

UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF MICHIGAN
NORTHERN 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
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,

v

MICHIGAN DEPARTMENT OF
HEALTH AND HUMAN SERVICES;
NICK LYON, 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; HARRY HAWKINS, sued in
his 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.

No. 18-cv-10472

HON. THOMAS L. LUDINGTON

MAG. JUDGE PATRICIA T.
MORRIS

**STATE DEFENDANTS' MOTION
TO DISMISS FIRST AMENDED
COMPLAINT**

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**STATE DEFENDANTS' MOTION TO DISMISS FIRST AMENDED
COMPLAINT BASED ON FEDERAL RULES OF CIVIL PROCEDURE
12(b)(1) AND 12(b)(6)**

Pursuant to Fed. R. Civ. P. 12(b)(1) and (6), Defendants the Michigan Department of Health and Human Services (MDHHS), Nick Lyon, Dr. Sandip Shah, Sarah Lyon-Callo, and Mary Kleyn (collectively, “State Defendants”) move this Court to dismiss Plaintiffs’ First Amended Complaint. State Defendants say in support:

1. Plaintiffs lack standing to bring Counts I, II, IV and V. They lack standing to bring Counts I and II because they are based on the children’s rights as “competent persons” to have their parents or guardians make medical decisions on their behalf, and no such absolute right exists under the Fourteenth Amendment. As to Counts IV and V regarding storage of residual blood samples, they have no injury or causation and there is nothing this Court can redress.

2. Defendant MDHHS, a state agency, and the individual State Defendants sued in their official capacities for money damages or retroactive relief, are entitled to Eleventh Amendment immunity.

3. Plaintiffs do not meet the factors for injunctive relief, and this Court should decline to exercise its jurisdiction to grant the requested declaratory relief.

4. Alternatively, with respect to any remaining claims, Plaintiffs fail to state a claim on which relief may be granted because neither the initial heel stick and testing nor the storage of residual blood samples violates the Fourteenth or Fourth Amendments or constitutes a conspiracy to violate Plaintiffs’ Fourth

Amendment rights. And State Defendants are entitled to qualified immunity as to all money-damages claims against them in their individual capacities.

5. Pursuant to E.D. Mich. L.R. 7.1(a), counsel for State Defendants contacted counsel for Plaintiffs on May 29, 2018, and there was a conference in which counsel explained the nature of this motion and its legal basis and requested, but did not obtain, concurrence in this motion.

WHEREFORE, for the reasons set forth in this motion and the attached brief, State Defendants ask this Court to grant their motion under Rule 12(b)(1) or 12(b)(6), and dismiss, with prejudice, Plaintiffs' First Amended Complaint against them in its entirety.

Respectfully submitted,

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Dated: May 29, 2018

CERTIFICATE OF SERVICE

I hereby certify that on May 29, 2018, I electronically filed the above document(s) with the Clerk of the Court using the ECF System, which will provide electronic copies to counsel of record.

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**BRIEF IN SUPPORT OF STATE
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**BRIEF IN SUPPORT OF STATE DEFENDANTS' MOTION TO DISMISS
FIRST AMENDED COMPLAINT BASED ON FEDERAL RULES OF
CIVIL PROCEDURE 12(b)(1) AND 12(b)(6)**

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CONCISE STATEMENT OF ISSUES PRESENTED

1. Plaintiffs do not have an injury to their liberty interests (Counts I and II) where children possess no absolute right to have their parents or guardians make medical decisions for them, and where no Plaintiffs' stored blood spots have been used in any manner or "sold" to a third-party. Plaintiffs have no injury-in-fact, causation, or redressability based on storage (Counts IV and V) where parents can request destruction of residual samples. Plaintiffs lack standing to bring Counts I, II, IV, and V.
2. State agencies such as MDHHS have Eleventh Amendment immunity, regardless of the relief sought, and state officials in their official capacities have Eleventh Amendment immunity unless the relief sought is prospective injunctive relief. Plaintiffs' claims against MDHHS, and their claims for money damages or retroactive relief against the individually-named State Defendants in their official capacities, are barred by the Eleventh Amendment.
3. Plaintiffs have not pled facts establishing that the unconstitutional harm they allege will recur and cause an injury specific to them, and the injunctive-relief factors also weigh in State Defendants' favor. The *Grand Trunk* factors for declaratory relief likewise weigh in State Defendants' favor. Plaintiffs are not entitled to injunctive relief, and this Court should decline to issue declaratory relief.
4. Children do not have an absolute right to have their parents or guardians make medical decisions for them; it is well-established that the State can intervene to protect the child. Plaintiffs have failed to state a claim that State Defendants have violated their Fourteenth Amendment rights.
5. There is no Fourth Amendment violation because it is not settled law that government-based medical procedures conducted for purely medical, non-criminal purposes are a search, and even if the initial heel stick and testing *is* a search, it is not an unreasonable one. Subsequent storage of the blood samples is also reasonable, especially where protections are in place and parents can request destruction of these samples. And there can be no conspiracy where Plaintiffs have not alleged facts supporting the elements of a conspiracy. Plaintiffs

have failed to state a claim that State Defendants have violated their Fourth Amendment rights.

6. Not only has there been no violation of Fourth or Fourteenth Amendment rights, but there also is no clearly established law that would have put reasonable state employees in State Defendants' positions on notice that the taking, testing, and storing of Plaintiffs' blood samples—pursuant to a state-mandated program that is designed to protect important health interests and that allows for the destruction of residual samples—violates constitutional rights. Plaintiffs have failed to plead in avoidance of State Defendants' qualified immunity as to the money-damages claims against them in their individual capacities.

CONTROLLING OR MOST APPROPRIATE AUTHORITY

- *Lujan v. Defs. of Wildlife*, 504 U.S. 555 (1992).
- *McKay v. Federspiel*, 823 F.3d 862 (6th Cir. 2016).
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- *Nat'l Treasury Employees Union v. Von Raab*, 489 U.S. 656 (1989).
- *Washington v. Glucksberg*, 521 U.S. 702 (1997).
- *EJS Properties, LLC v. City of Toledo*, 698 F.3d 845 (6th Cir. 2012).
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- *Anderson v. Creighton*, 483 U.S. 635 (1987).
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- *Higgins v. Texas Dep't of Health Servs.*, 801 F. Supp. 2d 541 (W.D. Tex. 2011).
- *Spiering v. Heineman*, 448 F. Supp. 2d 1129 (D. Neb. 2006)

INTRODUCTION

The entire country recognizes that newborn screening is important to public health. All 50 states have implemented screening programs—many partially funded by, and all endorsed by, federal legislation—to test newborns for serious or fatal medical disorders that can be prevented or treated with early intervention.

Michigan law mandates taking newborn blood samples, testing them for disorders such as sickle cell anemia, phenylketonuria, and hypothyroidism, and storing them for quality-control and approved medical research. Plaintiffs concede that this program is “a noble public policy idea” (R. 26, 1st Am. Compl. ¶ 2, Pg. ID# 301.) And parents can request that their child’s residual samples be destroyed entirely once the newborn screening tests are completed (i.e., never stored), that previously-stored samples be destroyed entirely, or that they be stored but not used for research—options that are central to State Defendants’ arguments here. Nevertheless, Plaintiffs allege that the initial heel stick, testing, and storage violate their Fourth and Fourteenth Amendment rights, and they request not only declaratory and injunctive relief but also money damages.

Plaintiffs’ claims fail basic jurisdictional requirements. They lack standing to bring Counts I and II because the asserted right does not exist, and to bring Counts IV and V because there is no injury, causation, or redressability related to storage. And all claims against the Department and the claims against the

individual State Defendants in their official capacities for money damages or retroactive relief are barred by the Eleventh Amendment. Also, Plaintiffs are not entitled to injunctive relief, nor should this Court grant declaratory relief.

Even if this Court reaches the merits, any remaining claims fail. There are no due-process violations because a child does not have an absolute liberty interest in having their parent make medical decisions on their behalf. Michigan can intervene for the child's medical welfare, and its newborn screening program is rationally related to early detection, treatment, and prevention of childhood disease. The initial heel stick and testing are arguably not a Fourth Amendment search, and even if they are, the search is reasonable because this screening is minimally invasive and the State's interest is compelling. The storage is likewise arguably not a search, and in any case is reasonable given the protections in place and the ability to request destruction of stored samples. Finally, State Defendants are entitled to qualified immunity on all individual-capacity claims for money damages.

STATEMENT OF FACTS

Newborn screening tests for (and provides follow-up and medical management to infants with) certain rare, insidious medical disorders that can result in serious disability or death.¹ (Ex. 1, *MDHHS Michigan Newborn Screening*

¹ The Newborn Screening Clearinghouse, housed on the website BabysFirstTest[®], is supported by the Health Resources and Services Administration (HRSA) of the U.S. Department of Health and Human Services and provides valuable information

Questions and Answers, p. 1.)² Newborn screening is so beneficial to public health that all 50 states, Washington D.C., and Puerto Rico have implemented screening programs, many partially funded by, and all endorsed by, federal legislation. *See Baby's First Test, Newborn Screening 101*, available at <http://www.babysfirsttest.org/newborn-screening/screening-101> (last accessed May 25, 2018); *see also* 42 U.S.C. § 300b-8 – § 300b-11; § 300b-16.

Michigan began its newborn screening program (NBS) in 1965. (Ex. 1, p 1.) The Michigan Legislature passed, and the Governor signed, 1965 PA 119, now codified at Mich. Comp. Laws § 333.5431, which required that physicians in charge of the care of a newborn test for the disorder phenylketonuria. Michigan's NBS has evolved greatly since that early beginning, and by 1978 the statute was amended to allow additional diseases to be tested and to provide that a person who

to the public about newborn screening performed across the country. Available at <http://www.babysfirsttest.org/> (last accessed May 25, 2018).

² The Sixth Circuit has “recognized that if a plaintiff references or quotes certain documents, or if public records refute a plaintiff's claim, a defendant may attach those documents to its motion to dismiss, and a court can then consider them in resolving [a] Rule 12(b)(6) motion without converting the motion to dismiss into a Rule 56 motion for summary judgment[]” because “[f]airness and efficiency require this practice.” *KBC Asset Mgmt. N.V. v. Omnicare, Inc.* 769 F.3d 455, 466 (6th Cir. 2014); *see also Gavitt v. Born*, 835 F.3d 623, 640 (6th Cir. 2016) (same). Further, Federal Rule of Evidence 201 authorizes the court to take judicial notice of adjudicative facts, which courts have determined include “[p]ublic records and government documents available from reliable sources on the Internet, such as websites run by governmental agencies.” *United States ex rel. Modglin v. DJO Global Inc.*, 48 F. Supp. 3d 1362, 1381 (C.D. Cal. 2014) (citation omitted).

violates the statute's newborn screening requirements is guilty of a misdemeanor.³ *Id.*; Mich. Comp. Laws § 333.5431(5).

To ensure the quality, consistency, and efficiency of the NBS through centralized testing, the statute was amended in 1987 to permit MDHHS to require that NBS testing be performed at the MDHHS Laboratory.⁴ *Id.*; Mich. Comp. Laws § 333.5431(2). In 2000, the statute was again amended to, *inter alia*, expressly exempt NBS testing from informed consent requirements and mandate MDHHS to: (1) develop a schedule for the retention and disposal of residual dried blood spots (DBS) after newborn screening is completed; (2) enable medical research using de-identified residual DBS during the established retention period; and (3) publish a pamphlet explaining the NBS program and statutory requirements, including the retention and disposal period for residual DBS and that they may be used for medical research. Mich. Comp. Laws § 333.5431(2), (7), and (8).

³ Numerous new disorders have been added to the newborn screening blood spot panel, increasing from one in 1965 to fifty-four today (plus hearing and critical congenital heart disease tested through other means). (R. 26-2, 1st Am. Compl., Ex. A, Pg. ID# 335.) Disorders are added through operation of the Newborn Screening Quality Assurance Advisory Committee, established in 2006 and codified at Mich. Comp. Laws § 333.5430. This committee includes representatives of Michigan's medical associations, hospitals, MDHHS, and the public.

⁴ The MDHHS Laboratory is accredited by the College of American Pathologists and the Centers for Medicare & Medicaid Services and bases testing protocols on the Clinical and Laboratory Standards Institute's Guidelines for Health Care Excellence. *See* http://www.michigan.gov/mdhhs/0,5885,7-339-71551_2945_5103-14582--,00.html (last accessed May 25, 2018).

Pursuant to Mich. Comp. Laws § 333.5431, Michigan's NBS uses six DBS collected on a filter paper collection card. (Ex. 1, p. 2; Ex. 2, *MDHHS Michigan Newborn Screening Pamphlet*, p. 2; Ex. 3, *MDHHS APF-111 – Newborn Screening Specimens*, p. 1; R. 26, 1st Am. Compl. ¶ 35, 36, 51 Pg. ID# 309, 314.) The collected DBS are then transported from Michigan birthing sites (e.g., hospitals, home births) to the MDHHS Laboratory, where the specimens are tested; MDHHS newborn screening follow-up staff then inform healthcare providers when a disorder is identified. (Ex. 1, p. 2.). Every year more than 250 infants (roughly one in 400 to 500 births) are found to have a disorder. (*Id.*, p. 1.) Since the NBS program began, approximately 6,000 Michigan infants have been identified with disorders. (*Id.*)

After the newborn screening tests are completed, parents or legal guardians have the option to require destruction of their child's residual DBS stored pursuant to Mich. Comp. Laws § 333.5431. (Ex. 3, p. 1; Ex. 4, *MDHHS Residual Newborn Screening Blood Spot Directive*.) A parent or legal guardian may request that their child's DBS be destroyed by providing the name, date of birth, and their relationship to the individual from whom the DBS was collected and must provide copies of the individual's birth certificate and a government-issued identification to confirm that they have authority to make the request. (*Id.*) Upon reaching age 18, the individual from whom the DBS was collected must make the request and

provide the requisite documentation. (*Id.*) DBS destruction adheres to a defined policy, is witnessed, and destruction is confirmed to the requestor. (Ex. 5, *MDHHS APF-114 – Guidelines for Research Use of Dried Blood Spots*, p. 5.)

Absent a destruction request, MDHHS stores residual DBS for potential, future, authorized uses. Those uses are limited to internal NBS quality improvement/test development, parent- or guardian-directed uses including medical research, approved de-identified medical research projects, and crime-victim identification (the only approved law-enforcement use). (Ex. 3, p. 1; Ex. 5, pp. 2-5; Ex. 6, *MDHHS Application for Designation as a Medical Research Project & Approval Letter*, p. 2.) DBS are stored under the retention schedule that § 333.5431(7) requires MDHHS to establish—currently up to 100 years. (Ex. 3, p. 1; Ex. 7, *MDHHS After Newborn Screening - Your Baby's Blood Spots Pamphlet*, p. 2.) One of the six DBS is de-identified, assigned an anonymous numeric code, and securely stored at the MDHHS Laboratory for parental use, if needed (e.g., future disease diagnosis, deceased child identification, or autopsy); the other five are likewise de-identified, assigned the same anonymous numeric code, and stored at a secure site, the Michigan Neonatal Biobank (Biobank) in Detroit. (Ex. 7, pp. 1-2; Ex. 8, *MDHHS BioTrust Frequently Asked Questions*, p. 1.) MDHHS serves as the honest broker and maintains the sole link that would enable re-coding to identify a stored DBS; Biobank cannot access this identifiable information. (Ex. 5,

p. 4; Ex. 6, p. 3; Ex. 8, p. 1.) MDHHS retains qualified ownership of DBS while in storage. (Ex. 3, p. 1.) MDHHS may release part, or all, of the de-identified DBS for use by the MDHHS Laboratory in performing NBS quality assurance, test improvement, and test development. (*Id.*; Ex. 7, p. 2.)

Responding to the statutory mandate to permit medical research, MDHHS created the Michigan BioTrust for Health (BioTrust) to facilitate research access to de-identified, stored DBS. (Ex. 7, p. 2.) In 2010, MDHHS/BioTrust implemented an “opt-in” consent process, which permits parents to opt in to research for the stored DBS of their children born on or after May 1, 2010. (*Id.*, pp. 1-2.) Since May 1, 2010, a parent or legal guardian directs—at the time of collection—whether their newborn’s stored DBS can be used for research and may change their mind later by completing the directive form. (*Id.*; Ex. 8, p. 2; Ex. 9, *MDHHS Michigan BioTrust for Health – Consent Options*, pp. 1-2; Ex. 10, *BioTrust Research Consent Form*.) Accordingly, stored DBS for children born on or after May 1, 2010 may be used for research through the BioTrust only if a parent or legal guardian returns a signed consent form allowing it. (*Id.*) Parents are also expressly informed that their child’s DBS will be stored even if they say “no” to research unless they complete the directive form to destroy. (*Id.*) For stored DBS of children born before May 1, 2010, their de-identified DBS are available for health research under a waiver of informed consent granted by the MDHHS

Institutional Review Board. Individuals whose DBS are included in this group can similarly “opt-out” at any time by completing the directive form to have their DBS destroyed entirely or stored but not used for research. (*Id.*)

Here, no parents have submitted a form requesting destruction of their children’s stored DBS. Moreover, for five of the Plaintiff children, their parents completed an opt-in form directing that the child’s stored DBS be made available for research. (Ex. 11, *Completed BioTrust Research Consent Forms* (Redacted).) And in response to Plaintiffs’ request “to advise the Parents for what purposes Defendants are or have been used the blood samples and spots of the Infants” (R. 26, 1st Am. Compl. ¶ 118(i), Pg. ID# 332), State Defendants have confirmed that none of the Plaintiff children’s stored DBS have been used after newborn screening testing was completed. (Ex. 12, *Stanley Aff.*; Ex. 13, *Kleyn Aff.*)

STANDARD OF REVIEW

This Court must dismiss a complaint if it lacks jurisdiction. Fed. R. Civ. P. 12(b)(1). When reviewing a 12(b)(1) motion that attacks the factual basis for the court’s jurisdiction, rather than a facial deficiency of the complaint, “a trial court has wide discretion to allow affidavits, documents and even a limited evidentiary hearing to resolve disputed jurisdictional facts.” *Ohio Nat. Life Ins. Co. v. United States*, 922 F.2d 320, 325 (6th Cir. 1990). Further, the court “is free to weigh the evidence and satisfy itself as to the existence of its power to hear the case.” *RMI*

Titanium Co. v. Westinghouse Elec. Corp., 78 F.3d 1125, 1134 (6th Cir. 1996). No presumptive truthfulness attaches to a plaintiff's allegations, and disputed material facts do not preclude the trial court from evaluating the merits of jurisdictional claims. *Id.* Plaintiffs have the burden of proof. *Id.*

A complaint may be dismissed pursuant to Rule 12(b)(6) “when an affirmative defense . . . appears on its face,” *Jones v. Bock*, 549 US 199, 215 (2007), or if factual allegations, taken as true, are insufficient “to raise a right to relief above the speculative level,” *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 555 (2007). In deciding a Rule 12(b)(6) motion to dismiss, the Court “may consider exhibits attached to the complaint, public records, items appearing in the record of the case, and exhibits attached to defendant’s motion to dismiss, so long as they are referred to in the complaint and are central to the claims contained therein, without converting the motion to one for summary judgment.” *Gavitt*, 835 F.3d at 640.

ARGUMENT

I. Plaintiffs lack standing to bring Counts I, II, IV, and V.

Plaintiffs lack standing to bring any claims related to due-process (Counts I and II) or storage (Counts IV and V). The standing doctrine prompts courts to ask “whether the plaintiff has alleged such a personal stake in the outcome of the controversy as to warrant . . . federal-court intervention and to justify exercise of the court’s remedial powers.” *McKay v. Federspiel*, 823 F.3d 862, 867 (6th Cir.

2016) (internal quotation marks and citations omitted). Plaintiffs must establish standing, *Spokeo, Inc. v. Robins*, 136 S. Ct. 1540, 1547 (2016), and must do so “for each type of relief sought,” *McKay*, 823 F.3d at 867, and “for each claim [they seek] to press.” *DaimlerChrysler Corp. v. Cuno*, 547 U.S. 332, 352 (2006).

Standing has three elements: (1) an “injury in fact” that is (2) “fairly traceable to the challenged action of the defendant” and (3) is capable of being “redressed” by the court. *McKay*, 823 F.3d at 867 (citing *Lujan v. Defs. of Wildlife*, 504 U.S. 555, 560-61 (1992)). The injury needed to invoke constitutional standing must be “concrete and particularized” and “actual or imminent, not conjectural or hypothetical.” *Spokeo*, 136 S. Ct. at 1548 (citing *Lujan*, 504 U.S. at 560). “[P]ast exposure to illegal conduct does not in itself show a present case or controversy regarding injunctive relief . . . if unaccompanied by any continuing, present adverse effects.” *Los Angeles v. Lyons*, 461 U.S. 95, 102 (1983) (citation omitted).

A. Plaintiffs lack standing to assert Fourteenth Amendment claims (Counts I and II).

At the outset, it is important to understand the Fourteenth Amendment rights Plaintiffs are asserting. The parents ostensibly have filed this lawsuit on behalf of their minor children, not on their own behalf as parents.⁵ Thus, the allegations such

⁵ If Plaintiffs’ response brief contends that the parents are in fact pursuing § 1983 claims on their own behalf, these claims would be subject to statute of limitations and other dispositive defenses that State Defendants will address in later briefing.

as “*the Parents* were never given the choice to decide whether to accept or reject the medical procedure of the testing” before the heel stick (R. 26, 1st Am. Compl. ¶ 87, Pg. ID# 322 (emphasis added)) or that they gave “incomplete informed consent” or “false consent” (*id.* ¶¶ 92, 96, Pg. ID# 323-24) are not properly before this Court. As to their allegation that “Defendants deprived the Infants their liberty interest in their guardians” making medical decisions for them, (*id.* ¶¶ 88, 99, Pg. ID# 322-23, 325), this appears to encompass both the initial heel stick (*id.* ¶ 87, Pg. ID# 322) and the “use” of the blood (*id.* ¶ 88, Pg. ID# 322-23)—i.e., storage.

These claims do not meet the *Lujan* elements. First, Plaintiffs have no injury to their liberty interests based on the heel stick, testing, or storage (including either the lack of, or manner of, informed consent associated therewith) because a child does not have a recognized, absolute right to have their parent or guardian make medical decisions on their behalf. *See, e.g., Jacobson v. Massachusetts*, 197 U.S. 11, 38 (1905) (holding that compulsory vaccination laws with only medical exemptions do not violate any federal constitutional right); *Nikolao v. Lyon*, 875 F.3d 310, 316 (6th Cir. 2017) (same); *see also Prince v. Massachusetts*, 321 U.S. 158, 166 (1944) (“But the family itself is not beyond regulation in the public interest [a]nd neither rights of religion nor rights of parenthood are beyond limitation Acting to guard the general interest in youth’s well being, the state as *parens patriae* may restrict the parent’s control in many [] ways.”) (citations

omitted). And as to the storage, these parents may request at any time that their child's DBS be destroyed.

Second, Plaintiffs have not alleged any personal involvement or injury that is "fairly traceable" to the *specific* conduct of any State Defendant. Third, as to storage, this Court can provide no prospective remedy that is not already available to Plaintiffs by their parents requesting destruction of all stored samples (without judicial intervention), which they have not done.

To the extent any claims remain, they should be considered only as to the nine children on whose behalf the First Amended Complaint was brought. Plaintiffs appear to seek statewide relief, but they cannot represent or seek relief for anyone else, including asserting generalized grievances they believe impact other citizens. *See Warth v. Seldin*, 422 U.S. 490, 499 (1975) (explaining that plaintiffs cannot rest a claim to relief on the legal rights or interests of third parties); *Coyne v. American Tobacco Co.*, 183 F.3d 488, 494 (6th Cir. 1999).

B. Plaintiffs lack standing to assert Fourth Amendment claims based on storage (Counts IV and V).

State Defendants understand Counts IV and V to relate only to storage. (R. 26, 1st Am. Compl. ¶ 110, Pg. ID# 327 ("indefinitely test, keep, store, and use the blood of the Infants").) These claims do not meet the standing elements.

First, any injury is speculative. Plaintiffs have not alleged facts showing that they have suffered injury from storage of their DBS; in fact, Plaintiffs' DBS have not been used except for required newborn screening. (Ex. 12; Ex. 13.) In other words, they have never been used for research, or for "law enforcement purposes" (i.e., crime-victim identification, see Ex. 6, p. 2), or "sold" to third parties (i.e., collecting a break-even administrative fee from approved researchers, see R. 26-10, 1st Am. Compl., Ex. I, Pg. ID# 362-63). Nor have they alleged that the parents' request for destruction of their children's samples was denied or ignored. And they cannot allege facts showing that they are in imminent danger of sustaining direct injury due to storage where any future injury could be prevented by requesting destruction of their children's DBS. To the contrary, Plaintiffs assert only unsubstantiated, vague "concern[] and fear" about *the potential* for misuse of the children's stored DBS and "fear [of] *the possibility* of discrimination against their Infants *and perhaps even relatives*" (whose interests they do not represent) should that DBS ever be used. (R. 26, 1st Am. Compl. ¶ 78, Pg. ID# 320-21 (emphasis added).) Under similar facts, courts have dismissed such speculative claims based on lack of standing. *See Higgins v. Texas Dep't of Health Servs.*, 801 F. Supp. 2d 541, 553 (W.D. Tex. 2011) (holding that plaintiffs lacked standing because they "simply did not know at the time they filed their complaint whether their children's blood had been distributed or destroyed (nor, as noted, had they asked for this

information or requested destruction).”); *Doe v. Adams*, 53 N.E.3d 483, 498 (Ind. Ct. App. 2016) (holding that the fear of potential misuse from storage was “speculative” and did “not constitute the type of direct injury necessary to support a finding of standing” where the State presented evidence that retained DBS samples were not used for medical research or any other purpose, would not be so used without parental authorization, and could be requested destroyed at any time).

Second, Plaintiffs have not alleged any injury that is “fairly traceable” to the *specific* conduct of any State Defendant relative to the storage of their DBS. Third, redressability is not met because Plaintiffs may obtain the relief they seek without resorting to the courts—by a request for destruction of their samples.

II. The Eleventh Amendment bars all claims against MDHHS and the money damages and retroactive-relief claims against the individual Defendants in their official capacities.

The Eleventh Amendment bars suits against a state and its departments and agencies, no matter the form of relief, *Pennhurst State Sch. & Hosp. v. Halderman*, 465 U.S. 89, 99–102 (1984), where there is no express waiver or Congressional abrogation, *Seminole Tribe of Florida v. Florida*, 517 U.S. 44, 72–73 (1996). The U.S. Supreme Court has expressly held that 42 U.S.C. § 1983 is not a Congressional waiver of jurisdictional immunity under the Eleventh Amendment. *Will v. Michigan Dep’t of State Police*, 491 U.S. 58, 66 (1989). Nor has Michigan consented to civil rights suits in federal court. *Abick v. Michigan*, 803 F.2d 874,

877 (6th Cir. 1986). Lawsuits against state officials in their official capacity are deemed to be lawsuits against the State itself and are also barred by the Eleventh Amendment. *Will*, 491 U.S. at 71. Further, it is long settled that the State, its agencies, and officials are not “persons” subject to 42 U.S.C. § 1983 liability. *Id.*

Ex parte Young does provide an exception for prospective injunctive relief in a suit challenging the constitutionality of a state official’s action. 209 U.S. 123 (1908). But “[r]etroactive equitable relief against state officials—often involving compensatory payments from the state treasury— [] is precluded by the Eleventh Amendment because it is effectively a suit against the state itself.” *Doe v. Cummins*, 662 F. App’x 437, 444 (6th Cir. 2016) (citation omitted).

Applying this framework, all claims against MDHHS must be dismissed, as it is a state agency. Likewise, the money-damages claims against the individuals in their official capacities must be dismissed, as well as the claims that purport to be prospective but are actually retroactive—namely those based on past storage.

III. Plaintiffs are not entitled to the extraordinary remedy of injunctive relief, and this Court should not grant the requested declaratory relief.

Plaintiffs have not pled facts that support a claim for injunctive relief. They have not pled facts establishing that the unconstitutional harm they allege will recur and cause an injury specific to them. Plaintiffs are bringing this action on behalf of their minor children, who will not have another NBS heel stick and

testing. And if any harm from future storage were to occur, it is only because Plaintiffs have failed to avail themselves of the opportunity to request destruction.

Plaintiffs also fail to meet the “well-established” four-factor test for injunctive relief: (1) that they have suffered an irreparable injury; (2) that remedies available at law are inadequate; (3) that considering the balance of hardships between the plaintiff and defendant, a remedy in equity is warranted; and (4) that the public interest would not be disserved by a permanent injunction. *Barry v. Lyon*, 834 F.3d 706, 720–21 (6th Cir. 2016) (citation omitted).

Plaintiffs cannot establish any of these factors. First, they have not suffered an irreparable, or any, injury. As discussed in Section VI below, it is not settled law that government-based medical procedures conducted for purely medical, non-criminal purposes are a search. And even if the initial heel stick and testing *is* a search, it is minimally invasive and reasonable under the Fourth Amendment. As to storage, Plaintiff children have suffered no harm because, despite Plaintiffs’ allegations about potential uses or the “selling” of blood spots (e.g., R. 26, 1st Am. Compl. ¶¶ 33, 41, 73, 80, Pg. ID# 309, 311, 319, 321) and conceivable harms that could arise from storage (*id.* ¶¶ 78, 79, Pg. ID# 320-21), *these children’s* DBS have not been used except for statutorily-mandated newborn screening (Ex. 12; Ex. 13). Second, Plaintiffs may submit a form at any time requesting destruction of the DBS at issue—an administrative remedy that is adequate. Third, the balance of

hardships weighs in favor of having Plaintiffs submit the simple form, rather than granting them overbroad relief that could adversely impact Michigan’s successful NBS program. Fourth, given the tremendous value of the NBS program—saving the lives of newborns and identifying infants with diseases to form early treatment plans—the public interest weighs in State Defendants’ favor. This Court should deny Plaintiffs’ requested injunctive relief.

This Court should also decline to exercise its jurisdiction to grant Plaintiffs’ requested declaratory relief. Declaratory relief is discretionary relief. *Grand Trunk W. R. Co. v. Consol. Rail Corp.*, 746 F.2d 323, 325 (6th Cir. 1984). The following five factors should guide this Court’s discretion:

- (1) whether the declaratory action would settle the controversy;
- (2) whether the declaratory action would serve a useful purpose in clarifying the legal relations in issue;
- (3) whether the declaratory remedy is being used merely for the purpose of “procedural fencing” or “to provide an arena for a race for res judicata;”
- (4) whether the use of a declaratory action would increase friction between our federal and state courts and improperly encroach upon state jurisdiction; and
- (5) whether there is an alternative remedy which is better or more effective. [*Id.* at 326.]

These factors weigh against granting declaratory relief here. Declaratory relief would not settle the matter. It would only create other controversies or shift them to a later point in time—for example, if newborn screening were optional or testing were decentralized, and a child subsequently developed one of the listed diseases because it was not detected early. Out of necessity to perform this vital

testing for the protection of the infant, Michigan has removed the parents' choice as to the newborn screening tests and MDHHS performing them. Nor would such relief clarify legal relations, because federal courts have recognized that the State can assert its interest in protecting the child where necessary. *See, e.g., Jacobson*, 197 U.S. at 38 (mandatory vaccinations); *Nikolao* 875 F.3d at 316 (same); *Spiering v. Heineman*, 448 F. Supp. 2d 1129 (D. Neb. 2006) (mandatory newborn screening). A declaration here would also create friction because Michigan's Legislature has already stepped in to protect children through the NBS statute. Finally, there is a more effective remedy: the parents can request destruction of their children's DBS. This Court should decline to issue declaratory relief.

IV. Plaintiffs have failed to state a substantive-due-process claim under the Fourteenth Amendment.

Plaintiffs fail to state any claim upon which relief can be granted. “[A] plaintiff must allege facts that state a claim to relief that is plausible on its face and that, if accepted as true, are sufficient to raise a right to relief above the speculative level.” *Bickerstaff v. Lucarelli*, 830 F.3d 388, 396 (6th Cir. 2016) (citation omitted). “A claim has facial plausibility when the pleaded factual content allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged.” *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009).

A. Plaintiffs have failed to state a claim against State Defendants in their individual capacities or for injunctive relief.

To state a claim under § 1983, a plaintiff must allege that: (1) a right secured by the Constitution or a federal statute has been violated; and (2) the violation was committed by a person acting under color of state law. *West v. Atkins*, 487 U.S. 42, 48 (1988). Further, “§ 1983 liability must be based on more than respondeat superior . . . a supervisory official’s failure . . . is not actionable unless the supervisor either encouraged the specific incident of misconduct or in some other way directly participated in it.” *Shehee v. Luttrell*, 199 F.3d 295, 300 (6th Cir. 1999) (citation omitted). A plaintiff must allege “with particularity” “what *each* defendant did to violate the asserted right.” *Terrance v. Northville Reg’l Psychiatric Hosp.*, 286 F.3d 834, 842 (6th Cir. 2002). Speculation and hypothetical argument regarding causation are insufficient to sustain a claim under § 1983. *Horn by Parks v. Madison Cnty. Fiscal Court*, 22 F.3d 653, 659 (6th Cir. 1994).

Plaintiffs appear to bring only as-applied challenges under the Fourteenth Amendment. However, they fail to allege with particularity what each State Defendant did to violate the stated liberty interests. These as-applied claims also fail as a matter of law because the named State Defendants merely followed the law, and Plaintiffs do not allege that the law was mis-applied in any way. Further, Plaintiffs fail to state a claim for prospective injunctive relief because they do not allege facts to support an ongoing violation that would require injunctive relief.

B. On the merits, Plaintiffs' Fourteenth Amendment claims fail.

The right to substantive due process prohibits the government from infringing on “fundamental rights” without sufficient justification. *Washington v. Glucksberg*, 521 U.S. 702, 720-21 (1997); *Range v. Douglas*, 763 F.3d 573, 589 (6th Cir. 2014) (“Substantive due process affords only those protections so rooted in the traditions and conscience of our people as to be ranked as fundamental.”) (citation omitted). But the list of fundamental rights is limited, and the Supreme Court has “always been reluctant to expand the concept of substantive due process.” *Glucksberg*, 521 U.S. at 720. The Supreme Court has recognized certain narrowly drawn, fundamental “liberty” interests implicit in the Due Process Clause, including “the rights to marry, to have children, to direct the education and upbringing of one’s children, to marital privacy, to use contraception, to bodily integrity, and to abortion.” *Id.* (citations omitted). None are involved here.

The Sixth Circuit also has recognized that a substantive due process right may arise without the deprivation of a fundamental right where the governmental conduct “shocks the conscience,” or fails to survive rational-basis review. *EJS Properties, LLC v. City of Toledo*, 698 F.3d 845, 861 (6th Cir. 2012). But it has made clear that courts must narrowly interpret substantive due process claims. *Bell v. Ohio State Univ.*, 351 F.3d 240, 249-50 (6th Cir. 2003). Thus, “[t]o state a cognizable substantive due process claim, the plaintiff must allege ‘conduct

intended to injure in some way unjustifiable by any government interest’ and that is ‘conscience-shocking’ in nature.” *Mitchell v. McNeil*, 487 F.3d 374, 377 (6th Cir. 2007) (quoting *Cty. of Sacramento v. Lewis*, 523 U.S. 833, 849 (1998)). “What seems to be required is an intentional infliction of injury . . . or some other governmental action that is arbitrary in the constitutional sense.” *Lewellen v. Metro. Gov’t of Nashville & Davidson Cnty.*, 34 F.3d 345, 351 (6th Cir. 1994) (internal quotation marks and citation omitted).⁶

Applying these standards, Plaintiffs’ liberty-interest claims fail. One argument Plaintiffs advance is that “the Parents were never given the choice to decide whether to accept or reject the medical procedure.” (R. 26, 1st Am. Compl. ¶ 87, Pg. ID# 322.) But again, the parents’ rights are not before the Court because they are not parties to this lawsuit, and due-process rights are personal and may not be vicariously asserted. *See Kowalski v. Tessmer*, 543 U.S. 125 (2004).

Plaintiffs also argue that “Defendants deprived the Infants their liberty

⁶ In addition, substantive due process protects only against state action that is not otherwise proscribed by the plain text of other constitutional amendments. “Where a particular Amendment provides an explicit textual source of constitutional protection against a particular sort of government behavior, that Amendment, not the more generalized notion of substantive due process, must be the guide for analyzing these claims.” *Lewis*, 523 U.S. at 842 (citations omitted). Because Plaintiffs ask this Court to evaluate Michigan’s NBS program under the Fourth Amendment, and warrantless blood draws are generally examined under the Fourth Amendment, *e.g.*, *Missouri v. McNeely*, 569 U.S. 141, 147-48 (2013), the Fourth Amendment analysis controls and this Court need not reach Plaintiffs’ Fourteenth Amendment claims.

interest in their guardians self-making [informed] personal and private medical procedure decisions without due process of law.” (Cf. R. 26, 1st Am. Compl. ¶¶ 88, 99, Pg. ID# 322-23, 325.) But Plaintiffs provide no authority showing that a child has a fundamental right or liberty interest in having a parent or guardian make medical decisions on their behalf, or more specifically in having the parent refuse minimally invasive and potentially life-saving medical care.

Even if such a right exists, the initial heel stick at issue is minimally invasive and there is an available avenue to request destruction of the samples. Moreover, it is not conscience-shocking or irrational that Michigan, like every other State, runs a newborn screening program and recognizes its importance to public health.

Plaintiffs rely on *Cruzan v. Director, Missouri Dep’t of Health*, 497 U.S. 261 (1990), for the proposition that “a competent person ha[s] the constitutionally protected liberty interest in refusing unwanted medical procedures.” (R. 26, 1st Am. Compl. ¶ 86, Pg. ID# 322.) But *Cruzan* does not apply. The children on behalf of whom this action is brought are not competent to make their own medical decisions. Nor did *Cruzan* hold that children had a blanket right to have their parents refuse medical treatment on their behalf. Instead, *Cruzan* explained that “whether respondent’s constitutional rights have been violated must be determined by balancing his liberty interests against the relevant state interests.” *Cruzan*, 497 U.S. at 279 (citation omitted). The Court also recognized that the right

to refuse treatment is different for a child than for an adult and that a State has a great interest in preserving life. *Id.* at 280-82.

Indeed, “[a] parent’s right to control the custody and care of her children is not absolute, as the State has a legitimate interest in protecting ‘the moral, emotional, mental, and physical welfare of the minor.’” *In re Sanders*, 852 N.W.2d 524, 532 (Mich. 2014) (quoting *Stanley v. Illinois*, 405 U.S. 645, 652 (1972)). Further, it is well settled that a State may pass laws protecting the public health and safety or invest that authority in local administrations. *See Jacobson*, 197 U.S. at 25 (“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.”). For example, a state may require vaccinations. *See id.* at 38. A state may similarly institute and maintain a newborn screening program in the interests of its most vulnerable citizens—newborn infants. *See Spiering*, 448 F. Supp. 2d at 1142 (holding that Nebraska’s mandatory newborn screening program without a religious exemption did not violate any Fourteenth Amendment substantive due process right because Supreme Court precedent recognizes “that the right of a parent to parent and the right of a child to safety are of equal value; that ‘strict scrutiny’ does not apply; and that the statute is rationally related to the legitimate governmental objective of protecting children from death or serious injury.”).

In sum, Plaintiffs cannot argue, and have not adequately pled, that any State Defendant did anything that infringes a fundamental right or “shocks the conscience.” And given the minimal intrusion involved in the procedure, and the parents’ ability to request destruction of the DBS at any time, the State’s conduct does not fail rational basis review. Accordingly, Plaintiffs’ due-process claims fail.

V. Plaintiffs have failed to state a Fourth Amendment claim.

Plaintiffs appear to bring both facial claims (challenging Mich. Comp. Laws § 333.5431 because it does not require informed consent, permits MDHHS to require centralized testing, and requires residual DBS to be stored and made available for research) and as-applied claims under the Fourth Amendment. For the same reasons as articulated in Argument IV(A) above, Plaintiffs have not pled facts that support an as-applied claim against State Defendants in their individual capacities or for injunctive relief. Moreover, Plaintiffs’ real complaint is about the law in place, not State Defendants’ specific actions in complying with the law. These facial claims under the Fourth Amendment similarly fail on the merits.

A. Plaintiffs have failed to state a claim based on the initial heel stick and testing (Count III).

The Fourth Amendment to the United States Constitution protects “against unreasonable searches and seizures” U.S. Const. amend. IV. The standing and search and seizure inquiries “merge into one: whether governmental officials

violated any legitimate expectation of privacy held by petitioner.” *Rawlings v. Kentucky*, 448 U.S. 98, 106, (1980). The Fourth Amendment does not protect all subjective expectations of privacy, “but only those expectation[s] that society is prepared to recognize as ‘reasonable.’” *Oliver v. U.S.*, 466 U.S. 170, 177 (1984). Furthermore, Fourth Amendment rights may not be vicariously asserted. *Rakas v. Illinois*, 439 U.S. 128, 133–34 (1978).

Whether a search is reasonable “depends upon all of the circumstances surrounding the search or seizure and the nature of the search or seizure itself,” *United States v. Montoya de Hernandez*, 473 U.S. 531, 537 (1985), and “is judged by balancing its intrusion on the individual’s Fourth Amendment interests against its promotion of legitimate governmental interests.” *Skinner v. Ry. Labor Execs. Ass’n*, 489 U.S. 602, 619 (1989). “[S]pecial needs [can] . . . make the [usual] warrant and probable cause requirement impracticable.” *Vernonia Sch. Dist. 47J v. Acton*, 515 U.S. 646, 653 (1995) (citations omitted). Such cases require a balancing of the invasion of the individual’s privacy interest against the “special needs” supporting the program. *Ferguson v. City of Charleston*, 532 U.S. 67, 78 (2001).

If the initial heel stick and testing is a Fourth Amendment search, it is a reasonable one. Michigan has a compelling interest in conducting its NBS without parental consent to protect the lives of newborn citizens, while Plaintiffs have no reasonable interest in interfering with this life-saving law. The U.S. Supreme Court

has held that the government mandating tests for “latent or hidden conditions, or to prevent their development, is sufficiently compelling to justify the intrusion on privacy.” *Nat’l Treasury Employees Union v. Von Raab*, 489 U.S. 656, 668 (1989) (holding that drug tests were reasonable where the government had a compelling interest in assuring that employees who were required to carry a firearm or involved in drug interdiction were not drug users); *see also Skinner*, 489 U.S. at 633 (holding that safety interests warranted Federal Railroad Administration blood and urine testing program); *Vernonia*, 515 U.S. at 663-65 (holding that random drug-testing program for high school students engaged in interscholastic athletic competitions was justified by interest in deterring drug use and risk of injury).

As in *Von Raab*, *Skinner*, and *Vernonia*, Michigan’s NBS program is an exercise of Michigan’s “police powers to protect the health and safety of [its] citizens.” *Medtronic, Inc v. Lohr*, 518 U.S. 470, 475 (1996). The State has an interest in the health and welfare of all children born in Michigan and has determined that it is essential to test for certain rare and hidden diseases soon after a child is born to provide early detection and treatment. The child’s health and safety are of concern, as are the potential social burdens created by children who suffer these devastating disorders when they are not identified or treated early. Accordingly, the State’s interest is compelling, while the intrusion on the privacy interest of the infant is limited; the DBS were taken “in a reasonable manner . . . by

[medical personnel] in a hospital environment according to accepted medical practices.” *Schmerber v. California*, 384 U.S. 757, 771 (1966).

Thus, Plaintiffs have failed to state a claim that any State Defendant, acting under color of law, directly violated Plaintiffs’ Fourth Amendment rights relating to the NBS initial heel stick and testing.

B. Plaintiffs have failed to state a claim based on storage or civil conspiracy (Counts IV and V).

Plaintiffs plead their Fourth Amendment seizure claim (as it relates to the storage of the DBS) separately from their Fourth Amendment search claim. But the same authority is applicable. The compelling governmental interest in early and accurate detection of congenital disorders in newborn infants, where time is crucial to prevent lifelong consequences, outweighs any reasonable expectation of privacy in Michigan’s storage of de-identified DBS for quality assurance of the NBS program and legislatively-mandated medical research. The privacy of the individual whose DBS are retained is protected through measures including de-identifying the DBS, assigning an anonymous numeric code, and using secured facilities. (Ex. 7, pp. 1-2; Ex. 8, p. 1.) And continuous involvement of the Community Values Advisory Board and Scientific Advisory Board, together with required oversight, review, and approval by the MDHHS Institutional Review Board, ensures that any research use adheres strictly to federal and state laws and

regulations governing human subject research. (Ex. 5.) Thus, Plaintiffs have failed to state a facially plausible claim that any State Defendant violated Plaintiffs' Fourth Amendment rights relating to the storage of DBS.

As to the conspiracy claim, a civil conspiracy under § 1983 is “an agreement between two or more persons to injure another by unlawful action.” *Revis v. Meldrum*, 489 F.3d 273, 290 (6th Cir. 2007). To prevail on such a claim, a plaintiff must show: (1) the existence of a single plan; (2) that the conspirators shared in a general conspiratorial objective to deprive the plaintiff of his constitutional rights; and (3) an overt act committed in furtherance of the conspiracy and that caused the alleged injury. *Hooks v. Hooks*, 771 F.2d 935, 944 (6th Cir. 1985).

Here, even accepting Plaintiffs' amended complaint as true, they offer only vague and conclusory allegations, unsupported by material facts, to suggest that there was a “plan” (other than the mere existence of state law), that these State Defendants had a conspiratorial objective of violating Plaintiffs' Fourth Amendment rights, or that they “agreed” to conspire.

VI. Plaintiffs have failed to state a claim in avoidance of State Defendants' qualified immunity as to the money damages claims against them in their individual capacities.

Public officials who perform discretionary duties within the scope of their employment are “shielded from liability for civil damages insofar as their conduct does not violate clearly established statutory or constitutional rights of which a

reasonable person would have known.” *Harlow v. Fitzgerald*, 457 U.S. 800, 818 (1982). Qualified immunity is not a defense to liability; it is an absolute immunity from suit. *Saucier v. Katz*, 533 U.S. 194, 200–01 (2001), *clarified by Pearson v. Callahan*, 555 U.S. 223 (2009). It protects “all but the plainly incompetent or those who knowingly violate the law.” *Ashcroft v. al-Kidd*, 563 U.S. 731, 743 (2011) (citing *Malley v. Briggs*, 475 U.S. 335, 341 (1986)).

Once qualified immunity is asserted, the plaintiff must allege facts sufficient to show that: (1) the official’s acts violated a federal right; and (2) the right at issue was clearly established at the time of the defendant’s alleged misconduct. *Barker v. Goodrich*, 649 F.3d 428, 433 (6th Cir. 2011). Courts may address these prongs in any order, *Pearson*, 555 U.S. at 236, and “[i]f either one is not satisfied, qualified immunity will shield the officer from civil damages,” *Gradisher v. City of Akron*, 794 F.3d 574, 583 (6th Cir. 2015) (citation omitted). “Each defendant’s liability must be assessed individually based on his own actions.” *Binay v. Bettendorf*, 601 F.3d 640, 650 (6th Cir. 2010).

As argued above, there has been no constitutional violation. Nor have Plaintiffs pled facts sufficiently linking the individual Defendants’ conduct to the injuries alleged. On the merits of Plaintiffs’ claims, the NBS program is a reasonable search and seizure (if it even is a search). And there is no unreasonable seizure or conspiracy based on storage where Plaintiffs have identified no past

injury and could prevent future injury by simply requesting destruction of existing blood samples. Finally, children do not have an absolute right to have their parents make medical decisions on their behalf. But there is no need to reach the violations prong because the “clearly established” prong fails and is dispositive.

To determine if the right allegedly violated was clearly established, courts analyze claims on a “fact-specific, case-by-case basis.” *Pray v. City of Sandusky*, 49 F.3d 1154, 1158 (6th Cir. 1995). The right allegedly violated must have been “clearly established” not in an abstract sense, but in a “particularized” sense. *Anderson v. Creighton*, 483 U.S. 635, 640 (1987). “To be clearly established, a right must be sufficiently clear that *every* reasonable official would [have understood] that what he is doing violates that right.” *Reichle v. Howards*, 566 U.S. 658, 664 (2012) (emphasis added); *Gradisher*, 794 F.3d at 583. “In other words, existing precedent must have placed the statutory or constitutional question beyond debate.” *Reichle*, 566 U.S. at 664; *al-Kidd*, 563 U.S. at 741. Plaintiffs must “identify a case where an [official] acting under similar circumstances . . . was held to have violated” the constitutional right at issue. *White v. Pauly*, 137 S. Ct. 548, 552 (2017); *Arrington-Bey v. City of Bedford Heights, Ohio*, 858 F.3d 988, 993 (6th Cir. 2017). Here, qualified immunity bars all of Plaintiffs’ money-damages claims against the named State Defendants in their individual capacities.

Liberty interest in refusing medical procedures. Plaintiffs frame their due-process claims as a refusal of unwanted medical procedures and assert either the children's right to refuse medical treatment or the Parents' right to refuse medical treatment for their children, the former of which is not a right and the latter of which is not properly pled here.

Regardless, Plaintiffs fall well short of alleging with particularity a facially plausible claim that any of the State Defendants, under color of law, infringed on a fundamental right or engaged in conduct that shocks the conscience. Plaintiffs also have not provided any clearly established authority showing that at the time their children's samples were taken, tested, and stored, a child had a fundamental right to have their parents make any and all medical decisions on their behalf, or that it was conscience-shocking for state officials to collect newborn blood samples without consent. At a minimum, no caselaw places it beyond debate that a state official may not conduct minimally invasive procedures to protect the health and welfare of newborn children. Caselaw shows just the opposite. The State *can* intervene for the protection of the child. *E.g.*, *Jacobson*, 197 U.S. 11; *Spiering*, 448 F. Supp. 2d at 1142; *Douglas County v. Anaya*, 694 N.W.2d 601 (Neb. 2005), *cert. denied Anaya v. Douglas County*, 546 U.S. 826 (2005).

Nor have Plaintiffs shown it was beyond debate that storing samples that parents have not taken the available opportunity to destroy was a Fourteenth

Amendment violation. The issue was not “beyond debate” such that reasonable state officials would be on notice that they were violating due-process rights.

Initial heel stick. Plaintiffs allege a Fourth Amendment violation for the initial heel stick. Again, Plaintiffs have not alleged that any of the individually-named State Defendants were directly involved in, or took any action relating to, obtaining the DBS, and certainly not those Defendants who are alleged to have been involved only with storage. Nor have Plaintiffs provided any clearly established authority making it beyond debate that a newborn screening test is even a Fourth Amendment “search,” let alone an unreasonable search.

There is support, including in the Sixth Circuit, for the proposition that government-based medical procedures, conducted by medical professionals for the purpose of medical treatment rather than for criminal investigative or administrative purposes, do not constitute a “search” within the meaning of the Fourth Amendment. *See Herring v. Sliwowski*, 712 F.3d 275, 281 (6th Cir. 2013) (“Given that there is no direct precedent from this court holding that the *Fourth Amendment* applies to visual examinations conducted by medical professionals for medical purposes and some precedent indicating that the *Fourth Amendment* does not apply in such circumstances, we cannot say that it is clearly established under our precedent that” this conduct is subject to the Fourth Amendment’s reasonableness standard); *Peete v. Metro. Gov’t of Nashville & Davidson Cnty.*,

486 F.3d 217, 222 (6th Cir. 2007) (holding that the Fourth Amendment did not apply to the actions of paramedics responding to a 911 call who “were not acting to enforce the law, deter or incarcerate,” but rather were acting to “provide medical aid”); *United States v. Attson*, 900 F.2d 1427, 1433 (9th Cir. 1990) (holding that a blood sample drawn by government medical professionals for purely medical reasons was not a search for Fourth Amendment purposes).

Moreover, the Sixth Circuit has recognized that because the probable cause standard “is peculiarly related to criminal investigations,” it “may be unsuited to determining the reasonableness of administrative searches where the Government seeks to *prevent* the development of hazardous conditions.” *Int’l Union v. Winters*, 385 F.3d 1003, 1007 (6th Cir. 2004) (internal quotation marks and citations omitted). Indeed, it would be impossible (as Plaintiffs suggest) to obtain a search warrant to perform the NBS heel stick and testing because it is conducted for purely medical reasons and has no criminal investigative purpose to support the required “probable cause” for a search warrant. *See Illinois v. Gates*, 462 U.S. 213, 238 (1983) (noting that task of the magistrate issuing a search warrant is to decide whether “there is a fair probability that contraband or evidence of a crime will be found in a particular place”).

Even if it is clearly established that the heel stick and testing is a search, it is not clearly established that it is unreasonable. Caselaw supports this conclusion.

E.g., Von Raab, 489 U.S. 656, 671 (1989); *Skinner*, 489 U.S. at 633; *Vernonia*, 515 U.S. at 663-65. And the fact that every other State operates a newborn screening program evidences that these programs do not violate any clearly established Fourth Amendment right. In short, it is not “beyond debate” that newborn screening is a Fourth Amendment search, much less an unreasonable one.

Finally, Plaintiffs have not clearly established that newborns have a right (through their parents) not to have the NBS heel stick, such that reasonable officials in these Defendants’ positions would have known they were violating Plaintiffs’ Fourth Amendment rights by taking and testing blood without prior informed consent. Count III is barred by qualified immunity.

Retention of samples. Plaintiffs also allege a Fourth Amendment violation for the subsequent retention of DBS, allegedly without consent. But once again, Plaintiffs have not alleged any specific conduct on the part of any State Defendant sued in his or her individual capacity, and certainly not those State Defendants who are alleged to have been involved only with the initial heel stick and testing. Nor can they provide any authority that would have put reasonable state officials in their positions on notice that storing blood samples for medical research purposes with comprehensive protections in place constitutes an unreasonable “seizure” in violation of the Fourth Amendment—especially where the parents are able to prevent storage by requesting the destruction of all samples.

Plaintiffs also offer only vague, conclusory allegations that State Defendants had “a plan with shared general conspiratorial objectives” regarding storage. (R. 26, 1st Am. Compl. ¶ 113, Pg. ID# 328.) There is no clearly established authority for the proposition that state actors who merely play a part in complying with a state program mandated by state law have conspired against citizens of the State.

Thus, Plaintiffs cannot overcome State Defendants’ qualified immunity.

CONCLUSION AND RELIEF REQUESTED

Plaintiffs’ First Amended Complaint fails jurisdictionally and on the merits. Therefore, Defendants Michigan Department of Health and Human Services, Nick Lyon, Dr. Sandip Shah, Sarah Lyon-Callo, and Mary Kleyn respectfully request that this Honorable Court grant their Motion under Rule 12(b)(1) or 12(b)(6), and dismiss, with prejudice, all claims against them.

Respectfully submitted,

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Dated: May 29, 2018

CERTIFICATE OF SERVICE

I hereby certify that on May 29, 2018, I electronically filed the above document(s) with the Clerk of the Court using the ECF System, which will provide electronic copies to counsel of record.

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