UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF MICHIGAN
SOUTHERN DIVISION

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 LYNETTE 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.

Case. No. 18-10472-TLL-PTM

Honorable Thomas L. Ludington
Mag. Judge Patricia T. Morris

v.

MICHIGAN DEPARTMENT OF HEALTH AND HUMAN SERVICES; NICK LYONS, sued in his official and individual capacities; DR. SANDIP SHAH, sued in his official and individual capacities; DR. SARAH LYON-CALLO, sued in her official and individual capacities; MARY KLEYN, sued in her official and individual capacities; MICHIGAN NEONATAL BIOBANK, INC also known as MICHIGAN NEONATAL BIOREPOSITORY; DR. ANTONIO YANCEY, sued in his official and individual capacities,

Defendants.

DEFENDANTS MICHIGAN NEONATAL BIOBANK, INC. AND DR. ANTONIO YANCEY'S MOTION TO DISMISS PLAINTIFFS' FIRST AMENDED COMPLAINT

DEFENDANTS MICHIGAN NEONATAL BIOBANK, INC. AND DR. ANTIONIO YANCEY'S MOTION TO DISMISS PLAINTIFFS' FIRST AMENDED COMPLAINT

NOW COME the Defendants, MICHIGAN NEONATAL BIOBANK, INC. and DR. ANTONIO YANCEY in his capacity as Director of the Michigan Neonatal BioBank, and hereby moves that this Honorable Court dismiss the claims brought against them in Plaintiff's First Amended Complaint, pursuant to Rule 12(b)(6) of the Federal Rules of Civil Procedure. Plaintiffs lack Article III standing to bring this Complaint. The drawing of blood for medical purposes is not a search or seizure, or, alternatively, is not unconstitutional. Furthermore, the blood draw and storage of blood was consented to by the Parents. The BioBank Defendants rely on the facts and law cited in their attached Brief in Support of this Motion, and incorporate same herein.

The BioBank Defendants sought concurrence in this Motion from Plaintiffs' counsel pursuant to Local Rule 7.1, but same was not obtained.

Respectfully Submitted,

PEAR SPERLING EGGAN & DANIELS, P.C.

Dated: May 29, 2018

By: /s/ Jeremy C. Kennedy

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Defendants.

BRIEF IN SUPPORT OF DEFENDANT MICHIGAN NEONATAL BIOBANK, INC. MOTION TO DISMISS PLAINTIFFS' FIRST AMENDED COMPLAINT

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SUMMARY OF ISSUES AND RELIEF SOUGHT

Issue I:

Do Plaintiffs' lack Article III standing to bring this 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*
>
> This Court Should Answer: *Yes*

Issue II:

Does the drawing of blood from a newborn for the purpose of medical screening constitute a valid use of the state police power to protect public health, and not an illegal search or seizure?

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

Issue III:

Does the drawing of blood from a newborn for the purpose of medical screening constitute a valid use of the state police power to protect public health, and not a violation of a party's due process rights under the Fourteenth Amendment?

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

Issue IV:

If the parents or legal guardians of the minor children consented to the retention of the blood drawn, have they waived any claim that the search and/or seizure is unlawful?

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

This Court Should Answer: *Yes*

STANDARD OF REVIEW

A motion to dismiss pursuant to Rule 12(b)(6) tests the legal sufficiency of the complaint. *RMI Titanium Co. v. Westinghouse Elec. Corp.*, 78 F.3d 1125, 1134 (6th Cir. 1996). Fed. R. Civ. P. 12(b)(6) allows dismissal for "failure to state a claim upon which relief can be granted." 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:

> The Supreme Court has recently clarified the law with respect to what a plaintiff must plead in order to survive a Rule 12(b)(6) motion. *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 127 S. Ct. 1955, 167 L.Ed.2d 929 (2007). The Court stated that "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 1964–65 (citations and quotation marks omitted).

Additionally, 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).

INTRODUCTION

One of the most valuable health tools developed over the past fifty years has been newborn screening, which allows doctors to detect the presence of rare disorders in newborns, allowing them to receive necessary treatment as early as possible. Over the years, the process, which requires a small amount of blood to be taken from a baby's heel within the first 24-36 hours of life, has been refined to detect the presence of over 50 different medical disorders, some of which are quite serious. The Plaintiffs in the matter come to this Court seeking to undo this good work, claiming that a valid medical program is, in fact, an unlawful search and seizure, and seeking damages for alleged constitutional violations.

Plaintiffs' claims are lacking basis in fact and are not supported by the existing law. Furthermore, to the extent they seek injunctive relief, they can obtain the requested relief – destruction of the dried blood spot cards – by simply requesting that the Michigan Department of Health and Human Services destroy the cards. Furthermore, regarding Michigan Neonatal Biobank, Plaintiffs lack standing, have failed to show a search or seizure – let alone an unlawful one – occurred, and perhaps most importantly have consented to the Biobank storing the dried blood spot cards. Plaintiffs have no case. The claims against Michigan Neonatal Biobank, Inc. and Dr. Antonio Yancey in his capacity as its Director (collectively the "BioBank Defendants") should be dismissed with prejudice.

STATEMENT OF FACTS

For the purposes of this motion, all well-pled allegations made by the Plaintiffs shall be assumed, *arguendo*, to be true. The BioBank Defendants do not, by way of this Motion, admit that the allegations are true.

Plaintiffs in this action are each the parents-guardians ("Parents") of one or more children born in the State of Michigan. Since at least 1987 one or more of the Defendants – Plaintiffs do not specify which Defendants – 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.

Relevant to this case, Plaintiffs 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. Plaintiffs 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. (See, e.g., First Amended Complaint, Para. 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. 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 to the infant a test' for certain diseases, see MCL 333.5431(1)."[1] Plaintiffs' 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. The First Amended Complaint also alleges that parents are charged a fee for the cost of MDHHS undertaking the seizing, storage, and testing of the blood spots of their respective Infants, though they do not allege they 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

[1] 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.

Lyon-Callo, and/or Mary Kleyn. 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.[2] Per the Plaintiffs' 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. Regardless of whether those blood spots tested positive for any of the 50+ maladies, disorders, or diseases, MDHHS retained the remaining blood spots indefinitely. Defendant Michigan Neonatal Biobank, Inc. ("Biobank"), a nonprofit corporation that receives all or nearly all its funding from the State of Michigan, stores the DBS for MDHHS. Plaintiffs allege that this funding is provided to indefinitely store the Infants' blood and to conduct tests on the Infants' blood, including for medical studies, laboratory equipment calibration, and other uses. Plaintiffs 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 the Parents an option to donate their infants' blood to medical research, and admit they signed the document, but claim not to have understood what they were signing. (First Amended Complaint ¶48-49). Plaintiffs contend that they were

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

never presented with the option to simply opt out of the blood draw before it occurred, the use of the blood spots to create the DBS cards, the medical testing, or otherwise.

Plaintiffs 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. 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.

Plaintiffs’ primary concern is 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.” (First Amended Complaint, Para. 78). They are 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]." (First Amended Complaint, Para. 82). Plaintiffs 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. Plaintiff claims 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.[3] No support is made to back this allegation; it is purely speculative.

[3] There are, of course, several statutes that protect private health and genetic information, such as the Health Insurance Portability and Accountability Act or the Genetic Information Nondiscrimination Act of 2008. The Court may take judicial notice of the impact of those statutes if it so chooses.

ARGUMENT

I. PLAINTIFFS LACK STANDING TO BRING THIS ACTION

A. 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 plaintiffs 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 Plaintiffs cannot show that there has been an injury in fact that it concrete and particularized and actual or imminent. They lack constitutional standing, and their case should be dismissed.

B. Plaintiffs Have Not Pled 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. For the purposes of this motion, 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 there is no concrete in jury alleged. 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.

C. Plaintiffs' Alleged Injuries Are Conjecture

Plaintiffs' Complaint further fails to demonstrate any actual or imminent harm. "Actual or imminent" damages require 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 Plaintiffs indicated that they are seeking injunctive relief because they are 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]." (First Amended Complaint, Para. 82). Plaintiffs 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. Plaintiffs 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 by Plaintiffs to support their Complaint.

Exhibit B to Plaintiffs' 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.
> (Complaint, Ex. B, emphasis supplied).

Additionally, under MCL 333.5331, 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.

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. Plaintiffs have not alleged any non-speculative harm, and therefore do not have standing to sue. Their claim against the Biobank Defendants should be dismissed for lack of standing under Article III of the Constitution.

II. THE BIOBANK DEFENDANTS DID NOT VIOLATE THE FOURTH AMENDMENT

A. The Blood Draws and Screening for Chronic Medical Disorders Are 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.

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). 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.

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).

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).

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 Plaintiffs' 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 Complaint, Ex. B). The Parents in this matter have not elected to opt out of testing, and they have not requested the DBS cards be destroyed. As will be shown, the actions complained of here are neither unlawful, nor are they a "search" or a "seizure" in the manner protected by the Fourth Amendment. For the reason, the claims against the Biobank should be dismissed as a matter of law.

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

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

clear that the blood draw complained of in this suit was not intended as a search or seizure.

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 plaintiffs 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.

The blood draws taken from newborns to screen for congenital disease or disorder are very clearly done to preserve the public health, and are squarely within the authority of the legislature. As the Plaintiffs allege, once blood is drawn, the infants are screened for over 50 congenital conditions. 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*. A person is in compliance with this subsection if the person makes a good faith effort to report the positive test results to the infant's parents, guardian, or person in loco parentis." MCL 333.5431(3). Further, the Michigan process is overseen by a committee of ten (10) individuals. 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. As a matter of law, the newborn blood screening is a valid public health statute, not a "search" subject to the fourth amendment. Accordingly, there is no cause of action under 42 U.S.C. §1983.

B. As an Exercise of the State Power to Protect Public Health, the Blood Draw is not a Search or a Seizure.

1. 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[4] 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 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."

2. The Blood Draw is Not 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

[4] "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.

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). Under *Mendenhall*, 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. Plaintiffs 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."

C. In The Alternative, The Alleged Search and Seizure Was Lawful.

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. The seizure, apparently, consists of MDHHS retaining these specimens.

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[5], 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 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

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

> 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 Plaintiffs in their First Amended Complaint is exactly the type of action the Supreme Court found to be reasonable in *Schmerber*. This action is not unlawful, not unreasonable, does not require a warrant, and is not actionable under 42 U.S.C. §1983. Plaintiffs' First Amended Complaint against the Biobank Defendants should be dismissed.

III. THE BIOBANK DEFENDANTS DID NOT VIOLATE THE FOURTEENTH AMENDEMENT.

Count II of Plaintiffs' First Amended Complaint alleges 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 Plaintiffs' First Amended Complaint, is that the Defendants did not receive informed consent from Plaintiffs 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 – Count II should be dismissed.

A. Fourteenth Amendment Scope and Applicability to State Public Health Laws.

To determine whether the newborn screening violates the Fourteenth Amendment rights of the Plaintiffs, 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, Plaintiffs 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 Plaintiffs 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.

B. 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). Plaintiffs 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., First Amended Complaint, 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 Plaintiffs 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 legislature shall pass suitable laws for the protection and promotion of the public health." Const. 1963, Art. IV, §51.They have done so here; the laws in question do not impact the constitutional rights of the Infants, and are valid to protect and promote the public health and welfare. There is no violation of the fourteenth amendment, and Count II of Plaintiffs' First Amended Complaint should be dismissed.

IV. PLAINTIFFS OR THEIR LEGAL GUARDIANS CONSENTED TO THE RETENTION OF DRIED BLOOD SPOTS.

As Exhibits B and J of Plaintiffs' 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." (First Amended Complaint, Ex. B). 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. (First Amended Complaint, Ex. B). Further, as Plaintiffs' 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)." (First Amended Complaint, Ex. J).[6]

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, Plaintiffs 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." (First Amended

[6] 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 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.

Complaint, Ex. J). Plaintiffs 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 harm. Accordingly, all claims as to the Biobank should be dismissed, as the Biobank was acting in accordance with the scope of any consent given by the Parents.

V. AS THERE IS NO CONSTITUTIONAL VIOLATION, THERE IS NO CONSPIRACY, AS A MATTER OF LAW.

To state a claim for civil conspiracy under §1983, plaintiffs have to show a deprivation of a constitutional right as a result of the alleged conspiracy. This is because the gist of the cause of action was the deprivation of a right, not the conspiracy. "By its terms, §1983 creates no substantive rights; it merely provides remedies for deprivations of rights established elsewhere." *Gardenhire v. Schubert*, 205 F.3d 303, 310 (6th Cir. 2000). In this case, Plaintiffs cannot state a claim for a §1983 conspiracy in because they cannot show any deprivation of a federally-protected right. Because a deprivation of a federal constitutional right is an essential element of a §1983 conspiracy claim, and Plaintiffs cannot meet this standard, Plaintiffs' alleged §1983 conspiracy claim must be dismissed.

CONCLUSION AND RELIEF SOUGHT

Plaintiffs' First Amended Complaint against Michigan Neonatal Biobank, Inc. and Dr. Antonio Yancey fails as a matter of law and should be dismissed. The facts alleged in support of the counts against Michigan Neonatal Biobank, Inc., do not provide sufficient basis to demonstrate standing to bring an Article III claim, as they fail to demonstrate a concrete and non-speculative injury. Even if the Plaintiffs do have standing, 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. 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, consented to the withdrawal and storage of blood, and have not taken the allowed steps to have the dried blood spot cards either restricted from research, or destroyed entirely.

As to the claims of violations of the Fourteenth Amendment rights of the Infants, the Fourteenth Amendment does not create substantive rights separate from any other provision of the Constitution, nor does it hold state actors to standards separate from the standards to which federal actors are held. Michigan's Public Health Code specifically states that informed consent is not required to perform the initial newborn screening for chronic disease. Case law holds,

repeatedly, and for over a century, that the Fourteenth Amendment does not strip states of their ability to pass laws to protect the public health and welfare.

For the reasons stated above, the claims against Defendant MICHIGAN NEONATAL BIOBANK, INC. and DR. ANTONIO YANCEY in his capacity as Director of the Michigan Neonatal BioBank, Inc. should be dismissed in their entirety.

Respectfully Submitted,

PEAR SPERLING EGGAN & DANIELS, P.C.

Dated: May 29, 2018 BY: /s/ Jeremy C. Kennedy
Jeremy C. Kennedy (P64821)
Attorneys for Defendant Michigan Neonatal BioBank, Inc. and Dr. Antonio Yancey in his professional capacity only

CERTIFICATE OF SERVICE

I hereby certify that on May 29, 2018, I caused the electronic filing of the foregoing paper with the Clerk of the Court using the ECF system which will send notification of such filing to all attorneys and parties who are on the list to receive notifications for this case.

/s/ Jeremy C. Kennedy
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