No. 18-1896

In the
UNITED STATES COURT OF APPEALFS
FOR THE SIXTH CIRCUIT

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

Plaintiffs-Appellants,

v.

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

Defendants-Appellees.

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

BRIEF FOR DEFENDANTS-APPELLEES

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Dated: November 5, 2018

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STATEMENT IN SUPPORT OF ORAL ARGUMENT

This case presents a constitutional challenge to Michigan's Newborn Screening (NBS) Program. Given the significance of the matters presented in this appeal, the Defendants-Appellees the Michigan Department of Health and Human Services (MDHHS), Nick Lyon, Dr. Sandip Shah, Sarah Lyon-Callo, and Mary Kleyn (collectively, "State Defendants") believe oral argument will assist this Court in reaching a just resolution.

JURISDICTIONAL STATEMENT

The State Defendants agree with the plaintiffs-appellants' statement of jurisdiction.

STATEMENT OF ISSUES PRESENTED

1. Standing requires a plaintiff to show an injury that is redressable. Infants have no injury when they are tested to ameliorate disease – they have no capacity to make medical decisions. Parents are not injured – they have no absolute right to prevent tests where the child's health is at risk if disease is not detected and treated. Nor is there injury or redressability when stored blood spots can be destroyed on request. Should the district court have found that Plaintiffs lacked standing as to all Plaintiffs claims?

2. Infants have neither the capacity to refuse medical treatment nor the right to have only their parents make medical decisions on their behalf. And parents do not have the unfettered right to make medical decisions that may detrimentally impact their children's health and safety. Here, the plaintiffs filed a complaint that was based on these non-existent or non-applicable constitutional rights. Did the district court correctly dismiss the plaintiffs' substantive-due-process claim?

3. The Fourth Amendment allows reasonable governmental action. The State's Newborn Screening Program is a reasonable exercise of the State's police powers because it is designed to protect the health and safety of newborn infants by facilitating early detection and treatment of potentially life-threatening diseases. Did the district court properly dismiss the plaintiffs' Fourth Amendment claim?

INTRODUCTION

Every State in the Nation—along with the Federal Government—recognizes the importance of Newborn Screening (NBS). As evidence of this, all 50 states have NBS programs that, with federal support, test newborns for rare, insidious, and sometimes fatal medical disorders that can be ameliorated or negated with early intervention. Michigan's NBS Program has been in place since 1965 and is aimed at protecting the health of newborn infants. It is a valid exercise of the State's police powers.

The plaintiffs concede that NBS programs are "a noble public policy idea" (1st Am. Compl. ¶ 2, R. 26, Page ID # 301), yet nevertheless allege that Michigan's program violates the Fourth and Fourteenth Amendments. But their challenges to both the initial heel stick requirement and the subsequent storage of the residual dried blood spots (DBS) rest on fundamental legal misconceptions. The district court properly dismissed the plaintiffs' claims—a decision that leaves intact all components of Michigan's important, longstanding, and successful NBS Program.

STATEMENT OF THE CASE

A. Facts

The district court summarized the operative facts in this case, relying on only the facts as alleged in the plaintiffs' amended complaint:

> Since the 1960's, the State of Michigan has operated a newborn screening program, whereby medical professionals take blood samples (dried blood spots, or "DBS cards") from newborn babies to test for various diseases. Am. Compl. ¶ 1, ECF No. 26. The DBS cards are ultimately transferred to the Michigan Neonatal Biobank and stored indefinitely for testing and further research. Id. ¶ 10-11, 33. The parents of the infant children in this case did not consent to the blood test or to the State taking custody of the blood samples. Id. ¶ 3-4. MCL 333.5431(1) directs health care professionals to administer the blood test. Violating the statute is a misdemeanor. MCL 333.5431(5). The statute exempts the blood sampling and testing from informed consent requirements. MCL 333.5431(2).
>
> Plaintiffs were never extended the option to opt-out of the blood test. Id. ¶ 45. Plaintiffs "might have been" presented with an option to opt out of donating the blood to research. Id. ¶ 46. In addition to the blood samples, healthcare professionals also submitted identifying information of the infants. Id. ¶ 50. MDHHS's public documentation promises confidentiality and promises to resist demands for information that could identify the infant. Id. ¶ 66. Despite these promises, "Blood samples on several occasions were provided pursuant to state court orders . . . and being sold to third party businesses and researchers." Id. ¶ 70. Michigan Neonatal Biobank "actively sells punches of various sizes to universities and businesses at different rates." Id. ¶ 80. "Since the blood spots contain deeply private medical and genetic information . . . the Parents are

> concerned and fear about the 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." Id. ¶ 78. "That [f]ear is well-founded and actual as the sharing of blood spots containing deeply private medical and genetic information has recently resulted in the arrest of an alleged killer but has already resulted in the wrongful arrest of persons who were not guilty of any crime." Id. ¶ 79.

(08/08/18 Order Granting Motions to Dismiss and Dismissing Complaint with Prejudice (Order Granting Motions to Dismiss), R. 50, Page ID # 826.)

The NBS Program is mandated by Michigan law. *See* i*d.* at 826, 836. It involves a minor heel stick to a newborn baby that draws approximately 5 blood spots, which are tested for disorders such as sickle cell anemia, phenylketonuria, and galactosemia[1], then stores the DBS for quality-control and approved medical research. *Id.* at 831, 835. Parents can request that their child's residual DBS are destroyed entirely once the newborn screening is completed (i.e., never stored), that previously-stored DBS be destroyed entirely, or that they be stored

[1] Galactosemia is a genetic disorder that can cause liver failure, brain damage, and even death if left untreated.

but not used for research. *See id.* at 837-38; MCL 333.5431 When a child turns 18 they may make these requests as well.

B. Proceedings below

On February 8, 2018, the plaintiffs filed their initial complaint. (Complaint, R. 1, Page ID # 1.) This complaint was deficient, and the plaintiffs filed a "corrected complaint" on February 17, 2018, which alleged that the initial heel stick, screening, and storage violate their Fourth and Fourteenth Amendment rights. (Corrected Complaint, R. 3, Page ID # 42.)

On April 17, 2018, the State Defendants filed a motion to dismiss. (State Defs.' Motion to Dismiss, R. 21, Page ID # 171.) This motion argued, among other things, that Plaintiffs' corrected complaint should be dismissed for failure to state a claim under Rule 12(b)(6), lack of standing, and governmental immunity.

Plaintiffs filed a motion to strike on April 18, 2018, taking issue with the attachments to the State Defendants' brief despite the inclusion of citation to the authority under which the attachments are allowable. (Motion to Strike Motion to Dismiss, R. 23, Page ID # 270.) Before the State Defendants could file a response to this motion, the

district court issued an order denying the motion to strike because it was not supported by the Federal Rules of Civil Procedure. (Order Denying Motion to Strike and Granting Mot. for an Extension, R. 25, Page ID # 298.)

Rather than respond to the State Defendants' Motion, Plaintiffs filed a First Amended Complaint on April 30, 2018. (First Amended Complaint, R. 26, Page ID # 300.) The First Amended Complaint raised substantially the same issues as the corrected Complaint.

On May 29, 2018 the State Defendants' filed their Motion to Dismiss addressing the First Amended Complaint. (State Defs.' Motion to Dismiss First Amended Complaint, R. 32, Page ID # 477.) The State Defendants reiterated that Plaintiffs had still failed to state a claim, failed to establish jurisdiction, and failed to plead in avoidance of governmental immunity. Plaintiffs responded to this motion on July 6, 2018. (Plaintiffs' Response to Certain State Defs.' Motion to Dismiss, R. 45, Page ID # 696.) The State Defendants filed a Reply on August 1, 2018. (Reply to Response to Motion to Dismiss Plaintiffs' First Amended Compl., R. 49, Page ID # 815.)

On August 7, 2018, the district court issued a notice cancelling the oral arguments previously scheduled for August 21, 2018. The next day, the district court issued its Order Granting Motions to Dismiss and Dismissing Complaint with Prejudice. (Order Granting Motions to Dismiss, R. 50, Page ID # 825.) Judgment was issued the same day (Judgment, R. 51, Page ID # 847.) Later that same day, Plaintiffs filed a notice of appeal. (R. 52, Notice of Appeal, Page ID # 848.)

C. The district court's opinion and order

The district court read the amended complaint as alleging that "Defendants violated Plaintiffs' fourteenth amendment liberty interest in refusing unwanted medical procedures by conducting the blood test without parental consent (count I) or by improper/incomplete/false consent (count II)" and "Defendants violated Plaintiffs' fourth amendment rights to be free from unreasonable searches and seizures where the initial extraction and seizure for testing was conducted without parental consent (count III), and then indefinite storage was also conducted without parental consent (count[s] IV and V)." (Order Granting Motions to Dismiss, R. 50, Page ID # 827.)

In reviewing the claims and arguments made below, the district court recognized that the plaintiff's appeared to allege three separate liberty interests: (1) the right of a child to have its parents make medical decisions on its behalf, (2) the right of a competent person to refuse unwanted medical procedures, and (3) a parent's right to make unfettered decisions regarding the care, custody, and control of their children. (Order Granting Motions to Dismiss and Dismissing Complaint with Prejudice, R. 50, Page ID # 829). In reviewing each, the district court found that the right either did not exist as alleged or was not implicated by the facts as alleged by the plaintiffs. (Order Granting Motions to Dismiss, R. 50, Page ID # 829-30, 833-38.)

The plaintiffs appealed, arguing that they had pled plausible causes of action for violations of the Fourth and Fourteenth Amendments. (Pls.' Appeal Br.,[2] p. 2, 10-11, Page ID # 13, 21-22.) For the reasons stated below, the district court's decision dismissing the plaintiffs' claims should be affirmed.

[2] Plaintiffs have filed multiple briefs with various corrections; this brief refers only to the most recent version.

STANDARD OF REVIEW

The standard of review for a district court's dismissal under 12(b)(6), failure to state a claim upon which relief can be granted, is de novo. *Bloch v. Ribar*, 156 F.3d 673 (6th Cir. 1998).

SUMMARY OF ARGUMENT

Standing requires a plaintiff to show an injury that is redressable. The district court properly found that infants have no injury when they are tested to ameliorate disease – they have no capacity to make medical decisions. And parents are not injured – they have no absolute right to prevent tests where the child's health is at risk if disease is not detected and treated. Additionally, there is no injury or redressability when stored blood spots can be destroyed on request. Thus, Plaintiff's cannot demonstrate standing in this case.

The district court properly dismissed this case for failure to state a claim upon which relief can be granted. While the plaintiffs argue that the district court made a merits determination as to a substantive due process right under the Fourteenth Amendment, in fact, the district court correctly determined that the plaintiffs did not allege a violation of *any* constitutional right.

Plaintiffs rely primarily on *Cruzan by Cruzan v. Dir., Missouri Dep't of Health*, 497 U.S. 261 (1990) and *Dubbs v. Head Start, Inc.*, 336 F.3d 1194 (10th Cir. 2003), for the proposition that a parent must be afforded the opportunity to refuse potentially life-saving medical treatment on behalf of their child. But neither case recognizes a constitutional right as alleged by the plaintiffs. The trial court was correct in holding that Plaintiffs' complaint should be dismissed.

ARGUMENT

I. The plaintiffs lack standing to bring any of their claims.

The district court found that the plaintiffs had not demonstrated standing for their Fourth Amendment claims regarding retention and use of the DBS. (Order Granting Motions to Dismiss, R. 50, Page ID # 844-45.) All of the plaintiffs' allegations were based on alleged injuries to third parties, not to the plaintiffs. *Id.* Their fears and vague allegations about a possibility of discrimination were entirely hypothetical. *Id.*

The district court did not address standing as to the remaining counts. However, as argued in the district court, the plaintiffs also lack standing for their Fourteenth Amendment claims, and their Complaint may be properly dismissed on that basis.

Plaintiffs lack standing to bring any claims related to due-process or storage. 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.

At the outset, it is important to understand the Fourteenth Amendment rights the plaintiffs are asserting. The parents ostensibly have filed this lawsuit on behalf of their minor children, not on their

own behalf as parents. Thus, the allegations such 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 (1st Am. Compl., R. 26, ¶ 87, Page ID # 322 (emphasis added)) or that they gave "incomplete informed consent" or "false consent" (*id.* ¶¶ 92, 96, Page ID # 323-24) were not properly before the district court. As to their allegation that "Defendants deprived the Infants their liberty interest in their guardians" making medical decisions for them, (*id.* ¶¶ 88, 99, Page ID # 322-23, 325), this appears to encompass both the initial heel stick (*id.* ¶ 87, Page ID # 322) and the "use" of the blood spots (*id.* ¶ 88, Pg. ID# 322-23)—i.e., storage.

These claims do not meet the *Lujan* elements. First, the 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.

Morever, as to storage, the court can provide no prospective remedy that is not already available – the parents can request destruction of all stored samples (without judicial intervention), which they have not done, nor alleged to have done.

Thus, the plaintiffs have failed to demonstrate that they have standing to bring Fourteenth Amendment claims regarding the initial test and subsequent use of the blood spots.

B. Plaintiffs lack standing to assert Fourth Amendment claims based on storage.

The plaintiffs' claims related to storage also 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. (State Defs.' Motion to Dismiss, R. 21, 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 id.* Ex. 6), or "sold" to third parties (i.e., collecting a break-even administrative fee from approved researchers, *see* 1st Am. Compl., R. 26-10, Ex. I, Page 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. (*Id.* ¶ 78, Page 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, the 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 the plaintiffs may obtain the relief they seek without resorting to the courts—by a request for destruction of their samples.

II. The plaintiffs have failed to state a viable legal claim under any theory alleged.

The plaintiffs have failed to state a claim on which relief may be granted as to either the substantive due process claim or the Fourth Amendment claim.

A. The plaintiffs misunderstand the "plausibility" standard.

As a threshold matter applying to all claims, the plaintiffs argue that the district court misapplied the proper standard. The opposite is true: the plaintiffs do not understand the standard or how it applies to their Complaint. They rely on both *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009) and *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 555 (2007), to argue that they have plausibly pled the existence of two constitutional rights that they believe were violated. (Pls.' Appeal Br. pp. 22-23.) But the plausibility standard applies to alleged *facts*—not legal theories, and Plaintiffs appear to misunderstand that distinction.

Here, the district court correctly observed that, as to substantive due process, there are actually three alleged constitutional rights at issue and recognized that, even assuming the truth of Plaintiffs' factual

allegations, Plaintiffs did not state any viable legal theory. (Order Granting Motions to Dismiss, R. 50, Pg. ID # 825-38.)

"[T]o survive a motion to dismiss, the complaint must contain either direct or inferential allegations respecting all material elements to sustain a recovery *under some viable legal theory*." *Eidson v. State of Tenn. Dep't of Children's Servs.*, 510 F.3d 631, 634 (6th Cir. 2007) (emphasis added). Further, the district court "need not accept as true legal conclusions or unwarranted factual inferences," *Jones*, 521 F.3d at 559, and "[c]onclusory allegations or legal conclusions masquerading as factual allegations will not suffice." *Eidson*, 510 F.3d at 634.

Here, the plaintiffs are not entitled to move forward in this litigation because their allegations, taken as true, are not brought under any "viable legal theory," *Eidson*, 510 F.3d at 634, as set forth in greater detail below. Their suggestion that an attempt to raise a merely plausible legal theory is enough to move forward with the litigation is simply not correct. And this is not a case where the plaintiffs' Complaint was dismissed because it stated implausible facts—though it did. Rather it was dismissed because, assuming the

truth of the allegations, Plaintiffs failed to state a violation of any constitutional right.

B. The plaintiffs have not alleged a violation of any Fourteenth Amendment substantive due process right.

To begin, a general discussion of substantive due process puts Plaintiffs' claims in perspective. 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 (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 that fundamental rights include those guaranteed by the Bill of Rights and certain narrowly drawn "liberty" and privacy interests implicit in the Due Process Clause and "the penumbra of constitutional rights." *Id.* at 720–21. These fundamental "liberty" interests include the rights to marry, to have

children, to marital privacy, to use contraception, to bodily integrity, and to abortion, *id.*, as well as a right of privacy directly related to these fundamental interests. *Kallstrom v. City of Columbus,*136 F.3d 1055, 1062 (6th Cir. 1998). None are involved here.

This Court has also recognized that a substantive due process right may arise without the deprivation of a fundamental right in exceptional circumstances 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 in doing so, 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).

In addition, substantive due process protects against only 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 the 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 the district court need not have reached the plaintiffs' Fourteenth Amendment claim.

With this general background in mind, the plaintiffs' substantive-due-process claims can be analyzed. The plaintiffs argue that only two substantive due process rights are at issue: (1) the right of a competent individual to make their own medical decisions, and (2) a parent's right

to raise their children. The district court correctly noted that the plaintiffs actually argue that a third right exists: a child's right to have a parent make medical decisions on the child's behalf. None of these rights exist as alleged.

1. A child is not a competent person with a right to refuse unwanted medical treatment.

The plaintiffs rely heavily on *Cruzan by Cruzan v. Dir., Missouri Dep't of Health*, 497 U.S. 261 (1990), for the principle that "a competent person has a constitutionally protected liberty interest in refusing unwanted medical treatment." *Id.* at 278. Although true, this interest is clearly inapplicable in this case, as newborns are not competent to make medical decisions. Moreover, even *Cruzan* 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.

Consequently, even assuming the truth of the allegations, the right recognized in *Cruzan* is inapplicable to the facts as pled. Accordingly, the plaintiffs have failed to plead a violation of a competent individual's right to refuse medical treatment. The district court properly dismissed this claim.

2. The parents are not the parties here, and the minors cannot raise their parents' right to care for their children—a right that is not absolute.

The plaintiffs argue that the NBS program violates a parent's right to the care, custody, and control of their children. (*See* Pls.' Appeal Br., p. 19-21.) But the rights of the plaintiffs' parents are not at issue in this case because the parents, as guardians and next-friends, are not the real parties-in-interest, and due process rights may not be asserted vicariously. Fed. R. Civ. P. 17(a); *Morgan v Potter*, 157 US 195, 198 (1895) ("The next friend, by whom the suit is brought on behalf of the infant, is neither technically nor substantially the party, but resembles an attorney, or a guardian ad litem, by whom a suit is brought or defended in behalf of another."); *see Kowalski v. Tessmer*, 543 U.S. 125 (2004); *Whitmore v Arkansas*, 495 U.S. 149, 163 (1990).

In any event, while parents have a fundamental right to make decisions concerning the care, custody, and control of their children, *Troxel v. Granville*, 530 U.S. 57, 66 (2000), "[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)). Indeed, as the Supreme Court has held, "a state is not without constitutional control over parental discretion in dealing with children *when their physical or mental health is jeopardized*." *Parham v. J.R.*, 442 U.S. 584, 603 (1979) (emphasis added). The district court recognized that binding "Supreme Court precedent recognizes 'two competing values of equal worth: the right of parents to parent and the right of children to safety.'" (Order Granting Motions to Dismiss, R. 50, Page ID # 830 (quoting *Spiering v. Heineman*, 448 F. Supp. 2d 1129, 1140 (D. Neb. 2006).)

Thus, in order to delineate the legal parameters of this claim, the district court looked "to the well-reasoned opinions" of courts that had "adjudicate[ed] comparable sets of facts." (Order Granting Motions to Dismiss, R. 50, Page ID # 831.) The district court found *Spiering v. Heineman*, 448 F. Supp. 2d 1129, 1140 (D. Neb. 2006), particularly instructive because it involved Nebraska's program of mandatory blood testing of infants for metabolic diseases. *Spiering* held that reasonable restrictions of a parent's right are permissible and that Nebraska's test

did not violate a parent's right to the care, custody, and control of their children.

The district court found the same here. Given that it is undisputed that Michigan has a legitimate interest in early detection of disease and safeguarding infant health and that the tests are minimally invasive, the district court held that the plaintiffs' allegations did not raise a potential violation of this substantive due process right.

The district court also recognized analogous support, reviewing cases addressing mandatory vaccination. Specifically, the district court cited *Jacobson v. Massachusetts*, 197 U.S. 11, 38 (1905), and *Nikolao v. Lyon*, 875 F.3d 310 (6th Cir. 2017), *cert. denied,* 138 S. Ct. 1999 (2018). Both cases found that mandatory vaccinations did not violate any constitutional rights and both pointed to the States' interest in promoting the health and safety of young children. *See also Prince v. Massachusetts*, 321 U.S. 158, 166 (1944) (noting that the family is not beyond regulation in the public interest and that "neither rights of religion nor rights of parenthood are beyond limitation. Acting to guard the general interest in youth's wellbeing, the state as *parens patriae* may restrict the parent's control in many [] ways . . . Its authority is not

nullified merely because the parent grounds his claim to control the child's course of conduct on religion or conscience.")

Contrary to the plaintiffs' assertions, this line of authority is not limited to simply vaccination cases. The rationale is more far-reaching. In *Jacobson v. Commonwealth of Massachusetts*, 197 U.S. 11, 38 (1905), the Supreme Court affirmed several key principles: that governments are instituted to protect their populations; that States exercise their police power[3] to effectuate that duty; and that "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*, 197 U.S. at 25. Moreover, the State's authority extends with yet greater discretion to activity aimed at protecting the health of minors. *See Schall v. Martin*, 467 U.S. 253, 265, 207 (1984) (especially in the context of minor children, "the State must play its part as *parens patriae*."); *Prince v. Massachusetts*, 321 U.S. 158, 168 645 (1944) (explaining that when acting to guard a child's

[3] As commentators have noted, the State's police power allows it to take actions that are based in public health necessity, via reasonable means, and are proportional to the issue being addressed and taken in furtherance of harm avoidance. *See School Vaccination Requirements: His., Soc., and Legal Persp.*, 90 Ky. L.J. 831, 856 (2002).

wellbeing, the State may restrict a parents control in many ways, in particular when the parents may expose the child to ill health or death).

Consequently, the State has broad discretion in this regard, and the plaintiffs' argument that they have a constitutional right to unfettered decision making related to their newborn infants is incorrect. Nor does the infant have a constitutional right to their parent having an unfettered right to medical decision making. Such a right simply does not exist given the rights and interests of the child and the State's own responsibility for the health and welfare of its citizens—including newborn infants. Thus, the district court did not err in finding that the plaintiffs failed to state a claim where the nature of the putative right as alleged by the plaintiffs does not exist.

The district court also expressly rejected the plaintiffs' argument that the vaccination cases are distinguishable because vaccines prevent harm to others, while NBS screening only prevents harm to an individual. This distinction is not supported by caselaw and ignores the benefits vaccines provide to individuals and the State's interest in promoting health in children. (*See* Order Granting Motions to Dismiss, R. 50, Page ID # 832-33.)

Furthermore, the district court was correct in recognizing that the plaintiffs' reliance on *Dubbs v. Head Start, Inc.*, 336 F.3d 1194 (10th Cir. 2003) was misplaced. In *Dubbs*, the Tenth Circuit did not determine whether the parents' substantive due process rights were violated by a school program mandating physical examinations and blood tests without parental consent. Instead, the case focused on the standard of review. *Dubbs* is thus both factually and legally distinguishable from the present case, and the theory the plaintiffs set forth has not been accepted in either the Tenth Circuit or this Circuit. *See Hearring v. Sliwowski*, 712 F.3d 275, 282 (6th Cir. 2013) (noting that the Tenth Circuit's holding in *Dubbs* is out-of-circuit authority that does not show a clearly established right); *PJ ex rel Jensen v. Wagner*, 603 F3d 1182, 1198 (10th Cir. 2010) (finding that a parent's "asserted right to direct [their child]'s medical care was not clearly established" and "cannot overcome the defendant's claims of qualified immunity."). In sum, *Dubbs* simply does not stand for the propositions relied upon by the plaintiffs, nor have the courts interpreted it as the plaintiffs suggest.

Again, assuming the allegations of fact to be true, the plaintiffs failed to state a claim for violation of a parent's right to the care, custody, and control of their children, as the contours of that right are not as the plaintiffs allege them to be.

3. A child does not have a substantive due process right to a parent making all medical decisions on their behalf.

The district court recognized that "[t]here does not appear to be any legal authority supporting the notion that children have a constitutionally protected liberty interest in their parent or guardian making medical decisions on their behalf." (Order Granting Motions to Dismiss, R. 50, Page ID # 830.)

A child's alleged right to have a parent make medical decisions on their behalf is not the same as a parent's right to make decisions concerning the care, custody, and control of their children. A parent's rights and a child's rights are not interchangeable, as the plaintiffs argue.

Additionally, while the above deals primarily with the plaintiffs' claims regarding the initial heel stick, the plaintiffs also made

allegations challenging the retention of the DBS. Even assuming this is intended as an independent violation, this claim must fail.

As an initial matter, the district court correctly concluded that the plaintiffs had not adequately developed or supported this issue. Furthermore, the plaintiffs may opt out of this program at any time, and at the very least were given forms explaining the retention program and opt-out procedures. (*Id.* at 825, 837-38.) Thus, the plaintiffs cannot establish that the DBS were used contrary to their wishes. Accordingly, the plaintiffs have failed to state a claim that retention of the DBS violates the Fourteenth Amendment.

III. The plaintiffs failed to state a claim upon which relief can be granted for a violation of the Fourth Amendment's prohibition of unreasonable searches.

The district court correctly determined that the plaintiffs also failed to allege a violation of the Fourth Amendment. (Order Granting Motions to Dismiss, R. 50, Page ID # 838-39.)

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. v. Jones*, 565 U.S. 400, 404 (2012). The touchstone of Fourth Amendment analysis is

"whether a person has a 'constitutionally protected reasonable expectation of privacy." *Oliver v. U.S.*, 466 U.S. 170, 177 (1984). "The [Fourth] Amendment does not protect the merely subjective expectations of privacy, but only those expectation[s] that society is prepared to recognize as reasonable." *Id.* And that right is personal and cannot be vicariously asserted. *Rakas v. Illinois*, 439 U.S. 128, 133–34 (1978) (citing *Brown v. United States*, 411 U.S. 223, 230 (1973)).

A. The heel stick is not a Fourth Amendment search.

The district court began its analysis by concluding that the heel stick qualified as a search. (Order Granting Motions to Dismiss, R. 50, Page ID # 841.) Defendants respectfully disagree with this, although they agree with the district court's ultimate conclusion. The heel stick does not invade any legitimate expectation of privacy and therefore is not a "search" as contemplated by the Fourth Amendment.

Many courts, including this Court, recognize that procedures undertaken for "purely medical reasons" are not Fourth Amendment searches. *See Hearring v. Sliwowski*, 712 F.3d 275, 281 (6th Cir. 2013) (Fourth Amendment does not apply to visual

inspection for medical purposes); *Peete v. Metro. Gov't of Nashville & Davidson Cty.*, 486 F.3d 217, 222 (6th Cir. 2007) (paramedics who "were not acting to enforce the law, deter or incarcerate" did not breach the Fourth Amendment); *United States v. Attson*, 900 F. 2d 1427, 1433 (9th Cir. 1990) (no Fourth Amendment search where procedures undertaken for "purely medical reasons").

B. Even if the heel stick is a search, it is a reasonable one.

Nevertheless, even if there was a search as contemplated by the Fourth Amendment, there can be no doubt that it is a reasonable one. As the district court explained, the "special needs doctrine" is an exception to the general principle that warrantless searches are per se unreasonable under the Fourth Amendment. *Bd. of Educ. of Indep. Sch. Dist. No. 92 of Pottawatomie Cty. v. Earls*, 536 U.S. 822, 843 (2002). The "special needs doctrine" may apply "when special needs, beyond the normal need for law enforcement, make the warrant and probable-cause requirement impracticable." *Id.* In such cases, courts are tasked with balancing the nature of the intrusion on the individual's privacy

against the promotion of legitimate government interests. *Id.* at 829.

The district court correctly concluded that because the exercise of government authority is distinct from law enforcement, has no individualized considerations of wrongdoing, and is designed to protect the health and safety of infants, Michigan's NBS program does not violate the Fourth Amendment. (Order Granting Motions to Dismiss, R. 50, Page ID # 842.)

The district court also contrasted the facts of this case with the search in *Dubbs*. That case was primarily concerned with a physical examination of children done in violation of the regulations under which the exam was ostensibly performed. (Order Granting Motions to Dismiss, R. 50, Page ID # 842) (citing *Dubbs*, 336 F.3d at 1213-14.) This case, in contrast, involves a minimally invasive heel stick explicitly required by statute. MCL 333.5431. And as the district court noted, there is a long line of precedential cases regarding equally, if not more, invasive programs in furtherance of similar public policy goals. *See, e.g., Nat'l Treasury Employees Union v. Von Raab,* 489 U.S. 656, 666

(1989); *Vernonia Sch. Dist. 47J v. Acton*, 515 U.S. at 657–58 (1995); *Bd. of Educ. of Indep. Sch. Dist. No. 92 of Pottawatomie Cty. v. Earls*, 536 U.S. 822 (2002); *Skinner v. Ry. Labor Executives' Ass'n*, 489 U.S. 602, 620 (1989). Thus, the district court was correct in its conclusion that *Dubbs* is factually distinct.

Considering all of the above, even assuming the plaintiffs' factual allegations are true they do not state a violation of the Fourth Amendment. This Court should affirm the district court's decision.

IV. Other issues also warrant dismissal of Plaintiffs' Complaint.

A. The Eleventh Amendment bars some of the plaintiffs' claims.

Although the district court did not address it, Defendants argued below that, to the extent Plaintiffs have pled a claim for money damages against DHHS or claims against State officials in their official capacities, those claims are barred by the Eleventh Amendment.

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 the State of 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 provides 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 these principles, all claims against MDHHS must be dismissed. MDHHS 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 testing and storage.

B. 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).

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.

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.

C. The State Defendants' exhibits were properly attached.

Plaintiffs continue to take issue with the exhibits properly attached to the State Defendants' motion to dismiss. Not only were they properly attached, but the district court did not appear to have considered them.

As explained in the State Defendants' brief, when reviewing a motion to dismiss under Rule 12(b)(1), "the court is empowered to resolve factual disputes." *RMI Titanium Co. v. Westinghouse Elec. Corp.*, 78 F.3d 1125, 1134 (6th Cir. 1996). Because the court's "very power to hear the case" is at issue, a trial court "is free to weigh the evidence and satisfy itself as to the existence of its power to hear the case." *Id.* at 1134. Specifically, "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). Given that the State

Defendants moved for dismissal under Rule 12(b)(1), the exhibits were properly attached.

The exhibits may also be considered under Rule 12(b)(6). 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).

The reasons and authority supporting inclusion of the exhibits were included in the State Defendants' brief below. (State Defs.' Motion

to Dismiss First Amended Complaint, R. 32, Page ID # 499 n. 2, 504-05.) Nevertheless, the district court appears to have only considered some of the exhibits for a very narrow purpose. Rather than find that some of the plaintiffs did provide actual consent, the district court considered the attachments only for the purpose of determining that the NBS program does provide an opportunity to consent—an allegation central to the plaintiffs' claims.

There is no procedural impropriety surrounding the exhibits and the district court's decision should be affirmed.

CONCLUSION AND RELIEF REQUESTED

Plaintiffs did not allege a violation of any substantive-due-process right because newborn infants do not have a right to refuse medical treatment, newborn infants do not have a right for their parents alone to make medical decisions on their behalf, and parents do not have an unfettered right to make medical decisions that are detrimental to the health and safety of their children. And Plaintiffs further failed to allege facts showing that the DBS were stored without consent. Plaintiffs have not stated a claim under the Fourth Amendment

because a heel stick is not a "search" and even if it were, it is reasonable.

Defendants request that this Court enter an Order affirming the trial court.

Respectfully submitted,

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CERTIFICATE OF COMPLIANCE

Certificate of Compliance with Type-Volume Limit,
Typeface Requirements, and Type Style Requirements

1. This brief complies with the type-volume limitation of Federal Rule of Appellate Procedure 32(a)(7)(B)(i) because, excluding the part of the document exempted by Federal Rule of Appellate Procedure 32(f), this brief contains no more than 13,000 words. This document contains 7,963 words.

2. This document complies with the typeface requirements of Federal Rule of Appellate Procedure 32(a)(5) and the type-style requirements of Federal Rule of Appellate Procedure 32(a)(6) because this document has been prepared in a proportionally spaced typeface using Word 2013 in 14-point Century Schoolbook.

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CERTIFICATE OF SERVICE

I certify that on November 5, 2018, the foregoing document was served on all parties or their counsel of record through the CM/ECF system if they are registered users or, if they are not, by placing a true and correct copy in the United States mail, postage prepaid, to their address of record (designated below).

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DESIGNATION OF RELEVANT DISTRICT COURT DOCUMENTS

Defendants-Appellees, per Sixth Circuit Rule 28(a), 28(a)(1)-(2), 30(b), hereby designated the following portions of the record on appeal:

Description of Entry	Date	Record Entry No.	Page ID No. Range
Complaint	02/08/2018	R. 1	1-40
Corrected Complaint	02/17/2018	R. 3	42-65
State Defendants' Motion to Dismiss	04/17/2018	R. 23	171-224
Motion to Strike State Defendants' Motion to Dismiss and Exhibits Attached Thereto	04/18/2018	R. 23	270-283
Order Denying Motion to Strike and Granting Motion for an Extension	04/25/2018	R. 24	298-299
1st Amended Complaint	04/30/2018	R. 26	300-333
State Defendants' Motion to Dismiss First Amended Complaint	05/29/2018	R. 32	477-582
Plaintiffs' Response to Certain State Defendants' Motion to Dismiss	07/06/2018	R. 45	696-760
State Defendants' Reply Brief	08/01/2018	R. 49	815-824

Order Granting Motions to Dismiss and Dismissing Complaint with Prejudice	08/18/2018	R. 50	825-846
Judgment	08/08/2018	R. 51	847
Notice of Appeal	08/18/2018	R. 52	848