

UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF MICHIGAN
NORTHERN DIVISION

ADAM KANUSZEWSKI et al.,

Plaintiffs,

Case No. 1:18-cv-10472

v.

Honorable Thomas L. Ludington
United States District Judge

MICHIGAN DEPARTMENT OF
HEALTH & HUMAN SERVICES et al.,

Defendants.

**OPINION AND ORDER FINDING DEFENDANTS LIABLE FOR FOURTH
AMENDMENT VIOLATIONS, ENTERING JUDGMENT FOR PLAINTIFFS,
ENJOINING STATE OF MICHIGAN FROM RETAINING PLAINTIFFS' BLOOD
SAMPLES AND DATA WITHOUT INFORMED CONSENT, AND DIRECTING
DEFENDANTS TO SUBMIT PROPOSED NOTICE FOR INFORMED CONSENT**

Under its Newborn Screening Program (NSP), the State of Michigan collects samples of newborn babies' blood and tests it for various medical conditions. But that practice is not at issue here. What is at issue, however, is the State's practice of storing, utilizing, and distributing the newborns' blood samples and related data for research and more without informed parental consent. Four families and their combined nine Michigan-born children claim the State and its agents have violated the Fourth and Fourteenth Amendments through these practices.

Michigan has been collecting and storing every newborn's blood samples since the 1960s. The statutory scheme provides for newborn genetic markers and demographic details to be maintained in an electronic information management system and effectively indefinite storage of the physical records and blood spots. Michigan's BioTrust for Health is employed to assist in, storing and furnishing the babies' blood samples to third parties.

The Sixth Circuit already had its say: under the Fourteenth Amendment, any conduct related to the blood spots and data without informed consent is subject to strict scrutiny. In that realm, the State’s conduct was found lacking. But that did not resolve the State’s potential Fourth Amendment violations.

The primary question presented here is whether Michigan’s “keep mum” practice with these blood samples violates the Fourth Amendment. The State says the Fourth Amendment does not apply here because parents can ask for the samples to be returned or destroyed, storage is necessary, and there are no reasonable privacy expectations. But these assertions fail to address the fundamental Fourth Amendment concerns implicated in the handling of the plaintiffs’ profoundly personal blood samples and data.

Thus, the remaining question is the suitable redress for these constitutional trespasses. The plaintiffs seek a declaratory judgment and an injunction to stop Michigan’s retention and use of their children’s blood samples and data. An injunction will be granted. As a result, the State will have to attempt to obtain informed consent from the parents for the retention and use of their children’s samples and the associated data. Failing to accomplish this within a year will require the State to destroy all the samples and data. In addition, the State will have to offer by mail the options to return and to destroy the samples and data.

I.

This § 1983 case arises from constitutional violations concerning Michigan’s Newborn Screening Program (NSP). That said, this case only involves the claims of nine Michiganders—it is not a class action. And it deserves mention once again that the tests completed for screening purposes are not at issue. The only issue here is the State’s conduct with the blood spots after the health screening is completed. Such posttesting conduct requires informed consent under the

governing state statutes. But the State lacks Plaintiffs’ informed consent, and so this case also does not implicate any blood spots or data that the State has obtained with informed parental consent.

The following facts have been truncated to address the narrow issues discussed below.

A.

Since the 1960s, the State of Michigan and its agents have pricked the heel of nearly every newborn within hours of birth to collect five or six drops of blood on a Dried Blood Spot (DBS) collection card.¹ *Kanuszewski v. MDHHS*, 927 F.3d 396, 403–04 (6th Cir. 2019). The DBS cards contain the babies’ key demographic information.² ECF No. 244 at PageID.6289. Over the past 60 years, the Michigan Department of Health and Human Services (MDHHS) has diagnosed roughly 0.2–0.25% of Michigan newborns with at least one of 58 disorders using this procedure. *See* ECF No. 147-2 at PageID.4243.³

Michigan saves all the data from the screening, including the newborn’s demographic details, disease diagnoses, and genetic markers, in a computerized laboratory information management system (“LIMS”). ECF No. 243 at PageID.6208–09. The retention rules for storing this data in the LIMS is currently indefinite, and the data is accessible to any “authorized” healthcare provider licensed in Michigan at will. ECF No. 244 at PageID.6291–92. Although parents may request the destruction of their babies’ blood spots or cards, deletion of data stored in

¹ In the scientific community, this procedure is called a “neonatal heel prick,” and the cards are called “Guthrie cards.” Tufik Y. Shayeb, *Informed Consent for the Use and Storage of Residual Dried Blood Samples from State-Mandated Newborn Genetic Screening Programs*, 64 BUFF. L. REV. 1017, 1020 & n.16 (2016).

² “The cards include, but may not be limited to, blood samples, baby’s name, gender, birthdate, birth time, weight, gestational weeks, birth order, specimen date, collection time, medical record number, race, information on the mother, physician information, and submitter information.” State of Michigan Rs. Retention and Disposal Schedule, Pls.’ Trial Ex. 7, at 2;

³ According to testimony from Michigan’s Deputy Director for Public Health Administration, Michigan’s NSP has eugenic ends. ECF No. 243 at PageID.6191 (“Michigan’s Newborn Screening Program is designed to . . . select those disorders [that] can result in death or significant permanent disability.”).

the LIMS is not “doable.” *Id.* at PageID.6311–12. That is, every healthcare provider in Michigan has access to an electronic database that contains the genetic markers and demographic information of every baby born in the State of Michigan since the 1960s.

Michigan also keeps the blood spots and physical copies of the babies’ demographic cards. It keeps the cards for 35 years and sends the blood spots to the Michigan Neonatal Biobank in Detroit, Michigan, for 100 years. *See id.* at PageID.6293–94. Michigan uses the babies’ blood samples not only to conduct retests, to research ways to improve its screening tests, to identify victims and suspects of crimes, but also to furnish it to other entities for miscellaneous research. *See id.* at PageID.6296–97.

The BioTrust for Health program, managed by the MDHHS, operates alongside the NSP to coordinate transactions with third parties, such as research institutions and law-enforcement agencies. ECF No. 243 at PageID.6193. Although these transactions now require informed parental consent, requested through a form provided immediately after the mother gives birth, this requirement was not established until 1987, *see* MICH. COMP. LAWS §§ 333.5431, 333.17020, 333.17520, and not implemented by MDHHS until May 1, 2010, ECF Nos. 147-24 at PageID.4351–54; 244 at PageID.6306. The BioTrust coordinator instructs the Biobank which specific blood spots to give to the third parties. ECF No. 243 at PageID.6199. Then the Biobank, acting as Michigan’s vendor, distributes the blood spots to the third parties. *Id.* at PageID.6198. Although the blood spots are partially de-identified, the MDHHS can reidentify the subject of any bloodspot, which it has done with parental consent as well as under court order. ECF No. 244 at PageID.6334–35.

As the Association of Public Health Laboratories⁴ (APHL) explains as *amicus curiae*, every state and territory in the United States has an NSP. *See* ECF No. 146 at PageID.4150. (“More than 98% of all children born in the United States receive [newborn blood screening].”). Although they are not profitable for “state governments,” *see id.* at PageID.4152, NSPs allow states to “research” the “biomarkers” of “nearly the entire population,” including their “DNA, RNA, proteins, metabolites, and evidence of exposures to environmental or infectious agents,” *id.* at PageID.4157, 4159. To that end, the APHL adds, “retention and storage of residual DBS specimens is crucial.” *Id.* at PageID.4152.

The preeminent concern about state-run NSPs is the lack of “consensus about or commitment to” obtaining parents’ informed consent. *See* Ellen Wright Clayton, *Screening and Treatment of Newborns*, 29 HOUS. L. REV. 85, 118 (1992).

Here, too—without obtaining informed consent—Michigan indefinitely stores babies’ blood to conduct “tests,” to identify victims and suspects of crimes, and to furnish it to private entities for “medical” and “health” research. *See* ECF Nos. 135-12 at PageID.2180–85; 148 at PageID.4847. *See generally Kanuszewski v. MDHHS*, 927 F.3d 396 (6th Cir. 2019). Considering the approximately 6,000 newborns that would not have otherwise been diagnosed, enjoining Michigan’s unconstitutional conduct would likely have significant consequences. Again, however, this case is limited to the blood spots and data of only nine Michiganders.

B.

Plaintiffs are four parents and their nine Michigan-born infants who contend that Michigan, four Michigan officials, the Biobank, and its director have violated the Fourth and Fourteenth

⁴ “The Association of Public Health Laboratories is funded by the [CDC].” *Boehringer Ingelheim Vetmedica, Inc. v. Schering-Plough Corp.*, 68 F. Supp. 2d 508, 520 (D.N.J. 1999).

Amendments by retaining, transferring, storing, selling, and using the babies' blood samples and data for research, criminal investigations, and other purposes without informed consent.

After the first round of dispositive motions, the Sixth Circuit reversed and remanded the case with specific instructions: "to apply strict scrutiny to any of Defendants' conduct that lacked informed consent." *Kanuszewski v. Shah*, No. 1:18-CV-10472, 2022 WL 4227875, at *4 (E.D. Mich. Sept. 13, 2022) (citations omitted); *see also Kanuszewski v. MDHHS*, 927 F.3d 396, 420–21 & 420 n.13 (6th Cir. 2019) (holding that Plaintiffs plausibly alleged Defendants' retention, transfer, storage, and "future use by the state or third parties" was "undertaken without informed parental consent" and "must survive strict scrutiny"). To wit: (1) Did Defendants obtain Plaintiff-parents' informed consent for the retention, transfer, storage, sale, or research of their children's blood spots? (2) If not, then does Defendants' conduct survive strict scrutiny?

All Defendants' conduct except the blood draw and initial screening test required informed consent, the Sixth Circuit held, because "parents" have "a fundamental right . . . to direct the medical care of their children." *Kanuszewski v. MDHHS*, 927 F.3d at 418–20 (holding that if Defendants "retain the samples, transfer the samples to the Neonatal Biobank, and store the samples indefinitely for further use by the state or third parties. . . . without informed parental consent," then "Defendants' actions constitute a denial of the parents' fundamental right to direct the medical care of their children, and their actions must survive strict scrutiny"). "[E]mphasiz[ing] that a fundamental right is at stake," the Sixth Circuit added that this Court must determine whether the "nature" of "any parental consent" was "informed" and whether Defendants' conduct fell within the "scope" of the informed consent. *Id.* at 420 n.13.

On remand, this Court followed the Sixth Circuit’s directive. *See Kanuszewski v. Shah*, 551 F. Supp. 3d 747, 766–68 (E.D. Mich. 2021) (applying strict scrutiny to Defendant’s conduct that lacked Plaintiffs’ informed consent).

On reconsideration, this Court held that all Defendants’ conduct lacked informed consent under Michigan’s informed-consent statutes, *see Kanuszewski v. Shah*, 627 F. Supp. 3d 832, 845–51 (E.D. Mich. 2022), and under the potentially applicable federal regulations, *Kanuszewski v. Shah*, No. 1:18-CV-10472, 2022 WL 11964348, at *3–5 (E.D. Mich. Oct. 20, 2022). Thus, questions of fact remained on three Fourth Amendment claims and the appropriate remedy for Defendants’ Fourteenth Amendment violations and any Fourth Amendment violations. *Kanuszewski*, 2022 WL 11964348, at *6.

On February 3, 2023, a bench trial was held to complete the fact finding. ECF Nos. 243–247. The Fourth Amendment violations will be addressed *infra* Part II, the remedies for the violations of the Fourth and Fourteenth Amendment will be addressed *infra* Part III.

II.

The remaining Fourth Amendment issues are whether Defendants are unconstitutionally keeping (1) the screened blood spot, (2) the additional blood spots, and (3) the data saved in the electronic LIMS database. *Kanuszewski*, 2022 WL 11964348, at *6.

The Fourth Amendment shelters citizens against governmental intrusions. The language—“persons, houses, papers, and effects”—is akin to an invisible fortress against “unreasonable searches and seizures.” U.S. CONST. amend. IV. Balancing the individual’s right to privacy with the Government’s interests, the Fourth Amendment stands guard against objectively unreasonable incursions by government officials. *Camara v. Mun. Ct.*, 387 U.S. 523, 528 (1967).

“To determine whether a Fourth Amendment violation has occurred, we ask two primary questions: first, whether the alleged government conduct constitutes a search within the meaning of the Fourth Amendment; and second, whether the search was reasonable.” *Taylor v. City of Saginaw*, 922 F.3d 328, 332 (6th Cir. 2019).

The Sixth Circuit has already answered the first question. *See Kanuszewski v. MDHHS*, 927 F.3d 396, 425 (6th Cir. 2019) (holding that “retaining the children’s blood samples” to “conduct research on children’s stored blood samples and []to derive profit from the children’s samples by selling them to third parties” is a “seizure”); *see also Birchfield v. North Dakota*, 579 U.S. 438, 455 (2016) (“[T]he taking of a blood sample or the administration of a breath test is a search.” (citations omitted)); *Missouri v. McNeely*, 569 U.S. 141, 159, (2013) (“[A]ny compelled intrusion into the human body implicates significant, constitutionally protected privacy interests.”); *Skinner v. Ry. Lab. Execs.’ Ass’n*, 489 U.S. 602, 616 (1989) (“The ensuing chemical analysis of the [blood] sample to obtain physiological data is a *further* invasion of the tested employee’s privacy interests.” (emphasis added) (citing *Arizona v. Hicks*, 480 U.S. 321, 324–25 (1987))); *L.W. ex rel. Williams v. Skrmetti*, No. 23-5600, 2023 WL 4410576, at *5 (6th Cir. July 8, 2023) (“This compulsory storage program, we held, violated nonconsenting parents’ rights ‘to make decisions concerning the medical care of their children.’” (quoting *Kanuszewski*, 927 F.3d at 418)); *cf. Chandler v. Miller*, 520 U.S. 305, 313 (1997) (holding that “government-ordered ‘collection and testing of urine’ are “searches under the Fourth Amendment” (citing *Skinner*, 489 U.S. at 617)).

Defendants, however, make a few arguments deserving of attention.

A.

Defendants assert the Fourth Amendment does not apply to their retention of the blood samples, “because Plaintiffs are, and have always been, free to request return or destruction of their []DBS.” ECF No. 253 at PageID.6870–72. But mere knowledge of an individual’s rights, or the availability of certain options, does not entirely eliminate the need for a Fourth Amendment analysis. This case pertains to an invasive act performed on a newborn baby—taking blood samples and then storing the same for later research and criminal investigations. It involves the matter of a choice offered not to the principal parties involved but rather to their guardians.

Defendants then cite *United States v. Mendenhall*, 446 U.S. 544, 554 (1980), asserting that since Plaintiffs remain free to walk away or to request the return or destruction of the blood samples, no Fourth Amendment issue exists. *Id.* at PageID.6870. But applying the *Mendenhall* principle here would bend it beyond its original context. The *Mendenhall* Court was addressing the particularized scope of the Fourth Amendment in the context of an encounter between police officers and an adult who had the full faculty of understanding her rights, unlike the current situation involving newborns and their parents. *Mendenhall*, 446 U.S. at 558. The Fourth Amendment right at issue here belongs to the infants, who are all still minors, which merits closer scrutiny. *Kanuszewski v. MDHHS*, 927 F.3d 396, 425 (6th Cir. 2019).

Defendants also say that, because of the MDHHS’s extensive public-education efforts, a reasonable person would understand the options available. ECF No. 253 at PageID.6870–71. While efforts made by the MDHHS to educate the public are commendable, the salient point remains that the State’s duty does not end at its efforts at public outreach or the clarity of consent forms. It extends to ensuring that those who interact with the system have a substantial understanding of their rights and the consequences of their choices. *Kanuszewski*, 927 F.3d at 420

(requiring informed consent). Plaintiffs’ contention that they were not adequately informed in a timely manner, especially about the option of opting out, thus merits consideration.

As for Defendants’ argument regarding the timing of the BioTrust consent forms, ECF No. 253 at PageID.6871–72, the feasibility of providing these forms during the prenatal period does not dismiss the contention that parents may be better prepared to make informed decisions if they were given this information before the baby’s birth. And, as explained, under every possible standard at issue here, Michigan has failed to obtain informed consent from Plaintiff-parents for all the conduct at issue in this case. *Kanuszewski v. Shah*, 627 F. Supp. 3d 832, 845–51 (E.D. Mich.), *vacated in part*, No. 1:18-CV-10472, 2022 WL 11964348, at *3–5 (E.D. Mich. Oct. 20, 2022). A low response rate to outreach efforts is not a justification for relinquishing the responsibility of informing parents during prenatal care. Besides, the reality that not all births are preceded by prenatal care does not absolve Defendants from striving to reach all expectant parents in a more systematic manner.

Nor can it be said that merely because none of Plaintiff-parents contacted the MDHHS to ask about the destruction or return of the blood samples, ECF No. 253 at PageID.6872, Plaintiff-infants were fully aware and accepting of the implications of the NSP. The silence of Plaintiffs might well have been the product of the opacity of the system, the infants’ nascent existence in the world, or the result of the overwhelmed state of their new parents.

B.

Next, Defendants argue the Fourth Amendment does not apply, “because retention is done for purely medical purposes.” ECF No. 253 at PageID.6872–75.

But the record indisputably demonstrates that the State has used the blood samples to identify victims and perpetrators of crimes. ECF No. 246 at PageID.6608–09 (“Generally that

process looks like a detective reaching out to the department to inquire about the availability of a blood spot for that purpose.”). And that such requests have been made and approved numerous times under court order. Subpoena, Pls.’ Trial Ex. 30.

Yet the Fourth Amendment’s dual-purpose doctrine acknowledges that governmental conduct can have both medical and law enforcement objectives. *See Caniglia v. Strom*, 141 S. Ct. 1596, 1602 (2021) (Alito, J., concurring) (“Searches and seizures conducted for other non-law-enforcement purposes may arise and may present their own Fourth Amendment issues.”); *United States v. Dionisio*, 410 U.S. 19, 50 n.8 (1973) (Marshall, J., dissenting) (“But it does not follow that the application of the Fourth Amendment is inappropriate when a suspect is subpoenaed for these dual purposes.”); *see also Bond v. United States*, 529 U.S. 334, 339 n.2 (2000) (“[T]he subjective intent of the law enforcement officer is irrelevant in determining whether that officer’s actions violate the Fourth Amendment.”). Courts have recognized that when a search or seizure serves both medical and law-enforcement purposes, it may be subject to Fourth Amendment scrutiny. *E.g., Ferguson v. City of Charleston*, 532 U.S. 67, 85 n.24 (2001) (refusing to find the Fourth Amendment inapplicable where “medical personnel used the criteria set out . . . to collect evidence for law enforcement purposes, and law enforcement officers were extensively involved in the initiation, design, and implementation of the program”).

Even if the drawing and retention of the blood samples was carried out for purely medical reasons—which is not the case here—it would not provide blanket immunity from Fourth Amendment examination. The NSP, while undeniably providing a significant medical benefit, also involves the routine collection and indefinite retention of samples that contain highly personal genetic information. The crucial distinction lies in the nature of the information derived from these samples and its acknowledged use beyond immediate medical needs.

The potential uses for Plaintiff-infants' blood samples beyond the realm of immediate medical aid raises concerns about unwarranted government intrusion into individual privacy. The central question is whether the indefinite retention of Plaintiff-infants' personal genetic information constitutes an unreasonable search or seizure, even if its initial collection may have been medically justified and fell within the bounds of the Fourth Amendment.

And the unique and sensitive nature of genetic information—which now includes personal and private details about a person's health, ancestry, vaccinations, and potential future health risks—has increased the potential implications of genetic information, making it even more vital to protect this information from unwarranted government intrusion.

As will be discussed further *infra*, Defendants have not demonstrated that the retention of the blood samples and data obtained without informed consent is essential for the best possible medical care of future children. Even assuming the importance of retaining these samples, there are legitimate questions about the duration of retention and the processes in place for potential future use of these samples. It is an oversimplification to categorize the act of retention as purely medical when it has significant implications for privacy rights. In this way, Defendants' argument that any potential secondary use is outside the purview of traditional law enforcement is not persuasive. The issue of privacy here transcends traditional law enforcement and falls into the broader domain of potential government intrusion into personal life.

C.

Defendants also argue that "Plaintiffs failed to establish subjectively or objectively reasonable expectations of privacy." ECF No. 253 at PageID.6879–81 (emphasis omitted).

But the Sixth Circuit has answered that question too. *Kanuszewski v. MDHHS*, 927 F.3d 396, 410 (6th Cir. 2019) ("[C]onducting chemical analysis on blood samples invades the subject's

privacy interests.” (citing *Skinner v. Ry. Lab. Execs.’ Ass’n*, 489 U.S. 602, 616 (1989))). That decision is controlling. See *L.W. ex rel. Williams v. Skrmetti*, No. 23-5600, 2023 WL 4410576, at *5 (6th Cir. July 8, 2023) (“This compulsory storage program, we held, violated nonconsenting parents’ rights “to make decisions concerning the medical care of their children.” (quoting *Kanuszewski*, 927 F.3d at 418). Even so, parents have a duty and right to protect the privacy interests of their children’s genetic information and to make informed decisions about how it is collected, stored, and used. See F. Lee Francis, *Who Decides: What the Constitution Says About Parental Authority and the Rights of Minor Children to seek Gender Transition Treatment*, 46 S. ILL. U. L.J. 535, 539–40, 549–61 (2022) (“American law, then, rightly presumes that children lack the requisite capacity to make critical reasoned decisions and thus necessitates adult direction. Our law, as it was similarly reflected at common law, granted broad authority to parents over their children.”).

Defendants next assert that their posttesting conduct is acceptable because Plaintiff-parents provided informed consent and that the State nevertheless waived the informed-consent requirement on their behalf. ECF No. 253 at PageID.6881–85.

But those arguments have also been rejected. *Kanuszewski v. Shah*, 627 F. Supp. 3d 832, 845–51 (E.D. Mich.), *vacated in part*, No. 1:18-CV-10472, 2022 WL 11964348, at *3–5 (E.D. Mich. Oct. 20, 2022). And the bench hearing, where Defendants repeatedly relied on sanctimonious rationales for their conduct, only affirmed those findings. See, e.g., ECF No. 244 at PageID.6306 (“We’re scientists, you know. . . . After 2010 it so happened that we realized we had to have informed consent.”); ECF No. 243 at PageID.6248–49 (testifying that the MDHHS still refuses to seek informed consent from parents regarding their rights to refuse their children’s blood spots and data being used for the NSP’s internal uses); ECF No. 246 at PageID.6640–41 (testifying

that the MDHHS refuses to seek informed consent from parents regarding their rights to have their children's blood spots and data destroyed because "[o]nce a specimen is destroyed, [the State] can't get that specimen back").

In sum, the matter at hand grapples with the bounds of the Fourth Amendment within a complex domain of newborn blood samples and their ensuing retention. Defendants' attempts to sidestep constitutional scrutiny fall flat in the face of the imperatives of the Fourth Amendment. Even within the confines of medical and law-enforcement purposes, the retention and usage of blood samples bear implications that tread on personal privacy rights. The lack of informed consent, and an overreliance on the notion of public education as a coverall, obfuscates the serious nature of the situation—taking and keeping blood from infants who are unequipped to consent, and whose parents are often inadequately informed or incapable of being informed. Defendants' arguments, though deserving of attention, fail to absolve the fundamental Fourth Amendment concerns inherent in the retention of these blood samples and the information they contain and produce.

III.

The next question, then, is whether it is reasonable under the Fourth Amendment for Defendants to keep Plaintiffs' (1) screened blood spot, (2) additional blood spots, or (3) data saved in the electronic LIMS database. *Kanuszewski v. Shah*, No. 1:18-CV-10472, 2022 WL 11964348, at *6 (E.D. Mich. Oct. 20, 2022). And because the retentions in this case are occurring without a warrant and are therefore "presumptively *unreasonable*," *Taylor v. City of Saginaw*, 11 F.4th 483, 487 (6th Cir. 2021) (emphasis added) (citing *Brigham City v. Stuart*, 547 U.S. 398, 403 (2006)), *reh'g denied* (Sept. 14, 2021), the question becomes whether one of the "few specifically established and well-delineated exceptions" to the warrant requirement applies, *id.* (quoting *City*

of Los Angeles v. Patel, 576 U.S. 409, 419 (2015)); *see also Coolidge v. New Hampshire*, 403 U.S. 443, 455 (1971) (noting that the exceptions are “few,” meticulously “established,” scrupulously “delineated,” “jealously and carefully drawn”).

Defendants bear the mantle of demonstrating an exception, or else the retentions at issue are unconstitutional. *Taylor*, 11 F.4th at 487 (6th Cir. 2021) (“It is the government’s burden to establish the applicability of an exception to the warrant requirement.” (citing *Liberty Coins, LLC v. Goodman*, 880 F.3d 274, 281 (6th Cir. 2018))).

Defendants raise two exceptions to the warrant requirement: (1) the *de minimis* exception and (2) the administrative-search exception. *See* ECF No. 253 at PageID.6885–902. Each exception is considered in turn below.

A.

Defendants first raise the *de minimis* exception: retaining the babies’ blood samples and data without their parents’ informed consent is reasonable because the degree of intrusion is minimal compared to the benefits of retention to the NSP. ECF No. 253 at PageID.6885–900.

The term “*de minimis*” translates to “of the least” and denotes something “trifling,” “negligible,” or “so insignificant that a court may overlook it in deciding an issue or case.” *See De Minimis*, BLACK’S LAW DICTIONARY, (11th ed. 2022). The term is a reduction of the Latin phrase “*de minimis non curat lex*,” meaning “the law does not take account of trifles.” *See Threat v. City of Cleveland*, 6 F.4th 672, 678 (6th Cir. 2021). Although courts primarily invoke this principle in copyright, labor, and employment cases, *see, e.g., id.* (Title VII); *In re Amazon.com, Inc.*, 942 F.3d 297, 303 (6th Cir. 2019) (Fair Labor Standards Act); *Mihalek Corp. v. Michigan*, 821 F.2d 327, 328 (6th Cir. 1987) (copyright), they sometimes invoke it for Fourth Amendment purposes, *see,*

e.g., *Andrews v. Hickman Cnty.*, 700 F.3d 845, 855 (6th Cir. 2012) (holding that a sheriff deputy’s warrantless entry into a home was not *de minimis*).

1.

The *de minimis* exception does not apply here, because the intrusion is not minimal. “Properly understood, the *de minimis* exception allows government officials to make minor, warrantless intrusions in favor of only ‘substantial’ government interests.” *Taylor v. City of Saginaw*, 620 F. Supp. 3d 655, 664 (E.D. Mich. 2022) (quoting *United States v. Jacobsen*, 466 U.S. 125 (1984)). But Plaintiffs’ interests in their blood spots, demographic information, and genetic-marker test data are not minimal. *See* discussion *supra* Section II.C. Supporting the great weight of the intrusion, Defendants heavily rely on the importance of the blood spots and data as “necessary.” ECF No. 253 at PageID.6895. That is, Defendants’ level of interest in Plaintiff-infants’ blood spots and data demonstrates that the intrusion is substantial. By contrast, Defendants do not believe the purposes of the NSP are “substantial” as required, but merely “reasonable.” ECF No. 253 at PageID.6893.

Nor is the requisite individualized suspicion present here. “The *de minimis* exception does not allow government officials to ignore the bedrock requirement of ‘individualized suspicion.’” *Taylor*, 620 F. Supp. 3d at 664 (quoting *City of Indianapolis v. Edmond*, 531 U.S. 32, 37 (2000)); Here, the MDHHS keeps—without informed consent—the blood spots, demographic information, and blood-test results of every baby regardless of whether the baby has one of the tested diseases. *See* discussion *supra* Part I. Even then, more than 99.75% of all babies test negative. *Id.* Without “some quantum of individualized suspicion” before the test, *United States v. Martinez-Fuerte*, 428 U.S. 543, 560 1116 (1976) (citing *Terry v. Ohio*, 392 U.S. 1, 21 (1968)), the *de minimis* exception does not justify the retention here.

2.

Yet the *de minimis* exception would not absolve the retention even if it applied. Determining the reasonableness of this postseizure conduct under the *de minimis* exception requires a “balanc[ing] [of] the nature and quality of the intrusion on the individual’s Fourth Amendment interests against the importance of the governmental interests alleged to justify the intrusion.” *Jacobsen*, 466 U.S. at 125 (quoting *United States v. Place*, 462 U.S. 696, 703 (1983)). The analysis must be done “from the perspective ‘of a reasonable [government actor] on the scene, rather than with the 20/20 vision of hindsight.’” *Plumhoff v. Rickard*, 572 U.S. 765, 774–75 (2014) (citations omitted).

As explained above, Defendants’ assertion that retention is harmless lacks merit. The specific contentions—that the potential for misuse is negligible and that the retention poses minimal intrusion—require an unreasonable leap in logic. The very act of retention implicates a potential intrusion: misuse or abuse. *See generally* Mary R. Anderlik & Mark A. Rothstein, *Privacy and Confidentiality of Genetic Information: What Rules for the New Science?*, 2 ANN. REV. GENOMICS HUM. GENETICS 401 (2001) (covering “the ethical, legal, and policy issues associated with the generation and dissemination of genetic information”). While this potential exists, the threat of an infringement on privacy looms over the infants whose information the State retains. *See* Orin S. Kerr, Essay, *Buying Data and the Fourth Amendment*, HOOVER INST. AEGIS SERIES PAPER NO. 2109, July 2021, at 6–11 (explaining that governments that obtain records from “buying databases could gut *Carpenter*[v. *United States*, 138 S. Ct. 2206 (2018)]”). Control over society is similarly at risk. Bob Barr, *Aldous Huxley’s Brave New World—Still a Chilling Vision After All These Years*, 108 MICH. L. REV. 847, 849 (2010) (“[B]y using the power of technology to deliver pleasure and a sense of stability and security to its subjects, the government in Huxley’s

vision could actually minimize the use of force to coerce the populace; thereby also disguising what it is in fact doing.” (citing ALDOUS HUXLEY, *BRAVE NEW WORLD* (1932))).

It is not the realization of harm that constitutes the privacy intrusion, but the risk and the lack of control and consent. And that risk is at its peak here, where the BioTrust has approved every disposition of blood spots since 2012, ECF No. 244 at PageID.6324, yet has “no known record of the number of samples that have actually been submitted to third-party researchers as part of the BioTrust,” ECF No. 246 at PageID.6624.

Secondly, Defendants’ reliance on the Fourth Amendment’s touchstone of reasonableness, viewed in light of *United States v. Knights*, 534 U.S. 112 (2001), is not appropriate in the present context. The nature of the alleged intrusion here is fundamentally different than the situation in *Knights*, which involved a probationer with a reduced expectation of privacy. *Knights*, 534 U.S. at 119 (“[P]robationers “do not enjoy the absolute liberty to which every citizen is entitled.”” (internal quotation marks omitted) (quoting *Griffin v. Wisconsin*, 483 U.S. 868, 874 (1987))). Defendants’ attempt to transpose the *Knight* standard from criminals on probation to babies in a hospital is misguided, as the context and nature of the alleged intrusion differ significantly.

Moreover, Defendants believe that retaining Plaintiffs’ blood spots and data without informed consent is essential. ECF No. 244 at PageID.6297–978 (“You mentioned research. That’s like a side effect. We want to keep it for our own purpose also. That’s the main purpose.”). They say they need the spots to increase the accuracy of the screening process, *see* ECF No. 246 at PageID.6676, to develop new tests, *id.* at PageID.6692–93, and to calibrate the equipment they use for the initial screening, *id.* at PageID.6667.

Yet among the “millions” of blood spots the State has stockpiled in a freezer, ECF No. 244 at PageID.6322, Defendants only need some “5 to 10,000” spots to maintain the NSP because they

“use the same specimens” to calibrate “all [the] instruments,” ECF No. 246 at PageID.6667. Considering that Defendants get approximately 600,000 blood spots per year, *see* ECF No. 245 at PageID.6549, and can secure spots from numerous other sources, ECF No. 246 at PageID.6705, they no longer need to retain Plaintiffs’ 54 blood spots without informed consent to do so. For the same reason, Defendants also do not need to keep Plaintiffs’ data without informed consent; there are ample current and future bloods spots that Defendants can use to increase the accuracy of their tests and to develop new tests. Indeed, Defendants have made no attempt to determine the exact number of spots they need for those purposes, as is their burden. ECF No. 246 at PageID.6676 (“It’s one of those relationships that the more you have the better.”). Nor do Defendants need the spots to develop new tests, which are developed by outside researchers—not the State. ECF No. 244 at PageID.6298. Nor do Defendants need to retain Plaintiffs’ blood spots for third-party projects without informed parental consent; the babies’ parents pay for the NSP in their hospital bill. ECF No. 243 at PageID.6246–47 (“I think that says \$158.91 for the newborn screening card.”). And Defendants have made no effort to prove these funds are insufficient to maintain the efficacy of the NSP.

While the importance of newborn screening is undeniable, there are less intrusive alternatives that could serve the same purpose without retaining Plaintiff-infants’ samples indefinitely. For example, the State could implement a robust and thorough consent process rather than obtaining it within hours of one of the most painful and exhausting labors the human body can endure. Or Defendants could develop a consent form that provides all the information legally required to constitute informed consent about all the nuances of the program—as opposed to providing as little information as possible to increase participation. *Kanuszewski v. Shah*, 627 F. Supp. 3d 832, 847 (E.D. Mich. 2022) (“If, by contrast, the informed-consent form had a checkbox

for parents to confirm that they understood the contents of the pamphlet, then the form's reference to pamphlet might lend a triable issue. But that is not the case.” (internal footnote omitted)). Or they could use the address or phone number on record to request informed consent after the mother leaves the hospital and has a clearer head. Or simply rely on submissions of the form available online for parents to provide informed consent. *See Michigan BioTrust for Health—Consent Options*, MICH. DEP’T HEALTH & HUM. SERVS. (2023), <https://www.michigan.gov/mdhhs/adult-child-serv/childrenfamilies/hereditary/biotrust/michigan-biotrust-for-health-consent-options> [<https://perma.cc/WA9Y-UWU8>]. Indeed, it is critical that our laws not only work to protect public health but also balance it against the preservation of our civil liberties. *See* Sherman J. Clark, *The Courage of Our Convictions*, 97 MICH. L. REV. 2381, 2404 (1999).

Finally, Defendants argue newborn screening and BioTrust research causes little harm because it does not, and cannot, include whole-genome sequencing⁵—only some 160 biomarkers. *See* ECF Nos. 244 at PageID.6332; 253 at PageID.6889–90. This, again, is a limitation of current capability, not a guarantee of future practice. *See* ECF No. 246 at PageID.6634 (testifying to known limitations on the MDHHS’s authority to change its policy to permit whole-genome sequencing). The objective reasonableness of government intrusion under the Constitution is not dictated by the current state of technology, but by its underlying “principles.” *See generally* *Carpenter v. United States*, 138 S. Ct. 2206 (2018). Here, those principles have been violated.

In conclusion, though the public-health benefits of the NSP are of the utmost importance, it may not operate in a manner that unnecessarily infringes on Plaintiffs’ constitutional rights. The

⁵ Whole-genome sequencing is the process of determining the complete sequence of a person’s entire genome, encompassing around six billion specific letters representing the genetic information present in their chromosomes, unlike current genetic-testing methods that focus on specific genes or a limited number of genetic loci. W. Nicholson Price II, *Unblocked Future: Why Gene Patents Won’t Hinder Whole Genome Sequencing and Personalized Medicine*, 33 CARDOZO L. REV. 1601, 1603–04 (2012).

Fourth Amendment guards against unreasonable searches and seizures, and this guard must remain impregnable. Defendants’ arguments, while well reasoned, are ultimately insufficient to meet the standard of reasonableness under the Fourth Amendment.

B.

Defendants also invoke the “special-needs and administrative-search cases, where actual motivations do matter.” ECF No. 253 at PageID.6900–02 (quoting *Ashcroft v. al-Kidd*, 563 U.S. 731, 736 (2011)).

But those arguments are unconvincing as well because they stretch the bounds of Fourth Amendment jurisprudence. In ascribing broad, benevolent purposes to the retention of Plaintiffs’ residual dried blood spots and data, Defendants impermissibly appeal to our communal instinct. For the liberties protected by the Fourth Amendment were not designed to buckle under the weight of communal convenience. *See Katz v. United States*, 389 U.S. 347 (1967) (holding that the Fourth Amendment protects people’s reasonable expectation of privacy in public places); *United States v. Jones*, 565 U.S. 400 (2012) (holding that the attachment of a GPS tracking device to a suspect’s car without a warrant violated the Fourth Amendment); *Kyllo v. United States*, 533 U.S. 27 (2001) (holding that the use of thermal imaging to detect heat emissions from a suspect’s house was a “physical intrusion” that constituted a search under the Fourth Amendment); *Riley v. California*, 573 U.S. 373 (2014) (holding that the police cannot search a cell phone without a warrant).

The Fourth Amendment is not meant to be pruned back by such “utilitarian calculations,” however laudable the outcome may seem. *See* Eugene Milhizer, *The Exclusionary Rule Lottery*, 39 U. TOL. L. REV. 755, 760 (2008) (“If police deterrence and the unspecified social cost of acquitting guilty criminals is all that is calibrated, then fundamental concerns involving individual rights and values, and the common good, are ignored or shortchanged.” (internal footnotes

omitted)); *see also* Eugene R. Milhizer, *Exclusionary Rules and Deterrence After Vega v. Tekoh: The Trend Toward a More Consistent Approach Across the Fourth and Fifth Amendments*, 101 NEB. L. REV. 835, 872 (2023) (warning against “the further erosion of judicially created bright lines in favor of utilitarian balancing based on all the relevant circumstances”); Roy G. Spece, Jr., *COVID-19 Control: Disrupting Doctor-Patient Relationships*, 100 NEB. L. REV. 150, 156 (2021) (“[I]t is primarily public health actors who stand behind the push for delay pronouncements and other severe pandemic countermeasures, although they have virtually ignored the former but paid attention to the latter.”); Vincent J. Samar, *Cyber-Security, Privacy, and the COVID-19 Attenuation?*, 47 J. LEGIS. 1, 35 (2021) (reasoning that the Fourth Amendment can “provide the needed tools for preventing the most egregious invasions of personal information, provided the institutions of our democracy are willing to afford these tools their necessary attention”).

Exceptions to the Fourth Amendment’s warrant requirement, including the special-needs and administrative-search cases, are limited and subjected to careful scrutiny. The “primary purpose” of the seizure being “[d]istinguishable from the general interest in crime control” is just one aspect of this scrutiny. *City of Los Angeles v. Patel*, 576 U.S. 409, 420 (2015). To assign a broad “primary purpose” that neatly sidesteps this criterion, as Defendants’ arguments do above, ignores the potential for misuse and abuse of retained blood spots data in ways that could trench upon the Fourth Amendment’s bulwark against unreasonable searches; the distinguishable primary purpose must be clearly defined. *See Benjamin ex rel. Rebekah C. Benjamin Tr. v. Stemple*, 915 F.3d 1066, 1069 (6th Cir. 2019) (collecting cases); *see also City of Ontario v. Quon*, 560 U.S. 746, 755 (2010) (“It is well settled that the Fourth Amendment’s protection extends beyond the sphere of criminal investigations.” (citing *Camara v. Mun. Ct.*, 387 U.S. 523, 530 (1967))).

More critically, the Fourth Amendment safeguards are not dispensable when their application seems “impracticable” or, indeed, “absurd.” *E.g.*, *Riley v. California*, 573 U.S. 373, 376 (2014) (“That proposal is not appropriate in this context, and would prove no practical limit at all when it comes to cell phone searches.”). Defendants’ assertion that no warrant could ever be issued because the primary purpose of retention is not criminal investigation echoes a troubling refrain from the trial testimony: the ends justify the means. This perspective forgets that the Fourth Amendment was drafted with a keen eye on the misuse of governmental powers. *Carpenter v. United States*, 138 S. Ct. 2206, 2223 (2018) (“[T]his tool risks Government encroachment of the sort the Framers, ‘after consulting the lessons of history,’ drafted the Fourth Amendment to prevent.” (quoting *United States v. Di Re*, 332 U.S. 581, 595 (1948))). Even so, a “warrant” in this context would be the parents’ informed consent, *see Dubbs v. Head Start, Inc.*, 336 F.3d 1194, 1214–15 (10th Cir. 2003), which is not impracticable or absurd based on the record.

Furthermore, the test articulated in cases like *Earls* and *Lidster* invites a more nuanced analysis than Defendants have presented in three brief sentences. *See* ECF No. 253 at PageID.6901–02. The assessment of “the gravity of the public concerns served by the seizure, the degree to which the seizure advances the public interest, and the severity of the interference with individual liberty” demands a balance. *See Illinois v. Lidster*, 540 U.S. 419, 426–27 (2004); *Bd. of Educ. of Indep. Sch. Dist. No. 92 v. Earls*, 536 U.S. 822, 829, 843 (2002). Here, however, the record reflects a lopsided emphasis on the State’s interest in newborn screening and an under-appreciation for the controlling privacy invasions linked to the retention and possible misuse of data. That balancing weighs against the special-needs and administrative-search exception, which nevertheless have never been extended to the nonindividualized medical context of newborn screening at issue here. *See Dubbs*, 336 F.3d at 1214–15 (holding that special-needs exception

does not excuse warrantless blood tests on children if “[t]here is no reason . . . to think that parental notice and consent is ‘impracticable’ in this context”).

It is the duty and privilege of federal courts to maintain vigilance over the liberties afforded to the people by the Fourth Amendment. This task does not provide easy answers or convenient exceptions. And while neither the importance of newborn screening nor the benefits of retention should be minimized, federal courts may not green light a policy or practice that leaves too much room for Fourth Amendment encroachments without due and proper safeguards—as is the case here.

For those reasons, Defendants have not rebutted the presumption of unreasonableness for retaining Plaintiff-infants’ (1) screened blood spot, (2) additional blood spots, and (3) data saved in the electronic LIMS database without a warrant or informed consent. Consequently, Defendants are liable for all three Fourth Amendment claims.

IV.

What is left is the determination of the adequate remedy for Defendants’ constitutional violations. Remedies for the Fourteenth Amendment violations and remedies for the Fourth Amendment violations.

In no uncertain terms, Plaintiffs seek to halt the State’s arbitrary and unconstitutional use of their infants’ blood samples and related genetic data. They argue that Defendants, under the aegis of state law, have overstepped their boundaries and violated the Fourth and Fourteenth Amendments. Plaintiffs further contend that Defendants’ purported consent is a farce, rendering their actions illegitimate. Their arguments are compelling.

A.

Delving into the matter at hand, Plaintiffs seek declaratory relief—a judgment to clarify and to settle the legal disputes involved. ECF No. 242 at PageID.6115. Indeed, it is within this Court’s jurisdiction and duty to issue such a relief,” 28 U.S.C. § 2201, particularly if it aids in resolving the “uncertainty, insecurity, and controversy” bred by this case, *Poole v. Fed. Nat’l Mortg. Ass’n*, 768 F. App’x 332, 338 (6th Cir. 2019) (quoting *Grand Trunk W. R.R. v. Consol. Rail Corp.*, 746 F.2d 323, 326 (6th Cir. 1984)). Although this Court’s primary goal is to adjudicate the propriety of the State’s actions and to ascertain the constitutionality of the same, a declaration may not be used as a tool for procedural maneuvering or to intrude unjustly on state jurisdiction. *Grand Trunk*, 746 F.2d at 326. This task requires a delicate balance.

Under the Declaratory Judgment Act, federal courts “may declare the rights and other legal relations of any interested party seeking such declaration, whether or not further relief is or could be sought.” 28 U.S.C. § 2201(a). District courts enjoy “substantial discretion” when deciding whether to exercise declaratory jurisdiction, as “facts bearing on the usefulness of the declaratory judgment remedy, and fitness of the case for resolution, are peculiarly within their grasp.” *Scottsdale Ins. v. Flowers*, 513 F.3d 546, 554 (6th Cir. 2008) (quoting *Wilton v. Seven Falls Co.*, 515 U.S. 277, 289 (1995)). The Sixth Circuit has identified five factors that district courts should consider:

- (1) [W]hether 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.

United Specialty Ins. v. Cole's Place, Inc., 936 F.3d 386, 396 (6th Cir. 2019) (quoting *Grand Trunk*, 746 F.2d at 326). The fourth factor is divided into three subfactors:

- (1) [W]hether the underlying factual issues are important to an informed resolution of the case;
- (2) whether the state trial court is in a better position to evaluate those factual issues than is the federal court; and
- (3) whether there is a close nexus between underlying factual and legal issues and state law and/or public policy, or whether federal common or statutory law dictates a resolution of the declaratory judgment action.

Id. (quoting *Scottsdale Ins.*, 513 F.3d at 560).

Here, the factors do not weigh in favor of exercising declaratory jurisdiction. Because this case turns on whether the ongoing, warrantless retention of Plaintiff-infants' blood samples and data without informed consent is constitutional, a declaratory judgment would both "settle the controversy" (except as to damages) and "clarify[] the legal relations in issue." *See Cole's Place*, 936 F.3d at 396. There is also no indication that Plaintiffs are seeking a declaratory judgment for "procedural fencing," or that such a judgment would encroach on state-court jurisdiction. *See id.* Most importantly, however, a declaratory judgment is not the most effective remedy—although damages are unavailable, an injunction is more appropriate. *See discussion infra* Section IV.B.

B.

On to the matter of injunctive relief. Plaintiffs next seek to permanently enjoin Defendants from using their blood spots or data. *See* ECF No. 242 at PageID.6117–21. "Injunctive relief is 'an extraordinary remedy that may only be awarded upon a clear showing that the plaintiff is entitled to such relief.'" *EMW Women's Surgical Ctr., P.S.C. v. Friedlander*, 978 F.3d 418, 429 (6th Cir. 2020) (quoting *Winter v. Nat. Res. Def. Council, Inc.*, 555 U.S. 7, 22 (2008)). "A party is entitled to a permanent injunction if it can establish that it suffered a constitutional violation and will suffer continuing irreparable injury for which there is no adequate remedy at law." *Women's Med. Pro.*

Corp. v. Baird, 438 F.3d 595, 602 (6th Cir. 2006). “If [a plaintiff] succeed[s] in demonstrating an actual constitutional violation and continuing irreparable injury, [then she] must also show ‘that the public interest would not be disserved by a permanent injunction.’” *Friedlander*, 978 F.3d at 429 (quoting *eBay Inc. v. MercExchange, LLC*, 547 U.S. 388, 391 (2006)).

Simply declaring the State’s actions unconstitutional will not put an end to the infringement on Plaintiffs’ rights. Indeed, Defendants have repeatedly relied on the notion that they can ask for forgiveness rather than for permission for their constitutional violations. *E.g.*, ECF No. 252, PageID.6850 (“Here, the fact that the [D]BS remain available for return or destruction at Plaintiffs’ request, which request Plaintiffs have inexplicably withheld, mitigates any alleged injury.”). But peoples’ ability to ask the State to stop violating their constitutional rights is not an adequate legal remedy; it is an equitable one. *See* Robert L. Brown III, Note, *Is There a Jury Trial Right in Title VII Actions?*, 33 ARIZ. L. REV. 655, 660–61 (1991) (explaining that legal remedies do not include equitable “[p]ublic rights, those which belong to or exist against the government”). Here, the State has been and continues to maintain possession of Plaintiff-infants’ blood samples and data without informed parental consent. This warrantless seizure, coupled with the lack of an adequate remedy at law, makes the case for an injunction solid.

Here, the State’s continued, nonconsensual retention of Plaintiff-infants’ blood samples for purposes beyond NSP screening is an ongoing, irreparable injury to them. *Reed v. Presque Isle Cnty.*, 594 F. Supp. 3d 884, 888 (E.D. Mich. 2022) (“When constitutional rights are threatened or impaired, irreparable injury is presumed.” (quoting *Obama for Am. v. Husted*, 697 F.3d 423, 436 (6th Cir. 2012))); *Norman-Bloodsaw v. Lawrence Berkeley Lab.*, 135 F.3d 1260, 1269 (9th Cir. 1998) (“One can think of few subject areas more personal and more likely to implicate privacy interests than that of one’s health or genetic make-up.”); SHELDON KRIMSKY & TANIA SIMONCELLI,

GENETIC JUSTICE 235–36 (2011) (explaining that indefinite retention of DNA samples is the most significant privacy concern associated with DNA data banking based on the immense amount of private data).

The State’s intentions, while couched in altruistic aspirations, are inappropriate in the absence of informed parental consent. *See, e.g., Troxel v. Granville*, 530 U.S. 57, 61–62, 69 (2000) (holding that government conduct made “in the best interest of the child” without “deference” to the parents’ preferences violates their fundamental liberty interest “in the care, custody, and control of their children”); Matthew N. Preston II, *The Tweet Test: Attributing Presidential Intent to Agency Action*, 10 BELMONT L. REV. 1, 15 (2022) (“Federal courts have an extensive history of examining governmental intent in constitutional law.”).

And seeking informed consent from Plaintiffs would not be too burdensome or harm the public interest. *See* discussion *supra* Section III.A.2. Indeed, as explained earlier, neither Defendants nor the NSP would suffer irreparable harm by giving back or destroying the blood spots data it retains without informed consent; they already have the blood spots and data from countless others who provided informed consent and countless more to come. *See* discussion *supra* Section III.A.2.

Although it might *seem* fitting to enjoin Defendants from any further use or distribution of Plaintiff-infants’ blood samples without informed consent, this case has potential implications for future cases, and injunctions must be narrowly drawn so as not to disserve the public interest. *See Women’s Med. Pro. Corp.*, 438 F.3d at 602.

Therefore, an injunction will issue directing Defendants to use the addresses they have for each Plaintiff-parent to send by mail a notice providing the options (1) to return Plaintiff-infants’ blood samples, (2) to destroy Plaintiff-infants’ blood samples, and (3) to provide informed consent

for (a) posttesting retention at the Biobank, sale to third parties, testing and research conducted by the State and private parties, disposal based on the current retention schedule, use for maintaining and expanding the NSP, future identification for law-enforcement purposes, any other use by the State and private parties; and (b) posttesting retention of the tested blood spot, the additional blood spots, and the data in the LIMS. If no informed consent is provided for any of these purposes within one year⁶ of Defendants mailing the request, then Defendants must destroy all Plaintiffs' blood samples and data. This opt-in requirement provides the narrowest path to the adequate protection of Plaintiffs' constitutional rights, in contrast to the opt-out approach Defendants have offered to remedy their ongoing constitutional violations. *See* ECF No. 252 at PageID.6848–51.

Lastly, this Court must address the question of the postscreening storage of the medical and genetic data derived from Plaintiff-infants' blood samples. This too is an overreach on the part of the State. Defendants have no rightful claim to this data and must either destroy, return, or seek informed consent to keep it—the same as with the blood samples. And the record is clear that the State does not destroy data according to its own retention schedule. *E.g.*, ECF No. 244 at PageID.6300.

In the absence of clear precedent on this issue, there is ample guidance from analogous cases where government overreach has been remedied through the destruction or return of inappropriately retained data. *E.g.*, *United States v. Comprehensive Drug Testing, Inc.*, 621 F.3d 1162, 1174 (9th Cir. 2010) (en banc) (per curiam) (affirming “an order requiring the government to return or destroy all copies of records that it has seized”), *overruled on other grounds as recognized in Demaree v. Pederson*, 887 F.3d 870, 876 (9th Cir. 2018) (per curiam); *Norman-Bloodsaw v. Lawrence Berkeley Lab’y*, 135 F.3d 1260, 1275 (9th Cir. 1998) (holding that

⁶ One year is apt because posttesting retention is one year in most States, and “12 months or less” of retention would keep Michigan’s NSP “operational.” ECF No. 246 at PageID.6711–12.

“expungement of the test results would be an appropriate remedy” for “the continued storage, against plaintiffs’ wishes, of intimate medical information that was allegedly taken from them by unconstitutional means” (quoting *Fendler v. United States Parole Comm’n*, 774 F.2d 975, 979 (9th Cir. 1985)); *Fendler*, 774 F.2d at 979 (“Federal courts have the equitable power ‘to order the expungement of Government records where necessary to vindicate rights secured by the Constitution or by statute.’” (citation omitted)); *Basey v. United States*, No. 3:21-CV-08688, 2022 WL 4485817, at *4 n.1 (N.D. Cal. Sept. 27, 2022) (“[D]estruction of property may be an appropriate remedy.”).

Implicit in these types of orders that require return of data is that the government may not make or keep a copy for itself. See *Comprehensive Drug Testing*, 621 F.3d at 1172 (explaining that “forcing the government to return property that it had not properly seized” would not only “preserv[e] the integrity of [the plaintiffs’] business” but also “protect[] the privacy and economic well-being of [the plaintiffs’] members”).

Accordingly, Defendants will be directed to seek informed consent to retain all Plaintiff-infants’ data and to describe any use and disclosures of it. If Defendants do not obtain informed consent for any of this conduct, then they must destroy Plaintiffs’ data—every genetic marker, demographic detail, and any information derived from it in Defendants’ possession, custody, or control.

In sum, Plaintiffs have made a compelling case for injunctive relief. The State’s continued retention and use of Plaintiff-infants’ blood samples and related data, without informed consent, violates the Constitution. And as this Court has always held, violations of the Constitution demand remedy. Therefore, Plaintiffs’ request for injunctive relief will be granted.

V.

Accordingly, it is **ORDERED** that Defendants' Objection to Plaintiffs' Surreply, ECF No. 260 is **SUSTAINED**.

Further, it is **ORDERED** that judgment is **ENTERED** as follows:

Claim	Plaintiffs	Status
Data-retention (Count IV)	All	Judgment for Plaintiffs
Tested DBS-retention (Count IV)	All	Judgment for Plaintiffs
Additional DBS-retention (Count IV)	All	Judgment for Plaintiffs
Tested DBS—research (Count II)	All	Summary Judgment for Plaintiffs
Tested DBS—storage (Count II)	All	Summary Judgment for Plaintiffs
Tested DBS—transfer (Count II)	All	Summary Judgment for Plaintiffs
Tested DBS—sale (Count II)	All	Summary Judgment for Plaintiffs
Tested DBS—maintain and expand NSP (Count II)	All	Summary Judgment for Plaintiffs
Tested DBS—other posttesting State use (Count II)	All	Summary Judgment for Plaintiffs
Tested DBS—other posttesting private-party use (Count II)	All	Summary Judgment for Plaintiffs
Tested DBS—disposal (Count II)	Kanuszewskis (DWL, RFK, CKK); Laporte (MTL); Wiegand (LRW, CJW, HJW)	Summary Judgment for Plaintiffs
Tested DBS—disposal (Count II)	Laporte (EMO); Wiegand (MLW)	Summary Judgment for Defendants
Additional DBS—research (Count II)	All	Summary Judgment for Plaintiffs
Additional DBS—draw (Count II)	All	Summary Judgment for Plaintiffs
Additional DBS—storage (Count II)	All	Summary Judgment for Plaintiffs
Additional DBS—transfer (Count II)	All	Summary Judgment for Plaintiffs
Additional DBS—sale (Count II)	All	Summary Judgment for Plaintiffs
Additional DBS—future identification purposes (Count II)	All	Summary Judgment for Plaintiffs

Additional DBS—maintain and expand NSP (Count II)	All	Summary Judgment for Plaintiffs
Additional DBS—other State use (Count II)	All	Summary Judgment for Plaintiffs
Additional DBS—other private-party use (Count II)	All	Summary Judgment for Plaintiffs
Additional DBS—disposal (Count II)	Kanuszewskis (DWL, RFK, CKK); Laporte (MTL); Wiegand (LRW, CJW, HJW)	Summary Judgment for Plaintiffs
Additional DBS—disposal (Count II)	Laporte (EMO); Wiegand (MLW)	Summary Judgment for Defendants

Further, it is **ORDERED** that Defendants are **ENJOINED** as follows:

Defendants are **DIRECTED** to use the addresses they have for each Plaintiff-parent and to send notices by mail a Notice that provides the options (1) to return Plaintiff-infants' blood samples and data, (2) to destroy Plaintiff-infants' blood samples and data, and (3) to provide informed consent for (a) posttesting retention at the Biobank, sale to third parties, testing and research conducted by public and private entities, disposal based on the current retention schedule, use for maintaining and expanding the Newborn Screening Program, future identification for law-enforcement purposes, any other use by public and private entities; and (b) posttesting retention of the tested blood spot, the additional blood spots, and the data in any Library Information Management System. If no informed consent is provided for any of these purposes **within one year** of the date that Defendants mail the notices, then Defendants are **DIRECTED** to destroy Plaintiffs' blood samples and data. To that end, Defendants are **DIRECTED** to submit a Proposed Notice to this Court for approval **on or before August 14, 2023**. Defendants will later be directed to mail the Approved Notice **within 30 days** of approval.

This is a final order and closes the above-captioned case.

Dated: July 28, 2023

s/Thomas L. Ludington
THOMAS L. LUDINGTON
United States District Judge