOR LACK OF STANDING

A. The District Court's reliance

As the District Court correctly noted, to bring a claim in federal court, a plaintiff must be able to demonstrate that they have Article III standing, meaning the plaintiffs must "demonstrate that *they* (and not some third party) suffered an injury in fact." (RE 50, p. 845). As to the retention and storage of the blood samples, the District Court correctly noted that the First Amended Complaint alleges merely that the Parents "are concerned and fear about the misuse of [their private medical and genetic 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." (RE 50, p. 845, quoting RE 26).

As noted by the U.S. District Court for the Western District of Texas in *Higgins v. Tex. Dep't of Health Servs*., 801 F.Supp.2d 541 (W.D. Tex, 2011), a similar case involving newborn screening and retention of blood spot cards,

> Plaintiffs' alleged ongoing harm is the possible expropriation of their children's previously taken blood by its release to third parties and those third parties' retention and use of the blood specimens. … But there is no allegation that, at the time Plaintiffs filed this suit, they had even requested information about the fate of their children's blood specimens, much less that they had done so and were refused. Nor had they requested that the blood specimens be destroyed and been

> informed that this was not possible due to their release to third parties. Thus, their informational claims were not ripe at the time they filed suit and/or they lacked standing because they had suffered no injury in fact with regard to the denial of information or the denial of a request for destruction.
> *Higgins v. Tex. Dep't of Health Servs*., 801 F.Supp.2d 541 (W.D. Tex, 2011). *See also, Doe v. Adams*, 53 N.E.3d 483 (Ind. 2016)(*upholding trial court's dismissal of Plaintiff's claim for lack of standing when the only harm was fear of potential misuses of DBS cards*) (Ex. 1).

In this case, much as in *Higgins*), there is no harm, there is no injury in fact, and therefore there is no standing. The District Court summarized its reasons for dismissing for lack of standing as follows:

> Plaintiffs further allege that their fear is "well-founded and actual as the sharing of blood spots containing deeply private medical information has recently resulted in the arrest of an alleged killer but has already resulted in the wrongful arrest of persons who were not guilty of any crime." Id. Am. Compl. ¶ 79. It is entirely unclear what Plaintiffs are referring to when they discuss their fear of the "possibility of discrimination," or how that fear is connected to the alleged misuse of blood samples. In a roundabout way, Plaintiffs appear to be trying to establish that law enforcement use of blood samples in other cases poses a realistic threat that the government will use Plaintiffs genetic information to take some action against them. But this contention is entirely hypothetical. It is clear that the "possibility of discrimination" is an insufficient injury to support article III standing.
> (**RE 50**, p. 21).

This decision was correct, for the reasons shown below.

B. General requirements for standing to bring an Article III Claim.

A federal court may only adjudicate "cases" and "controversies." U.S. CONST. ART. III, § 2, cl. 1. The standing doctrine is derived from the case or controversy

requirement and obligates a plaintiff to show a "personal stake in the outcome of the controversy as to . . . justify [the] exercise of the court's remedial powers on [their] behalf." *Town of Chester, N.Y. v. Laroe Estates, Inc.*, 137 S. Ct. 1645, 1650, 198 L. Ed. 2d 64 (2017). To invoke the jurisdiction of the federal courts, a party must have standing under Article III. "[T]he irreducible constitutional minimum of standing contains three elements." *Lujan v. Defenders of Wildlife*, 504 U.S. 555, 560, 112 S. Ct. 2130, 119 L. Ed. 2d 351 (1992). These elements are (1) an injury in fact that is (a) concrete and particularized and (b) actual or imminent, not conjectural or hypothetical; (2) a causal connection between the injury and the conduct complained of – the injury has to be fairly traceable to the challenged action of the defendant and not the result of independent action of some third party not before the court; and (3) the likelihood that a favorable decision will redress the injury. *Id.* ; *Croft v. Governor of Texas*, 562 F.3d 735, 745 (5th Cir. 2009). "The party invoking federal jurisdiction bears the burden of establishing these elements." *Lujan*, 504 U.S. at 561. In this matter, The Parents could not show that there has been an injury in fact that it concrete and particularized and actual or imminent. The trial court correctly concluded that they lacked constitutional standing, and dismissed their claim, at least as it relates to a) the Biobank Defendants and b) the claims that the DBS cards were illegally stored.

C. The Parents did not plead an injury in fact that is concrete and particularized

In order to establish standing, a plaintiff must be able to show an injury in fact that is concrete and particularized. As used in regard to standing, a particularized injury means "that the injury must affect the plaintiff in a personal and individual way." *Lujan*, 504 U.S. at 560 n.1. When reviewing the claimed injuries to determine whether a party has standing, the court must look at the injuries alleged to determine whether they are concrete and particularized; the "'injury in fact' test requires more than an injury to a cognizable interest. It requires that the party seeking review be himself among the injured." *Lujan* at 562, quoting *Sierra Club v. Morton*, 405 U.S. 727, 734-735 (1972).

Here, the Parents did not allege any concrete injury. As the District Court noted, the First Amended Complaint alleges only that the Infants had their heels pricked, blood drawn, and that the blood was stored by MDHHS at the Biobank. The blood draw was undertaken for a valid public health reason: to test for chronic diseases or disorders, pursuant to the Michigan Public Health Code. *See* MCL 333.5431). This does not constitute an injury that is concrete and particularized; it constitutes a routine medical procedure that has been carried out hundreds of thousands of times. As the Parents' First Amended Complaint points out in Exhibit B, MDHHS policy reads in relevant part:

> Parents, legal guardians of, and/or persons from whom the specimen was collected after reaching the age of majority, may request that their specimen not be used for any research, by contacting DCH by telephone or mail. ***Parents, legal guardians of, and/or persons from whom the specimen was collected after reaching the age of majority, may request that their specimen be destroyed*** … (RE 26-3, emphasis supplied).

Accordingly, there is a known process for having the DBS cards destroyed, but the Parents do not claim to have attempted to have the minor children's DBS cards destroyed, let alone had such a request denied.

D. The alleged injuries are conjecture

The First Amended Complaint failed to demonstrate any actual or imminent harm. Showing "actual or imminent" harm requires that the harm has happened or is sufficiently threatening, and not merely that it may occur at some future time. A plaintiff who has been subject to injurious conduct of one kind does not possess, by virtue of that injury, the necessary stake to litigating conduct to which he has not been subject, regardless of how similar the harms. See *Moose Lodge No. 107 v. Irvis*, 407 U.S. 163, 166-167 (1972). Of course, "[one] does not have to await the consummation of threatened injury to obtain preventive relief." *Pennsylvania* v. *West Virginia*, 262 U.S. 553, 593 (1923), quoted in *Babbitt v. Farm Workers*, 442 U.S. 289, 298 (1979). "[The] question becomes whether any perceived threat … is sufficiently real and immediate to show an existing controversy…" *O'Shea* v. *Littleton*, 414 U.S. 488, 496 (1974).

The Parents indicated that they are seeking injunctive relief because they are "concerned and fear that Michigan statutory law provides no legal protections from invasion or use by the courts, law enforcement, state actors, or private actors who gaining [sic] access to the blood spot collections and DBS cards held by [the BioBank]." (RE 26, ¶82). The Parents claim that it is easily possible to request and break the blind causing the private medical and genetic information of the Infants to be revealed. In the First Amended Complaint, the Parents claim that there are no current 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. These allegations are not only false, they are not even supported by the documentary evidenced attached to the First Amended Complaint.

Exhibit B to The Parents' First Amended Complaint is the State of Michigan Department of Community Health's Policy and Procedure on Newborn Screening Specimens, effective September 8, 2008. This document states, clearly and unambiguously, that not only can a parent or guardian request that a blood specimen not be used for research, but also that they can request that the specimen be destroyed. The policy reads in relevant part:

> The DCH will maintain, or cause to be stored, newborn screening dried blood spots indefinitely. Parents, legal guardians of, and/or persons from whom the specimen was collected after reaching the age of majority, ***may request that their specimen not be used for any research,*** by contacting DCH by telephone or mail. Parents, legal guardians of, and/or persons from whom the specimen was

> collected after reaching the age of majority, ***may request that their specimen be destroyed*** by providing the name, date of birth and their relationship to the individual from whom the specimen was collected and must provide copies of the individual's birth certificate and a government-issued identification (e.g., drivers license or passport) to confirm that they have authority to make such a request.
> (RE 26-3, emphasis supplied).

Additionally, under MCL 333.5431, while DBS cards may be used for medical research, this can only be done "as long as the medical research is conducted in a manner that preserves the confidentiality of the test subjects and is consistent to protect human subjects from research risks under subpart A of part 46 of subchapter A of title 45 of the code of federal regulations." MCL 333.5431 (7)(b). Not only are there protections under Michigan law that would assuage the fears of the Parents, but under the 2008 policy they have the option to opt out and have their children's blood samples destroyed entirely.

E. The District Court correctly dismissed the claims regarding the storage of the DBS Cards for lack of standing.

The damages claimed – that the specimens *might* be used for research – are speculative and hypothetical. Furthermore, there is a remedy available outside of litigation to prevent this speculative harm from occurring: The Parents can simply request that the dried blood spots either not be used for research, or they be destroyed entirely. The Parents did not take either such action prior to filing suit. The Parents have not alleged any non-speculative harm, and therefore do not have standing to

sue. The trial court properly determined that The Parents do not have standing to bring a claim against the Biobank Defendants under Article III of the Constitution, and correctly dismissed them from this matter. This Court should uphold that decision and affirm the Trial Court's grant of the Biobank Defendants' Motion to Dismiss.

II. THE DISTRICT COURT WAS CORRECT WHEN IT GRANTED THE MOTION TO DISMISS THE FIRST AMENDED COMPLAINT.

A. Michigan's newborn screening program to detect chronic medical disorders is a valid exercise of the State's inherent authority to pass laws to protect the public health.

1. The policy in question and the challenge to that policy.

As even the Parents concede, the policy in question here requires blood to be drawn from a newborn, at which time the infant is screened for over 50 congenital conditions. The Michigan Public Health Code requires that newborns be tested for chronic disorders. The statute at issue, MCL 333.5431), states, in relevant part:

> (1) A health professional in charge of the care of a newborn infant or, if none, the health professional in charge at the birth of an infant shall administer or cause to be administered to the infant a test for each of the following:
>
> (a) Phenylketonuria.
> (b) Galactosemia.
> (c) Hypothyroidism.
> (d) Maple syrup urine disease.
> (e) Biotinidase deficiency.
> (f) Sickle cell anemia.
> (g) Congenital adrenal hyperplasia.
> (h) Medium-chain acyl-coenzyme A dehydrogenase deficiency.
> (i) Other treatable but otherwise disabling conditions as designated by the department.
>
> MCL 333.5431(1).

The blood draws taken from newborns to screen for congenital diseases or disorders are self-evidently done to preserve the public health. If the results of a test come back "positive, the results shall be reported to the infant's parents, guardian, or

person *in loco parentis*" to allow them to determine the course of action to take. MCL 333.5431(3). Further, the Michigan process is overseen by a committee of ten (10) individuals. MCL 333.5430. The committee consists of two members from the general public and one member from each of the following groups: a Michigan nonprofit health care corporation; the Michigan health and hospital association; the Michigan state medical society; the Michigan osteopathic association; MDHHS's medical services administration; MDHHS's public health administration; a neonatologist with experience and background in newborn screening; and health maintenance organizations. *See* MCL 333.5430.

Once the initial screening is done, the law permits the DBS cards to be "to be used for medical research during the retention period established under subdivision (a), as long as the medical research is conducted in a manner that preserves the confidentiality of the test subjects and is consistent to protect human subjects from research risks under subpart A of part 46 of subchapter A of title 45 of the code of federal regulations." MCL 333.5431(7)(b). As the First Amended Complaint notes, under the policy put in place in 2008, parents have the option to opt out of all testing for their children if they wish, and may even have the DBS card destroyed entirely. (See RE 26-3). The Parents in this matter have not elected to opt out of testing, and they have not requested the DBS cards be destroyed.

Here, the First Amended Complaint asserts that the taking of a blood sample by a medical professional to screen for chronic disorders constitutes an illegal search and seizure. The First Amended Complaint further asserts that the storage of DBS by the Biobank Defendants constitutes either an illegal search or an illegal seizure. There is no allegation that the blood draw is undertaken in a manner that does not comply with MCL 333.5431). Indeed, the First Amended Complaint simply alleges that at the time of birth of an Infant, a medical professional using a needle pierces the Infant's skin, draws blood, and makes a DBS card. (See Complaint, Para. 32). A cause of action under 42 U.S.C. §1983 for an unlawful search under the fourth amendment exists where a plaintiff can allege facts that tend to show that a state actor exceeded the bounds of the fourth amendment. *Pruett v. Town of Spindale*, 162 F. Supp. 2d 442 (W.D.NC 2001). The District Court, when looking at the allegations contained in the First Amended Complaint, correctly determined that the actions complained of here are neither unlawful. The blood is taken to screen for the genetic conditions listed on the list established by the State Defendants. Accordingly, that Court dismissed the Complaint with prejudice.

2. General fourth amendment principles.

The fourth amendment protects the "right of the people to be secure in their persons, houses, papers, and effects, against unreasonable searches and seizures." U.S. CONST. AMEND. IV. It is not, however, a "general constitutional 'right to

privacy.' That Amendment protects individual privacy against certain kinds of governmental intrusion, but its protections go further, and often have nothing to do with privacy at all." *Katz v. United States*, 389 U.S. 347 (1967). This language implies that the amendment applies to a limited range of governmental conduct, and while some conduct will be prohibited, other conduct necessarily will be permitted. *United States v. Attson*, at 1429).

The phrase "searches and seizures" connotes that the type of conduct regulated by the fourth amendment must be somehow designed to elicit a benefit for the government in an investigatory or an administrative capacity. Governmental conduct which is not actuated by an investigative or administrative purpose[6] should not be considered a "search" or "seizure" for purposes of the fourth amendment. *United States v. Attson*, at 1431). Unlike the "state actor" requirement of the fourteenth amendment, the fourth amendment cannot be triggered simply because a person is acting on behalf of the government. Instead, the fourth amendment will only apply to governmental conduct that can reasonably be characterized as a "search" or a "seizure." This threshold inquiry is particularly appropriate where the challenged conduct falls outside the fourth amendment's common and traditional

[6] "Administrative purpose" searches were considered, for example, in *Camara v. Municipal Court of San Francisco*, 387 U.S. 523 (1967), where the Supreme Court ruled that a city building inspector needed consent or a warrant to inspect an apartment building to determine it complied with the local building code.

scope – law enforcement. *United States v. Attson,* at 1429-1430). Here, the search in question is the blood draw for purposes of medical diagnosis. This does not constitute a "search" or a "seizure."

3. The drawing of blood for medical purposes is a valid exercise of state authority to protect public health.

The Parents take the position that *Cruzan v Dir., Mo. Dep't of Health*, 497 U.S. 261 (1990) supports their contention that Michigan's newborn screening program violates their civil rights. As the District Court noted, *Cruzan* does not support this position. The *Cruzan* case stated that "[t]he principle that a competent person has a constitutionally protected liberty interest in refusing unwanted medical treatment may be inferred from our prior decisions." *Cruzan* at 278. The Infants, however, as minor children, are not competent people under the law, and *Cruzan* does not apply. Furthermore, immediately after affirming the common-law right of competent people to refuse medical treatment, *Cruzan* cited approvingly to *Jacobson v. Massachusetts*, noting that "the Court balanced an individual's liberty interest in declining an unwanted smallpox vaccine against the State's interest in preventing disease." *Cruzan*, at 278. As *Cruzan* itself noted, "determining that a person has a 'liberty' interest' under the Due Process Clause does not end the inquiry; 'whether respondent's constitutional rights have been violated must be determined by balancing his liberty interest against the relevant state interests.'" *Cruzan*, at 279.

The blood draws taken from newborns to screen for congenital disease or disorders is recognized as a valid governmental concern. As even the Parents admit, only five or six drops of blood are drawn, and once the blood is drawn, the infants are screened for over 50 congenital conditions. This is performed by "A health professional in charge of the care of a newborn infant or, if none, the health professional in charge at the birth of an infant." MCL 333.5431(1). If the results of a test comes back "positive, the results shall be reported to the infant's parents, guardian, or person in loco parentis." MCL 333.5431(3). The infant's parents can then determine what course of action to take regarding the infant's health. The statute does not mandate any course of treatment, and thus does not run afoul of *Cruzan* or any other law regarding the right to self-determination.

The Ninth Circuit, writing in *United States v. Attson*, 900 F.2d 1427 (9th Cir. 1990), held 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." *United States v. Attson* at 1431). It is undisputed that the states retain the authority to pass laws to protect the public health. The Supreme Court in *Jacobson v. Massachusetts*, 197 U.S. 11 (1905) , in upholding a Massachusetts law requiring mandatory vaccinations against small pox, stated that

> The authority of the State to enact this statute is to be referred to what is commonly called the police power – a power which the State

> did not surrender when becoming a member of the Union under the Constitution. Although this court has refrained from any attempt to define the limits of that power, yet it has distinctly recognized the authority of a State to enact quarantine laws and "health laws of every description;" … According to settled principles the police power of a State must be held to embrace, at least, such reasonable regulations established directly by legislative enactment as will protect the public health and the public safety.
> *Jacobson v. Massachusetts*, at 24-25, *internal citations omitted.*

The *Jacobson* Court continued, stating that "the liberty secured by the Constitution of the United States to every person within its jurisdiction does not import an absolute right in each person to be, at all times and in all circumstances, wholly free from restraint. There are manifold restraints to which every person is necessarily subject for the common good. On any other basis organized society could not exist with safety to its members." *Jacobson,* at 26.

Michigan courts have adopted the policy goals espoused by *Jacobson,* and have held that the state has broad authority to enact legislature to protect the public health. In *Rogowski v. Detroit*, 374 Mich. 408 (1965), the Michigan Supreme Court upheld the City of Detroit's fluoridation ordinance, citing to *Jacobson* and stating "With respect to the chief controversy herein, whether the ordinance is a reasonable and lawful exercise of the police power and hence constitutional, it is fortunate, for our guidance, that the Supreme Court of the United States has spoken in *Jacobson v. Massachusetts*, 197 U.S. 11 (25 S Ct 358, 49 L ed 643) ." *Rogowski* at 417. *Rogowski* continued to quote *Jacobson* at great length, deferring to the policy

decisions reached by the legislature in stating "[t]he court would usurp the functions of another branch of government if it adjudged, as matter of law, that the mode adopted under the sanction of the State, to protect the people at large, was arbitrary and not justified by the necessities of the case." *Rogowski* at 419, *quoting Jacobson* at 25, 26, 28-30.

The ultimate conclusion of the *Rogowski* Court was that public health decisions made by the legislature were not to be second guessed by the court.

> Further, that proofs of the character which The Parents say they might have adduced on trial could not have changed the results because a difference of opinion, whether expert or lay, as to the merits or demerits of fluoridation with respect to public health presents a question for legislative, not judicial, determination. It follows that this case could be and was properly disposed of, as a question of law, by summary judgment. This follows, as well, from the above cited Michigan decisions because there was no issue of material or controlling facts, the so-called factual disputes actually being matters of opinion, relating to the efficacy or effects of fluoridation. Hence, they could not be decisive of whether the police power was properly exercised within constitutional limitations. *Rogowski* at 424.

While *Rogowski* was decided in part by looking at language from the Michigan Constitution of 1908, which was in effect when the initial lawsuit was filed, the Michigan Constitution of 1963 contains similar language, emphasizing the importance of the legislature's obligation to protect the public health. Article IV, Section 51 states: "The public health and general welfare of the people of the state are hereby declared to be matters of primary public concern. The legislature shall

pass suitable laws for the protection and promotion of the public health." Const. 1963, Art. IV, §51.

4. As an exercise of the state power to protect public health, the blood draw is not a search or a seizure.

Determining whether the drawing of a blood sample is a "seizure" in the manner contemplated by the Fourth Amendment is straightforward. The Supreme Court has made clear that seizures apply only to police detentions of one or more individuals. "Only when the officer, by means of physical force or show of authority, has in some way restrained the liberty of a citizen may we conclude that a 'seizure' has occurred." *Terry v. Ohio*, 392 U.S. 1 (1968). In *United States v. Mendenhall*, Justice Stewart first transposed this analysis into a test to be applied in determining whether "a person has been 'seized' within the meaning of the Fourth Amendment." *United States v. Mendenhall*, 446 U.S. 544 (1980). *Mendenhall* held that the police can be said to have seized an individual "only if, in view of all of the circumstances surrounding the incident, a reasonable person would have believed that he was not free to leave." *United States v. Mendenhall* at 544. The Parents have alleged no police action restraining them, nor have they alleged that their freedom of movement or action has been restricted in any way. They have not, therefore, been "seized."

5. Even if the newborn blood screening program is a search and seizure, it is not an unreasonable search and seizure.

Even if the drawing of blood from a newborn by a trained medical professional in a hospital setting constitutes a search for fourth amendment purposes, and not a valid exercise of the police power to protect public health, the search is entirely lawful, done pursuant to a valid medical procedure for valid public health reasons. As the United States Supreme Court has held, "the Fourth Amendment's proper function is to constrain, not against all intrusions as such, but against intrusions which are not justified in the circumstances, or which are made in an improper manner." *Schmerber v. California*, 384 U.S. 757 (1966) . As Justice Powell wrote in concurrence in *Rakas v Illinois*, 439 U.S. 128 (1978), "[t]he ultimate question, therefore, is whether one's claim to privacy from government intrusion is reasonable in light of all the surrounding circumstances." *Rakas* at 152. Here, the allegations raised demonstrate that the search in question is a blood draw from a newborn, performed by a medical professional within the first 24-36 hours of the child's life, for the purpose of screening for serious medical conditions. This is not unreasonable, as a matter of law, as the District Court correctly concluded.

The test to determine if a person has a protected Fourth Amendment privacy right is whether that person has a reasonable expectation of privacy in the area invaded by the government. *Katz v United States*, 389 U.S. 347 (1967) . The test was articulated by the Michigan Supreme Court in *People v Smith*, 420 Mich. 1 (1984),

as "whether the defendant had an expectation of privacy in the object of the search and seizure and whether that expectation is one that society is prepared to recognize as reasonable." *People v. Smith* at 28. In discussing the parameters of the expectation test, the *Smith* Court stated that "It offers no exact template that can be mechanically imposed upon a set of facts to determine whether or not standing is warranted. It does, however, provide the normal common-law value of general direction and practical flexibility. *People v. Smith*, at 26.

The Michigan Supreme Court in *People v. Perlos*, 436 Mich. 305 (1990), when addressing a motion to suppress a blood sample drawn by a medical professional and then given to the police, held:

> The "search" performed here, *i.e.*, the removal of the blood sample from defendant, was done strictly for purposes of medical treatment and not at the direction of the police, the prosecutor, or state agents. … We agree with the distinction drawn by the *England* Court and its conclusion that the Fourth Amendment was not implicated when defendants had their blood withdrawn for medical treatment. Certainly there are various medical reasons for a doctor to order an alcohol analysis on a patient.
> *People v. Perlos*, at 315).

In the *Perlos* and *England* cases[7], blood was drawn for medical reasons, by medical personnel, and not in connection with any police investigation, but the blood samples were eventually used in a police investigation. The Michigan Supreme Court held

[7] Both of these Michigan Court of Appeals cases were considered together by the Michigan Supreme Court.

this was not an unlawful search. In this case, blood was drawn by medical personnel, for medical reasons, in a health care setting, unrelated to any police or administrative investigation.

In the *Schmerber* case, the Supreme Court held that a blood test taken in a manner similar to the facts alleged here was entirely reasonable. *Schmerber* held:

> Finally, the record shows that the test was performed in a reasonable manner. Petitioner's blood was taken by a physician in a hospital environment according to accepted medical practices. We are thus not presented with the serious questions which would arise if a search involving use of a medical technique, even of the most rudimentary sort, were made by other than medical personnel or in other than a medical environment – for example, if it were administered by police in the privacy of the stationhouse. To tolerate searches under these conditions might be to invite an unjustified element of personal risk of infection and pain.
> *Schmerber* at 771-772.

In this case, the allegations demonstrate an entirely reasonable blood draw. The Michigan statute requires a medical professional to draw blood from an infant to test for medical conditions. The facts alleged in the Complaint do not complain of anything other than what the state statute requires: a blood sample taken by a medical profession in a health care environment. The blood draw described by the Parents in their First Amended Complaint is exactly the type of action the Supreme Court found to be reasonable in *Schmerberr*. This action is not unlawful, not unreasonable, does not require a warrant, and is not actionable under 42 U.S.C. §1983.

The Parents argue that *Dubbs v. Head Start, Inc.*, 336 F.3d 1194 (10th Cir. 2003) is the closest, most on point case. Aside from the fact that this is clearly untrue, given *Higgins*), *Spiering*, and *Doe v. Adams*)all address newborn infant blood screening programs, *Dubbs*, as the District Court correctly points out, is not on point, and certainly does not compel reversal of the District Court. In reviewing *Dubbs*, the District Court held:

> In Dubbs, the plaintiffs pled fourth and fourteenth amendment claims challenging a school's practice of requiring blood tests and physical examinations without parental consent. *Dubbs v. Head Start, Inc.*, 336 F.3d 1194 (10th Cir. 2003). The district court dismissed all of the claims either pursuant to Federal Rule of Civil Procedure 12(b)(6), or at summary judgment pursuant to Federal Rule of Civil Procedure 56. The 10th Circuit reversed. *Id*.
>
> Notably, however, the 10th Circuit did not express an opinion as to whether the parents' substantive due process rights were violated by the school program. Rather, the 10th Circuit took issue with the district court's reasoning inasmuch as it misapprehended the legal standard by failing to recognize that the parents' had a substantive due process right to control the upbringing (including the medical care) of their children. *Id*. at 1203. The court described this right as one which is deeply rooted in the nation's history and tradition and which falls within the sphere of protected liberty. *Id*. The district court erred in limiting its analysis to the "shocks the conscience" standard applicable to tortious conduct challenged under the fourteenth amendment. In other words, the district court failed to recognize the existence of the parents' fundamental right. The 10th Circuit reversed and remanded on this basis. *Id*. The 10th Circuit did not, however, opine as to whether that right was violated or what standard of scrutiny applied. *Id*. Thus, the *Dubbs* decision does not support Plaintiffs' contention that the blood testing in this case violated their substantive due process rights.
> (RE 50, p. 10-11, citing *Dubbs v. Head Start, Inc.*) .

Given that *Dubbs* does was decided on procedural grounds, not substantive grounds, and given that *Higgins v. Tex. Dep't of Health Servs*.), *Doe v. Adams*,) and *Spiering v. Heineman* not only looked at newborn blood screening programs on constitutional grounds and decided the matters on substantive grounds, they are of far more use when reviewing the Parents' First Amended Complaint and whether it was properly dismissed than *Dubbs* is. The District Court correctly concluded that *Dubbs* is inapplicable in this case, and it properly concluded that the First Amended Complaint failed to state a claim for violations of the fourth amendment, as a matter of law. The claims of fourth amendment violations were properly dismissed by the District Court, as the newborn blood screening program is entirely reasonable, neutrally applied to all newborns in Michigan, and serves a valuable public health purpose. Even if it is a search for fourth amendment purposes, it is not an unreasonable one, and not prohibited.

B. The Biobank Defendants did not violate the fourteenth amendment rights of either the Parents or the Infants.

Count II of The Parents' First Amended Complaint alleged that the Biobank Defendants violated the Infants' fourteenth amendment due process rights to liberty. The alleged violation of the Fourteenth Amendment by the Biobank Defendants, per The Parents' First Amended Complaint, is that the Defendants did not receive informed consent from The Parents prior to taking blood samples from the Infants.

No such violation has occurred. Under Michigan's Public Health Code, newborn screening is explicitly exempt from informed consent laws. Because no informed consent is required, and as this is a valid use of the state police power to protect public health – a power the fourteenth amendment does not restrict – dismissal was appropriate.

1. Fourteenth amendment scope and applicability to state public health laws.

To determine whether the newborn screening violates the Fourteenth Amendment rights of the Parents, the Courts apply a two-part test. As the Sixth Circuit has stated,

> Section 1983 imposes liability for violations of rights protected by the Constitution, not for violations of duties of care arising out of tort law. *See Baker v. McCollan*, 443 U.S. 137, 146, 61 L. Ed. 2d 433, 99 S. Ct. 2689 (1979). To state a cause of action under Section 1983 for violation of the Due Process Clause, Appellants must show that they have asserted a recognized liberty or property interest within the purview of the Fourteenth Amendment and that they were intentionally or recklessly deprived of that interest, even temporarily, under color of state law. *See Ingraham v. Wright*, 430 U.S. 651, 672, 51 L. Ed. 2d 711, 97 S. Ct. 1401 (1977).
>
> *In re Cincinnati Radiation Litig.*, 874 F. Supp. 796 (6th Cir. 1995).

For the sake of this Motion only, it is assumed that the The Parents can demonstrate a liberty interest.

Determining that a person has a "liberty interest" under the Due Process Clause does not end the inquiry, however, as the court must then determine whether

a person's constitutional rights have been violated by balancing the liberty interest against the relevant state interests. *In re Cincinnati Radiation Litig*, at 813, *citing Youngberg v. Romeo*, 457 U.S. at 321. Several types of state actions discussed above have been held to have not violated a person's constitutional rights. As noted in *In re Cincinnati Radiation Litig.* , compulsory vaccinations in *Jacobson v. Massachusetts*, 197 U.S. 11 (1905), compelled blood tests in *Schmerber v. California*, 384 U.S. 757 (1966), and even extractions of contraband material from the rectal cavity in *Revas v. United States*, 368 F.2d 703 (9th Cir. 1966) *cert. denied*, 386 U.S. 945, 87 S. Ct. 978, 17 L. Ed. 2d 875 (1967), have been upheld on a showing of clear necessity, procedural regularity, and minimal pain. *In re Cincinnati Radiation Litig.*, at 813. The newborn screening is a clear exercise of a valid, necessary state power, it is performed with procedural regularity, and minimal invasiveness.

2. Michigan has explicitly waived the common law right of informed consent for the newborn screening program, as it is entitled to do.

"In Michigan, the common law prevails except as abrogated by the Constitution, the Legislature, or this Court. Mich. Const. 1963, Art. 3, §7; *People v Aaron*, 409 Mich 672, 722-723; 299 NW2d 304 (1980); *People v Duffield*, 387 Mich 300, 308; 197 NW2d 25 (1972)." *People v Stevenson*, 416 Mich 383 (1982). Similarly, Michigan recognizes and adheres to the common-law right to be free from nonconsensual

physical invasions and the corollary doctrine of informed consent. *See, e.g., In re Rosebush*, 195 Mich App 675 (1992). However, Michigan law also holds that:

> It is axiomatic that the Legislature has the authority to abrogate the common law. *Hoerstman Gen Contracting, Inc v Hahn*, 474 Mich. 66, 74; 711 N.W.2d 340 (2006). Further, if a statutory provision and the common law conflict, the common law must yield. *Pulver v. Dundee Cement Co*, 445 Mich. 68, 75 n 8; 515 N.W.2d 728 (1994). Accordingly, this Court has observed:
>
> In general, where comprehensive legislation prescribes in detail a course of conduct to pursue and the parties and things affected, and designates specific limitations and exceptions, the Legislature will be found to have intended that the statute supersede and replace the common law dealing with the subject matter. [*Hoerstman Gen Contracting, supra* at 74, quoting *Millross v Plum Hollow Golf Club*, 429 Mich. 178, 183; 413 N.W.2d 17 (1987), citing 2A Sands, Sutherland Statutory Construction (4th ed), § 50.05, pp 440-441].
> *Trentadue v. Gorton*, 479 Mich. 378 (2007).

The Michigan Supreme Court has held that "[t]his Court has previously recognized that the Legislature's constitutional power to change the common law authorizes it to extinguish common-law rights of action." *O'Brien v. Hazelet & Erdal*, 410 Mich. 1 (1980).

The law governing screening of newborns for chronic and congenital conditions specifically states that informed consent is not required for the test, abrogating that common-law requirement. MCL 333.5431 (2) states: "The informed consent requirements of sections 17020 and 17520 do not apply to the tests required under subsection (1). The tests required under subsection (1) shall be administered and reported within a time and under conditions prescribed by the department. The

department may require that the tests be performed by the department." MCL 333.5431 (3). Thus, the Michigan state legislature has, as far as newborn screening is concerned, abrogated the common-law requirement of informed consent.

3. Newborn Screening Under the Michigan Public Health Code Does Not Violate the Fourteenth Amendment.

The question before the Court, then, is whether the newborn blood screening meets the criteria set forth buy the Sixth Circuit. It does, as it is a valid exercise of the public health authority, done with regularity, and minimal invasiveness. The policy disputed here requires "A health professional in charge of the care of a newborn infant or, if none, the health professional in charge at the birth of an infant shall administer or cause to be administered to the infant a test for" over 50 congenital diseases. MCL 333.5431 (1). The Parents acknowledge that the extent of the taking of blood from newborns is limited to taking five or six drops by pricking the heel while the infant is in the hospital or under the care of a midwife. (See, e.g., RE 26, Para. 87). The law governing screening of newborns for chronic and congenital conditions specifically states that informed consent is not required for the test. MCL 333.5431 (2) states: "The informed consent requirements of sections 17020 and 17520 do not apply to the tests required under subsection (1). The tests required under subsection (1) shall be administered and reported within a time and under conditions prescribed by the department. The department may require that the tests be performed by the department." MCL 333.5431 (3). By its own terms, the

Michigan Public Health Code "shall be liberally construed for the protection of the health, safety, and welfare of the people of this state." MCL 333.1111. It is important to note from the outset that this is not a criminal law and the blood is not taken for use in criminal proceedings, unlike *Schmerber* and *Revas*; in this instance, blood is taken for valid public health reasons.

In one of the earliest cases to address the interaction between state laws and the Fourteenth Amendment, the Supreme Court upheld San Francisco municipal laws requiring certain local certificates be obtained by business owners before they could operate, stating "But neither the [Fourteenth Amendment] – broad and comprehensive as it is – nor any other amendment, was designed to interfere with the power of the State, sometimes termed its police power, to prescribe regulations to promote the health, peace, morals, education, and good order of the people…" *Barbier v. Connolly*, 113 U.S. 27 (1885). The Supreme Court has continually upheld that position since *Barbier*., stating, for example,

> Changing local conditions create new local problems which may lead a state's people and its local authorities to believe that laws authorizing new types of public services are necessary to promote the general well-being of the people. The Fourteenth Amendment did not strip the states of their power to meet problems previously left for individual solution. *Everson v. Bd. of Educ.*, 330 U.S. 1 (1947), *citing Davidson v. New Orleans*, 96 U.S. 97, 103-104; *Barbier v. Connolly*, 113 U.S. 27, 31-32.; *Fallbrook Irrigation District v. Bradley*, 164 U.S. 112, 157-158.

The function of government is to serve the people and to enhance the quality of life. The broad purpose of all constitutional limits on government power is to ensure that

government does not stray from that role or abuse its power. *In re Cincinnati Radiation Litig* at 817.

As noted, the blood draws taken from newborns to screen for congenital disease or disorders are very clearly done to preserve the public health and are minimally invasive. As even the The Parents admit, only five or six drops of blood are drawn, and once the blood is drawn, the infants are screened for over 50 congenital conditions. This is performed by "A health professional in charge of the care of a newborn infant or, if none, the health professional in charge at the birth of an infant". MCL 333.5431 (1). If the results of a test comes back "positive, the results shall be reported to the infant's parents, guardian, or person *in loco parentis*." MCL 333.5431(3). The infant's parents can then determine what course of action to take regarding the infant's health.

The drawing of five or six drops of a newborn's blood to screen for over 50 congenital and/or chronic conditions is a minimally invasive use of the state police power to protect the public health. Much like in *Jacobson* and *Rogowski*, here we have a policy designed to uphold the core obligation of the Michigan state legislature: "The public health and general welfare of the people of the state are hereby declared to be matters of primary public concern. The Parents are correct that the Due Process Clause of the Fourteenth Amendment protects the "fundamental right" of parents to make decisions as to the care, custody and control of their

children. See, e.g., *Troxel v. Granville*, 530 U.S. 57, 65-66, 120 S. Ct. 2054, 147 L. Ed. 2d 49 (2000)(striking down a statute that authorized a court to grant any person the right to visit a child if such visitation was in the best interests of a child even if a fit parent thought otherwise). But it is equally true that "a state is not without constitutional control over parental discretion in dealing with children when their physical or mental health is jeopardized." *Parham v. J. R.*, 442 U.S. 584, 603, 99 S. Ct. 2493, 61 L. Ed. 2d 101 (1979)(even where parents agree to mental health commitment, children are entitled to the decision of a neutral fact finder to determine whether statutory requirements for admission are satisfied) (emphasis added). The Michigan legislature is granted that power under the Michigan constitution of 1963, which states, simply, that "The legislature shall pass suitable laws for the protection and promotion of the public health." Const. 1963, Art. IV, §51. They have done so here with MCL 333.5431 *et seq*). The Michigan newborn infant screening program is a law of neutral applicability, effecting all babies born in Michigan, designed to promote the public health and welfare through a minimally invasive process.

This is similar to *Spiering v. Heineman*, 448 F. Supp. 2d 1129 (D.Neb. 2006), which addressed a challenge to Nebraska's neonatal disease testing program. As the District Court for Nebraska pointed out in *Spiering*, "this 'constitutional control over parental discretion' when a child's safety is at issue exists for Nebraska and every other state, even where religious and parental rights are asserted in

tandem." *Spiering* at 1140, *citing Prince v. Massachusetts*, 321 U.S. 158, 166-167, 64 S. Ct. 438, 88 L. Ed. 645 (1944)(upholding child labor laws applied to custodian of a child who allowed minor to distribute religious literature; the "right to practice religion freely does not include liberty to expose [a] . . . child . . . to ill health or death.").

In upholding Nebraska's newborn infant screening program, the U.S. District Court for Nebraska held:

> The precedents of the Court thus recognize two competing values of equal worth: the right of parents to parent and the right of children to safety. It is not plausible that the Supreme Court would apply "strict scrutiny" and thus tilt the table in favor of the rights of parents and against the safety of children. That is all the more true where, as here, the medical evidence establishing a "life and death" reason for testing infants is undisputed and, still further, where a parent's objection to either the test or treatment following the test will be resolved by a court after a hearing. As a result, it is not surprising that the plaintiffs have given me no case which stands as a precedent for the proposition they advance. See, e.g., Eugene Volokh, Parent-Child Speech and Child Custody Speech Restrictions, 81 N.Y.U. L. Rev. 631, 675 (2006)(recognizing that the Supreme Court's jurisprudence on "the substantive due process right to control the upbringing of one's child" has had "fairly modest force"; "The Supreme Court has never clearly articulated when they can be restrained. Lower courts have often assumed that various reasonable restrictions on such rights would be permissible, and that such restrictions need not be judged under the 'strict scrutiny' test.")(citing Anaya; other citations omitted). *Spiering* at 1140.

The instant case is fundamentally similar to *Spiering*, *Higgins*), and *Doe v. Adam*)*s*, all of which reviewed neonatal blood screening programs and upheld them. In

Michigan, you have a law of universal, neutral applicability that requires all newborns to be screened for congenital diseases within 24-36 hours of birth. This law serves an important public health purpose, and is authorized by Michigan's constitution. It is minimally invasive, requiring only a small prick to the heel of an infant, and 5-6 drops of blood to be taken. This program is largely, if not entirely identical to the programs upheld in Texas, Nebraska, Indiana and other states. The District Court correctly concluded that this is not a fourteenth amendment violation and dismissed those counts. This Court should affirm that decision.

III. The Parents' Claims that the District Court Improperly Considered Evidence Outside the Pleadings in Deciding the Motions to Dismiss Misunderstands the Legal Standards Applicable and Should be Disregarded.

The Biobank Defendants did not attach any outside exhibits to their Motion to Dismiss. Nevertheless, because the Parents spend a considerable amount of space complaining over whether the District Court improperly considered evidence not included in the pleadings when deciding the motions to dismiss, and because the District Court largely considered the Motions to Dismiss together, a brief comment is necessary. Putting aside the fact that the primary exhibits complained about, forms filled out by the parents of the Infants in this case, are known by the Parents and central to the case, thus allowing the District Court to look at them under *Gavitt v. Born*, 835 F.3d 623 (6th Cir. 2016), the principal fact misunderstood by the Parents

is the distinction between what the courts may review when looking at a motion filed under Fed.R.Civ.P. 12(b)(1), and one under Fed.R.Civ.P 12(b)(6) .

The Parents assert that the District Court may never view materials outside of the pleadings in deciding a motion to dismiss. One of the grounds on which the State Defendants moved for dismissal was Fed.R.Civ.P. 12(b)(1). Under that rule, the Court may consider materials outside of the pleadings. Moreover, the documents complained about are forms signed by the Parents. The only reason the Parents could complain about their own documents being used against them is that they are acting in bad faith. They knew that they had options to destroy the Infants' DBS cards, or restrict their use, and failed to do so. They then have attempted to hide that fact from the court by not attaching them as exhibits, despite referencing them throughout the First Amended Complaint. (RE 26, ¶46, e.g.). This is nothing more than sound and fury, and the Court should disregard the objections to the State Defendants' exhibits.

CONCLUSION AND RELIEF SOUGHT

The District Court correctly concluded that Appellants lacked standing to even bring a claim that their fourteenth amendment rights had been violated. The Appellants did not plead, and could not demonstrate, in any of the three Complaints they filed, a concrete and non-speculative injury caused by the storage of the DBS cards. Instead, their claims relied only on speculation of what *could* happen, not allegations of what *did* happen. To the extent the blood samples have been retained by MDHHS and held at the BioBank, the Parents, as legal guardians of the Infants in the case, had options available at their disposal to resolve this without litigation. The parents could have withdraw their consent to the use of the DBS cards for medical testing, which some of them had given, and each of them could have requested that the DBS cards be destroyed altogether. They have not taken these steps, and thus cannot demonstrate that they have been harmed by the storage of the DBS cards.

Even if this Court disagrees with the District Court and finds that the Appellants do have standing to bring their claim, the District Court correctly determined that as a matter of law, there has been no unlawful search or seizure, only the collection of a blood sample in a medical setting, by a medical professional, as part of a medical procedure. This Court should affirm that conclusion. Programs similar to Michigan's newborn screening program have been challenged across the

country in recent years, on the same bases that Appellants allege in their First Amended Complaint. Time after time, the courts reviewing these programs have looked at them and repeatedly upheld them. Finally, repeatedly, and for over a century, case law has held that the Constitution does not strip states of their ability to pass laws to protect the public health and welfare. Despite Appellants' claims to the contrary, this use of the police power is not limited to times of crisis. The District Court recognized this and dismissed Appellants' First Amended Complaint. This Court should affirm that dismissal.

For the reasons stated above, Appellees MICHIGAN NEONATAL BIOBANK, INC. and DR. ANTONIO YANCEY in his capacity as Director of the Michigan Neonatal BioBank, Inc. hereby respectfully request that this Honorable Court AFFIRM the decision of the United States District Court of the Eastern District of Michigan dismissing the First Amended Complaint for lack of standing and for failure to state a claim.

Respectfully Submitted,

PEAR SPERLING EGGAN & DANIELS, P.C.

Dated: November 5, 2018

BY: /s/ Jeremy C. Kennedy
Jeremy C. Kennedy (P64821)
Jerold E. Lax (P
Attorneys for Defendant Michigan Neonatal BioBank, Inc. and Dr. Antonio Yancey in his professional capacity only

CERTIFICATE OF COMPLIANCE

1. This brief complies with the word limit set forth in Fed.R.App.P. 32(a)(7)(B)(i) because, according to the word-count feature of Microsoft Word 365 MSO, it contains 12,168 words, excluding the parts of the brief exempted by Fed.R.App.P. 32(a)(7)(B)(iii).

2. This brief complies with the typeface requirements of Fed. R. App. P. 32(a)(5) and the type style requirements of Fed.R.App.P. 32(a)(6) because it has been prepared in a proportionally spaced typeface using Microsoft Office Word 365 MSO in Times New Roman 14 point font.

Respectfully submitted,

/s/ Jeremy C. Kennedy

Jeremy C. Kennedy
Jerold Lax
PEAR SPERLING EGGAN & DANIELS, P.C.
24 Frank Lloyd Wright Drive, Ste. D2000
Ann Arbor, Michigan 48105
Telephone: 734-665-4441
E-mail: jkennedy@psedlaw.com
Counsel for Michigan Neonatal BioBank, Inc. and Dr. Antonio Yancey in his capacity as director of the Michigan Neonatal Biobank, Inc. Only

Dated: November 5, 2018

CERTIFICATE OF SERVICE

Jeremy C. Kennedy, Counsel for Michigan Neonatal BioBank, Inc. and Dr. Antonio Yancey in his capacity as director of the Michigan Neonatal Biobank, Inc. Only, hereby certifies that on November 5, 2018, he caused the foregoing document to be served through the electronic filing system the attorneys/parties of record.

/s/ Jeremy C. Kennedy

Jeremy C. Kenney
Counsel for Michigan Neonatal BioBank, Inc. and Dr. Antonio Yancey in his capacity as director of the Michigan Neonatal Biobank, Inc. Only
jkennedy@psedlaw.com

DESIGNATION OF RELEVANT DISTRICT COURT DOCUMENTS

RE.	Page ID Range	Description of the Documents
26	#300-453	First Amended Complaint, including Exhibits A-R
26-3	#336-337	First Amended Complaint, Exhibit B
26-11	#364-365	First Amended Complaint, Exhibit J
26-12	#366	First Amended Complaint, Exhibit K
32	#477-532	Motion to Dismiss (State Defendants)
33	#583-624	Motion to Dismiss (BioBank)
34	#625-644	Motion to Dismiss (Yancey)
45	#696-741	Response to Motion to Dismiss
50	#825-846	Opinion
51	#847	Judgment
52	#848	Notice of Appeal
47	#797-805	Reply to Response to Motion to Dismiss (BioBank)
49	#815-824	Reply to Response to Motion to Dismiss (State Defendants)