No. 23-1733

In the United States Court of Appeals for the Sixth Circuit

ADAM KANUSZEWSKI, et al, Plaintiffs-Appellees, v. MICHIGAN DEPARTMENT OF HEALTH AND HUMAN SERVICES, et al, Defendants-Appellees.	Appeal from the United States District Court for the Eastern District of Michigan, Northern Division The Honorable Thomas Ludington, Judge Presiding

BRIEF OF AMICI CURIAE: ASSOCIATION OF PUBLIC HEALTH LABORATORIES, ALD ALLIANCE, AMERICAN COLLEGE OF MEDICAL GENETICS AND GENOMICS, AND HCU NETWORK AMERICA IN SUPPORT OF APPELLEES

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CIRCUIT RULE 26.1 DISCLOSURE STATEMENT

1. None of the amici joining this brief is a subsidiary or affiliate of a publicly owned corporation.

2. The amici joining this brief know of no publicly owned corporation with a financial interest in the outcome of this appeal.

/s/Kimberly A. Jansen

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STATEMENT OF INTEREST OF AMICI CURIAE

The Association of Public Health Laboratories (APHL) is a non-profit, 501(c)(3) organization dedicated to ensuring the strength of laboratory systems serving public health in the United States and globally. APHL's expert staff represent diverse disciplines, from infectious disease, environmental health, and food safety to newborn screening and public health preparedness.

The ALD Alliance is a non-profit 501 (c)(3) organization dedicated to advocating for newborn screening nationally, particularly for adrenoleukodsytrophy (ALD). Elisa Seeger started the ALD Alliance in 2012 after losing her seven-year old son Aidan to ALD. Although a newborn screening test for ALD existed at that time, it was not being used by a single state.

The American College of Medical Genetics and Genomics (ACMG) is the only nationally recognized medical professional organization solely dedicated to improving health through the practice of medical genetics and genomics, and the only medical specialty society in the U.S. that represents the full spectrum of medical genetics disciplines in a single organization. The ACMG is

dedicated to improving health through the clinical and laboratory practice of medical genetics and to guiding the safe and effective integration of genetics and genomics into all of medicine and healthcare, resulting in improved personal and public health.

HCU Network America is a non-profit, 501(c)(3) organization that represents those living with classical homocystinuria and remethylation disorders in the United States and is one of two patient organizations worldwide serving this population. HCU Network America works closely with and advocates for the community; provides education and support; and funds research.

Resolution of the weighty Constitutional issues raised in this case will significantly impact each of the amici. The Court's decision will significantly impact the availability of retained samples, which are necessary to help improve and expand newborn screening tests. Just as retained DBS were used to validate the NBS test for ALD, retained DBS from classical homocystinuria patients are needed to refine testing thresholds in order to address a high rate of false negatives in current NBS screening. Such improvements are only possible, however, if

researchers have access to an adequate repository of disease-specific residual DBS

Each of the amici believes that this Court will benefit from their insights, both as to how resolution of the constitutional questions will affect their important work and as to how the importance of their work affects the constitutional issues.

Amici file this brief with a motion for leave to file under Federal Rule of Appellate Procedure 29(b)(2)

No counsel for any party authored this brief in whole or in part. No entity or person, other than amicus curiae, its members, or its counsel, made any monetary contribution intended to fund the preparation or submission of this brief.

STATEMENT OF FACTS

While characterizing the district court's understanding of newborn bloodspot screening (NBS) and dried bloodspot (DBS) retention as "dystopian" might seem hyperbolic, the district court openly invites that characterization with claims that Michigan's NBS program has "eugenic ends" (ECF No. 261, p. 3, n.3) and that the valuable public health policies supporting this program are but a pretext for efforts "to coerce the populace" and "disguise[e] what [the government] is in fact doing." (ECF No. 261, p. 18)

The district court's perception of NBS as a tool to control the masses does not align with the reality of this important public health program. Embracing this erroneous perception will, as the district court itself acknowledged, have "significant consequences" for public health.

I. Historical Background of Newborn Bloodspot Screening

NBS began with a rare but devastating condition: phenylketonuria (PKU). In infants with PKU, deficiency in an enzyme necessary for protein synthesis leads to mental

retardation.[1] This outcome can be avoided if the condition is detected, and a special diet introduced, during the infant's first week of life.[2] In the early 1960s, Dr. Robert Guthrie developed a groundbreaking test to detect PKU using drops of blood collected on strips of filter paper.[3]

"Guthrie became a 'crusader' for universal screening of newborns for PKU."[4] By 1965, compulsory newborn screening laws had been enacted in 27 states (including Michigan); by "the mid-1970s, NBS for PKU had become routine in nearly every

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[1] Crowe, S., *A Brief History of Newborn Screening in the United States*, https://bioethicsarchive.georgetown.edu/pcbe/background/newborn_screening_crowe.html.

[2] Broscoe, J. and Paul, D. *The Political History of PKU: Reflections on 50 Years of Newborn Screening*, 132(6) Pediatrics 987 (December 2013).

[3] Levy, H., *Robert Guthrie and the Trials and Tribulations of Newborn Screening*, Int. J. Neonatal Screen. 7(1):5 (2021).

[4] McCabe,L., *et al*, *Newborn screening: rationale for a comprehensive, fully integrated public health system*, 77 Molecular Genetics and Metabolism 267 (2002).

industrialized nation."[5] "The premise of [NBS] is to detect disorders pre-symptomatically, such that effective treatments can be applied."[6]

Assays initially used to analyze DBS required one-at-a-time analysis of the analytes for each disorder included in the newborn screening program.[7] Technological advancements in the late 1990s allowed for simultaneous analysis of multiple analytes characteristic of numerous disorders.[8] Thanks to these scientific advancements, NBS expanded to include more than 50 different

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[5] Broscoe and Paul, *The Political History of PKU*, *supra,* at 987.

[6] Kwan, A. and Puck, J., *History and current status of newborn screening for severe combined immunodeficiency*, 39 Seminars in Perinatology 194, 195 (2015).

[7] Hertzberg, V., *et al.*, *Birth Prevalence Rates of Newborn Screening Disorders in Relation to Screening Practices in the United States*, 159(4) J. Pediatrics 555, 556 (2011)

Garg, U., and Dasouki, M., *Expanded newborn screening of inherited metabolic disorders by tandem mass spectrometry: Clinical and laboratory aspects*, 39 Clinical Biochemistry 315, 316 (2006).

[8] *Ibid.*; Hertzberg, *et al.*, *Birth Prevalence…*, *supra*, at 556.

life- or health-threatening conditions for which early detection and treatment are essential.[9]

In 2008, Congress enacted the Newborn Screening Saves Lives Act of 2007, which supports screening efforts by providing grants to improve screening and expand public education.[10] It also created the United States' Secretary of Health and Human Services' Advisory Committee on Heritable Disorders in Newborns and Children (HHS Advisory Committee), which provides "[r]ecommendations and advice" to the Secretary "regarding grants and projects funded, awarded, or authorized for the screening of genetic disorders in newborns and children" as well as

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[9] Therrell, Jr., B., *et. al*., *Current status of newborn screening worldwide: 2015*, 39 Seminars in Perinatology 171, 172 (2015).

See also, Health Resources & Services Administration, *Newborn Screening: Conditions*, https://newbornscreening.hrsa.gov/conditions (viewed Nov. 29, 2023) (listing more than 80 conditions detectable through newborn screening as of September 2023)

[10] Newborn Screening Saves Lives Act of 2007, Pub. Law No. 110–204, 122 Stat. 705 (2008).

regarding means of improving the NBS process.[11] The HHS Advisory Committee has approved a Recommended Uniform Screening Panel (RUSP[12]) and has developed "an evidence-based protocol for reviewing and recommending other conditions for inclusion on the RUSP."[13]

More than 98% of all children born in the United States receive NBS.[14]

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[11] The Advisory Committee on Heritable Disorders in Newborns and Children, Report to Congress, § 3 (2018).

[12] *Recommended Uniform Screening Panel Core Conditions*, https://www.hrsa.gov/sites/default/files/hrsa/advisory-committees/heritable-disorders/rusp/rusp-january-2023.pdf (a national guideline of conditions for which the United States Secretary of Health and Human Services recommends all newborns receive screening).

[13] Therrell, B., *Current status… , supra*, at 172.

[14] Association of Public Health Laboratories, Newborn Screening: Four Facts Policymakers Need to Know, 2, https://www.aphl.org/aboutAPHL/publications/Documents/NBS_2012Dec20_Newborn-Screening-Four-Facts-Policymakers-Need-to-Know.pdf.

II. Collection and Testing

The process of newborn bloodspot screening is straightforward.[15] The newborn's heel is warmed to increase blood flow, cleaned, and then pricked with a sterile lancet.[16] After the first drop of blood is wiped away, additional drops are collected to fill pre-printed circles on specialized filter paper (a "Guthrie card").[17] After drying at room temperature for several hours, the card is transported to an appropriate laboratory for testing.[18]

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[15] See, e.g., Minnesota Department of Health, *Newborn Screening Information for Providers: Blood Spot Collection*, https://www.health.state.mn.us/people/newbornscreening/providers/collection.html

Alabama Department of Public Health Bureau of Clinical Laboratories, *Newborn Screening Collection Guidelines* (2019), pp. 21–22 https://www.alabamapublichealth.gov/newbornscreening/assets/newbornscreeningbloodcollectionguidelines.pdf

[16] Garg and Dasouki, *Expanded newborn screening…*, *supra*, at 316.

[17] *Ibid.*

[18] Moat, S., *et al.*, , *Use of Dried Blood Spot Specimens to Monitor Patients with Inherited Metabolic Disorders*, Int. J. Neonatal Screen 6(2):26 (2020).

III. Retention and Storage of Residual Dried Blood Spots

An effective NBS program begins with the collection and testing of DBS specimens, but cannot end there. The program must also include follow-up based on the testing results, education of parents and families, and continuous process evaluation. Because the retention and storage of residual DBS specimens is crucial to many components of a comprehensive NBS program, APHL has endorsed the 2011 HHS Advisory Committee Report addressing the retention and use of residual DBS.[19]

A. Quality Assurance and Program Accountability.

"All NBS testing in the United States must be done by laboratories licensed by their respective states and must meet the

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[19] Association of Public Health Laboratories, *APHL Position Statement on Newborn Screening Residual Dried Blood Spot Specimens* (2017), https://www.aphl.org/policy/Position_Documents/DBS%20Final.pdf.

Therrell, Jr., B., *et al.*, *Committee report: Considerations and recommendations for national guidance regarding the retention and use of residual dried blood spot specimens after newborn screening*, 13(7) Genetics in Medicine, 621 (2011).

requirements of" the Clinical Laboratory Improvement Amendments of 1988 (CLIA) (Pub. L. No. 100-578, 102 Stat. 2903).[20] The NBS "screening laboratory is usually a specialized laboratory because of the micro-techniques used, the cost savings from centralized laboratory services, and improvements in quality realized when testing large quantities of specimens for relatively rare conditions."[21] The rarity of the disorders screened for, the exacting nature of the science and laboratory medicine involved, and the massive logistics required to perform screening and follow-up across the entire state all make the chances of profitability from NBS unlikely, making state governments the natural choice for administration of NBS programs.

Residual DBS specimens are retained for a number of "standard program uses" such as "program evaluation and quality

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[20] Pass, K., *et al.*, *US Newborn Screening System Guidelines II: Follow-up of Children, Diagnosis, Management, and Evaluation, Statement of the Council of Regional Networks for Genetic Services*, 137(4) J. Pediatrics S1, S41 (2000).

[21] Therrell, *et al.*, *Current status…*, *supra* at 172

assurance, treatment efficacy, test refinement, and result verification activities for the laboratory and program."[22] Residual DBS specimens are essential for certain program activities, such as:

> (1) laboratory quality control, quality assurance and improvement;
>
> (2) calibration of equipment;
>
> (3) evaluation of equipment, reagents, and methods of newborn screening tests for conditions approved for screening by the program;
>
> (4) validation of equipment and screening methods;
>
> (5) development, testing, and maintenance of a plan to ensure continuity of operations in the event of an emergency;
>
> (6) assuring competency of testing personnel.[23]

Residual DBS specimens are essential for quality assurance and quality improvement. Quality assurance is more than simply

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[22] Therrell, Jr., Committee report…, *supra*, at 622; Association of Women's Health, Obstetric and Neonatal Nurses, *AWHONN Position Statement: Newborn Screening*, 51(5) Journal of Obstetric, Gynecologic, & Neonatal Nursing, e3, e4 (2022).

[23] *APHL Position Statement on Newborn Screening Residual Dried Blood Spot Specimens, supra*. See also

quality control.[24] In the NBS process, quality control "is the mechanism of monitoring the degree of adherence to defined criteria, taking corrective action when the system fails and documenting all of these events to convey the total quality of performance."[25] Quality assurance "is a dynamic process of defining the quality of performance required for each step in the testing process" and "encompasses all parameters of the NBS system."[26] As high-complexity tests, newborn screening tests are subject to regulations under the CLIA, including requirements for "proficiency testing, facility administration, quality systems for the

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[24] Association of Public Health Laboratories, *APHL Position Statement: Quality Assurance in the Newborn Screening Laboratory* (2011), https://www.aphl.org/policy/Position_Documents/NBS_2011_Quality_Assurance_in_the_Newborn_Screening_Laboratory_no_implementation.pdf

[25] *Ibid*.

[26] *Ibid*.

total testing process (which consists of the preanalytic, analytic, and postanalytic phases)."[27]

Adequate quality assurance and improvement requires access to a large repository of retained samples. The district court mistakenly believed that "among the 'millions' of blood spots the State has stockpiled in a freezer… Defendants only need some '5 to 10,000' spots to maintain the NSP." (ECF No. 261, p. 18.) But the "5 to 10,000" figure refers to the number of spots *positive for a specific disease* needed to initially calibrate the testing instruments. (ECF No. 246 at PageID.6667.)

Many of the diseases and disorders tested for in NBS are rare. With an incidence of PKU at only 0.59 per 10,000 live births[28],

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[27] U.S. Department of Health and Human Services, Centers for Disease Control and Prevention, *Good Laboratory Practices for Biochemical Genetic Testing and Newborn Screening for Inherited Metabolic Disorders*, 61(2) Morbidity and Mortality Weekly Report 1, 5 (2012).

[28] Sontag MK, *et al. Infants with Congenital Disorders Identified Through Newborn Screening — United States, 2015–2017*, MMWR Morb Mortal Wkly Rep 2020;69:1265–1268.

every 100,000 DBS samples collected can be expected to yield fewer than 6 positive for PKU. Only 49 out of every 100,000 samples collected can be expected to be positive for sickle cell disease.[29] To preserve even a modest set of samples reflective of each of the specific diseases screened for requires retention of a significantly larger pool of samples.

The newborn period represents a unique time in measuring many of the biochemical analytes needed to screen for NBS disorders.[30] In fact, several biochemical analytes utilized for the purpose of NBS are not present in infants, children, or adults. Because of this, residual DBS samples from newborns are an important component of quality control for NBS programs.

B. Biomedical Research

The unique attributes of residual DBS collected during the neonatal period also make these samples particularly valuable in

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[29] *Id*.

[30] El-Hattab, A. *et al* , *Newborn Screening: History, Current Status, and Future Directions*, Pediatr Clin N Am 65(2) (2018) 389, 396

biomedical research. "They provide a nearly complete representation of the population[,]... can be integrated with existing public health data[,]… and contain a very wide range of biomarkers, including… evidence of exposures to environmental or infectious agents."[31]

The HHS Advisory Committee has encouraged state NBS laboratories to "consider the value of the [residual DBS] specimens as a promising resource for research."[32] The use of residual DBS specimens "for test development and research has accelerated discovery and has resulted in direct public health benefits."[33] Repositories of DBS, like that maintained at Michigan's Neonatal Biobank, "provide a unique and potentially powerful resource for

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[31] Olson, S. and Berger, A., *Challenges and Opportunities in Using Residual Newborn Screening Samples for Translational Research: Workshop Summary*, Institute of Medicine Roundtable on Translating Genomic-Based Research for Health. (2010) Washington (DC): National Academies Press (US), 11.

[32] Therrell, Jr., *et al.*, *Committee report…*, *supra*, at 622,

[33] U.S. Department of Health and Human Services, Centers for Disease Control and Prevention, *Good Laboratory Practices…*, *supra* at 5.

retrospective assessment of environmental exposures during the prenatal period," with "enormous potential to open up new research on the impacts of early chemical exposure on disease."[34] Residual DBS specimens "can be used for case studies of rare diseases, cross-sectional studies of the prevalence of a particular condition or exposure, case-control studies, and birth cohort studies."[35] Medical and public health research using residual DBS specimens has included: (1) studying the incidence of different gene variants for an inherited condition (hereditary hemochromatosis); (2) developing additional laboratory screening methods (sickle cell diseases); and (3) searching for new disease markers (childhood leukemia)."[36]

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[34] Batterman, S. and Chernyak, S., *Performance and storage integrity of dried blood spots for PCB, BFR and pesticide measurements*, 494–495 Science of the Total Environment 252, 252–53 (2014).

[35] Olson and Berger, *Challenges and Opportunities…, supra* at 14.

[36] *Id.*, at 26, (quoting "Newborn Screening Dried Blood Spots and Michigan's BioTrust Initiative," http://www.michigan.gov/documents/mdch/FAQbooklet_269087_7.pdf).

"Hundreds or even thousands of diseases and health outcomes could be studied using residual dried blood spots in case-control studies," including "cerebral palsy, hearing loss, severe combined immunodeficiency, sudden cardiac death, drug allergies, and childhood cancers."[37] Studies involving severe combined immunodeficiency (SCID) have already yielded new nationwide NBS tests.[38] Medical research using DBS has recently led to the development of a SARS-CoV-2 antibody assay to detect prior maternal infection, measure population-level trends of COVID-19, and monitor for resurgence of this disease.[39]

To understand the number of retained spots necessary to support this type of research, consider congenital cytomegalovirus

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[37] Olson and Berger, *Challenges and Opportunities…*, at 14.

[38] Gerstel-Thompson JG, et al, *High Throughput Multiplexed TREC qPCR Assay with Internal Controls for Detection of Severe Combined Immunodeficiency in Population-based Newborn Screening*, Clinical Chemistry 56(9):1466-74 (2010),

[39] Liu, F., *et al.*, *Newborn Dried Blood Spots for Serologic surveys of Covid-19*, 39(12) The Pediatric Infectious Disease Journal e454, e455 (2020).

(cCMV), a congenital viral infection which can lead to "sensorineural hearing loss, intellectual disability, cerebral palsy, seizure disorders, and learning delays," and which is present in approximately 4.5 out of 1000 live births.[40] Researchers seeking to develop "an optimal screening strategy for identifying newborns at risk for long-term cCMV-related sequelae" projected an enrollment sample of 25,000 "based on the group sample sizes required to evaluate DBS clinical sensitivity, i.e., the ability of a test to identify cases of cCMV disease present at birth or that manifests by age 3 to 4 years." Such research ultimately "showed it was feasible to use dried blood spots to screen for cCMV," enabling Minnesota to become the first state to screen all newborns for cCMV beginning in February 2023.[41]

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[40] Dollard, S., *et al*, *Sensitivity of Dried Blood Spot Testing for Detection of Congenital Cytomegalovirus Infection*, JAMA Pediatrics 175(3) (Feb. 2021), available online at: https://jamanetwork.com/journals/jamapediatrics/fullarticle/2775873.

[41] Minnesota Department of Health, *News Release: Minnesota becomes first state to screen all newborns for congenital cytomegalovirus* (Feb. 8, 2023)

A bill to expand Michigan's NBS program to include cCMV testing has been introduced in Michigan's legislature. H.B. 5140, 102 Leg., Reg. Sess. (Mich. 2023).

IV. The District Court's Judgment and Why it Matters

Following this Court's previous decision, two issues remained to be decided by the district court on remand:

1. Is the ongoing retention and storage of residual DBS an unreasonable seizure under the Fourth Amendment?

2. Does the ongoing retention and storage of residual DBS interfere with a fundamental right of parents under the Fourteenth Amendment to direct their children's medical care?

Answering these questions involves more than simply a policy determination as to whether parental consent should be required for the storage and use of residual DBS or what form such consent should take. Instead, these questions implicate important issues regarding property interests in DBS collected in the course of newborn screening and the scope, as a matter of substantive due

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https://www.health.state.mn.us/news/pressrel/2023/ccmv020823.html

process, of the fundamental rights parents possess with respect to their children.

The answers to these questions are legally consequential. They also, as the district court acknowledged, have "significant consequences" for public health given the hundreds of children diagnosed each year in Michigan thanks to NBS. The district court brushed these significant consequences aside, reasoning that "this case is limited to the blood spots and data of only nine Michiganders." (ECF No. 261, p. 5) But even though the relief granted by the district court is limited to those nine Michiganders, the impact of the court's decision is not. The district court's holding that the retention and use of the nine plaintiff children's residual DBS violates both the Fourth and Fourteenth Amendments will necessarily affect the use and retention of all specimens stored in Michigan. And this Court's decision, by establishing precedent regarding the application of those provisions to biological specimens, will necessarily affect the use and retention of biospecimens at biobanks throughout Kentucky, Michigan, Ohio, and Tennessee, and potentially throughout the country.

The Michigan Neonatal Biobank holds residual DBS dating back to the 1980s, and its repository now includes millions of specimens.[42] This repository is crucial to the Newborn Screening Program and the research potential of such archives is enormous—not simply because the raw number of samples is large, but because those samples stretch across all parts of the state population (including demographic groups that are often underrepresented in medical research) and reach back decades. How this Court resolves the issues presented by plaintiffs could affect the efficacy of the newborn screening program in Michigan and dramatically impact the biomedical research environment, potentially chilling scientific progress critical to protecting public health.

The Fourth Amendment's prohibition of unreasonable searches and seizures, and the Fourteenth Amendment's guarantee of substantive due process, indisputably protect important

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[42] Batterman and Chernyak, *Performance and storage…*, 494–495 Science of the Total Environment at 252.

interests that ought not be lightly disregarded. By the same token, these protections ought not be lightly invoked, to the detriment of universal access to critical public health services and scientific progress, where the interests those Constitutional provisions were designed to protect are under no threat.

ARGUMENT

I. Fourth Amendment

The Fourth Amendment "protects two types of expectations, one involving 'searches,' the other 'seizures.'" *Soldal v. Cook Cty.*, 506 U.S. 56, 63 (1992) (quoting *United States v. Jacobsen*, 466 U.S. 109, 113 (1984)). "Different interests are implicated by a seizure than by a search." *Segura v. United States*, 468 U.S. 796, 806 (1984). "A seizure affects only the person's possessory interests; a search affects a person's privacy interests." *Id*. The district court's decision focuses solely on the privacy interests at issue in determining the reasonableness of a search. Whether analyzed as a search or as a seizure, finding a violation here is an unwarranted and imprudent expansion of the Fourth Amendment.

A. Search—Privacy Interests

1. No "search" is conducted on the residual DBS.

"The Founding generation crafted the Fourth Amendment as a response to the reviled 'general warrants' and 'writs of assistance' of the colonial era, which allowed British officers to rummage through homes in an unrestrained search for evidence of criminal activity." *Carpenter v. United States*, 138 S. Ct. 2206, 2213 (2018) (cleaned up, quoting *Riley v. California*, 573 U.S. 373, 403 (2014).) "For much of our history, Fourth Amendment search doctrine was 'tied to common-law trespass' and focused on whether the Government 'obtains information by physically intruding on a constitutionally protected area.'" *Id*. (quoting *United States v. Jones*, 565 U.S. 400, 405, 406 n.3 (2012)).

While later cases emphasized the "reasonable expectation of privacy," the "reasonable-expectation-of-privacy test has been *added to*, not *substituted for*, the common-law trespassory test." *Jones*, 656 U.S. at 409 (emphasis in original). "A trespass on 'houses' or 'effects,' or [an] invasion of privacy, is not alone a search unless it is done to obtain information; and the obtaining of information is

not alone a search unless it is achieved by such a trespass or invasion of privacy." *Id.*, at 408, n.5.

a. The State did not obtain information from the retention and storage of plaintiffs' residual DBS.

Retention and storage can, under some circumstances, amount to a *seizure*, as this Court recognized. See *Kanuszewski v. Mich. HHS*, 927 F.3d 396, 424 (6th Cir. 2019). More on this below. But retention and storage of residual DBS cannot, on their own, constitute a *search* when the State obtains no information at all from retention and storage. The Supreme Court's decision in *Riley* illustrates this distinction. In *Riley*, seizure of the petitioners' was concededly lawful incident to their arrests. *Riley*, 573 U.S. at 388. Nevertheless, the Court held that the Fourth Amendment does not permit law enforcement officers to access the data stored on a cell phone as a search incident to arrest, "even when a cell phone is seized incident to arrest." *Id*. at 401. The lawfulness of the seizure and the lawfulness of the search are separate inquiries.

Assuming *arguendo* that storage and retention of residual DBS is a "seizure" under the Fourth Amendment, a "search" does

not occur unless and until information is extracted from the stored materials. Like the cell phones at issue in *Riley*, residual DBS samples may contain a wealth of valuable information. But until that information is accessed, no search has occurred.

The record indisputably demonstrates that none of the plaintiffs' residual DBS have been used for post-screening purpose. (ECF No. 253 at PageID.6607–08.) They were simply retained. Thus, in order to find an unlawful search, the district court pointed to the "*potential* uses" for the DBS and the nature of the information that could be extracted. (emphasis added, p. 12.) But the Supreme Court has "never held that potential, as opposed to actual, invasions of privacy constitute searches for purposes of the Fourth Amendment." *United States v. Karo*, 468 U.S. 705, 712 (1984). "[A]n attempt to find something or to obtain information" is necessary to establish a search. *Jones*, 565 U.S. at 408 n.5.

b. Post-screening uses of residual DBS do not invade privacy interests.

Even if plaintiffs' residual DBS had been used for post-screening research or quality improvement purposes, obtaining

information from residual DBS is only a search if information is obtained by "a trespass or invasion of privacy." *Id*. Again, the district court did not identify any *actual* intrusion on plaintiffs' privacy interests, instead pointing to a "potential intrusion" or "threat of… infringement." (ECF No. 261, p.17.) Again, the Supreme Court has "never held that potential, as opposed to actual, invasions of privacy constitute searches for purposes of the Fourth Amendment." *Karo*, 468 U.S. at 712.

The district court's suggestion that the State is "disguising what it is in fact doing" and retains and stores residual DBS to gain "[c]ontrol over society" is, like its assertion that NBS serves "eugenic ends," not borne out by the record. Suggesting NBS programs are driven by some nefarious agenda are deeply insulting to all of the researchers, medical providers, and public health advocates—in Michigan and around the world—who work tirelessly to develop, provide, and support newborn screening programs. These programs do not seek to usher in some "brave new world" of government control but instead serve to protect and

improve lives by enabling the early detection of medical issues that can have devastating consequences if left untreated.

There can be no *actual* invasion of plaintiff's privacy, even if their residual DBS were used for post-screening purposes, because the de-identified residual DBS used for research or quality purposes reveals no information about specific individuals. (*See* Def. Br. at 10.) Whatever information might be contained in each blood spot, APHL is aware of, no authority finding a privacy interest in where such information cannot be connected to a particular individual. To the contrary, de-identification is routinely viewed as eliminating privacy concerns. See 32 C.F.R. § 70.8 (requiring redaction of identifying details to "prevent a clearly unwarranted invasion of personal privacy"); 45 C.F.R. § 164.514(a) ("Health information that does not identify an individual… is not individually identifiable health information" protected under HIPAA); *Day v. California Lutheran University*, No. 22-55825, 2023 U.S. App. LEXIS 19760, at *3 n.2 (9th Cir. Aug. 1, 2023) (no violation of Family Educational Rights and Privacy Act where

statements did not disclose personally identifiable information or records).

Apparently recognizing that information must be personally identifiable to be private, the district court suggests that, despite de-identification, "the MDHHS can reidentify the subject of any bloodspot," and claims MDHHS "has done [so] with parental consent as well as under court order." (ECF No. 261, p. 4) But the district court does not suggest MDHHS has done so with respect to any of the plaintiffs' residual DBS or that re-identification without either proper consent or a court order would be permitted under the regulations followed by MDHHS.

The district court's speculation is simply a guess as to what could potentially occur in the future, not a finding as to what actually occurred. It bears repeating: the Supreme Court has "never held that potential, as opposed to actual, invasions of privacy constitute searches for purposes of the Fourth Amendment." *Karo*, 468 U.S. at 712.

2. Any "search" that occurred was reasonable.

Even if a search occurred, the "Fourth Amendment prohibits only *unreasonable* searches." *Grady v. North Carolina*, 575 U.S. 306, 310 (2015). "Where a search is undertaken by law enforcement officials to discover evidence of criminal wrongdoing, …reasonableness generally requires the obtaining of a judicial warrant." *Vernonia Sch. Dist. 47J v. Acton*, 515 U.S. 646, 653 (1995). Plaintiffs have not claimed defendants engaged in efforts to discover evidence of criminal wrongdoing.

"A search unsupported by probable cause can be constitutional… 'when special needs, beyond the normal need for law enforcement, make the warrant and probable-cause requirement impracticable.'" *Id.*, (quoting *Griffin v. Wisconsin*, 483 U.S. 868, 873 (1987)). Given that suspicions of criminal wrongdoing play no part in the retention, storage, and post-screening uses of residual DBS, the warrant and probable-cause requirements are not merely impracticable, they are inapplicable. Requiring defendants to establish a reasonable "belief that contraband or evidence of a crime will be found" in a dried blood spot collected from a

newborn in the first few days of its life would be nonsensical. See *Ornelas v. United States*, 517 U.S. 690, 696 (1996) (describing probable cause standard). Residual DBS is not retained, stored, or used for the purpose of detecting contraband or evidence of crime. Instead, these samples are retained, stored and used for the purpose of quality control and quality improvement as to the NBS program itself and for biomedical research.

The special needs analysis involves three factors: (1) "the nature of the privacy interest"; (2) "the character of the intrusion"; and (3) "the nature and immediacy of the governmental concern and efficacy of the means for meeting it." *Vernonia*, 515 U.S. at 654, 658, and 660. So long as de-identification protocols are followed, the privacy interest at stake and the character of any intrusion are negligible at best. Post-screening uses of residual DBS are wholly attenuated from the individual from whom the specimen was drawn. The final factor—"the nature and immediacy of the governmental concern and efficacy of the means for meeting it"—cannot be resolved "by answering in isolation the question: Is there a compelling state interest here?" *Id.*. at 661. "Rather, the phrase

describes an interest that appears *important enough* to justify the particular search at hand." *Id*..

The importance of the state's interest in protecting public health has long been well established. See, e.g., *Jacobson v. Massachusetts*, 197 U.S. 11, 25 (1904). As detailed above, residual newborn DBS specimens are uniquely valuable for carrying out the quality assurance and quality improvement aspects of the NBS program. Residual DBS specific to each disease or disorder included in NBS are necessary to calibrate instruments and to set and refine appropriate thresholds for each screening test. The interest in promoting public health through validation and refinement or NBS testing is more than "important enough to justify the particular search at hand"—particularly given that any intrusion into a reasonable expectation of privacy is vanishingly negligible.

B. Seizure—Possessory Interests

In contrast to a search, a Fourth Amendment seizure does not implicate privacy concerns. Instead, a seizure is a "meaningful interference with an individual's possessory interests in [the

seized] property." *Jacobsen*, 466 U.S. at 113. "Property interests are created and defined by state law." *Butner v. United States*, 440 U.S. 48, 55 (1979). Accord *Stop the Beach Renourishment, Inc. v. Fla. Dep't of Envtl. Prot.*, 560 U.S. 702, 707 (2010).

To establish a seizure, plaintiffs must show a possessory interest under Michigan law in their residual DBS specimens. Few cases have addressed ownership of biological samples once they have been extracted from an individual's body. See Edwards, L., *Note: Tissue Tug-of-War: A Comparison of International and U.S. Perspectives on the Regulation of Human Tissue Banks*, 41 Vand. J. Transnat'l L. 639, 641 (2008)

One of the few cases to have addressed this issue, *Moore v. Regents of Univ. of Cal.*, 51 Cal. 3d 120, 137 (Cal. S. Ct. 1990), recognized that whether to provide property interests in human biological materials is an issue "better suited to legislative resolution." *Id.* at 142. The court further emphasized that "[u]ncertainty about how courts will resolve disputes between specimen sources and specimen users could be detrimental to both academic researchers and the nascent biotechnology industry,

particularly when the rights are asserted long after the specimen was obtained." *Id*. (quoting U.S. Congress, Office of Technology Assessment, *New Developments in Biotechnology: Ownership of Human Tissues and Cells* (1987) at pp. 4, 27). Amici believe that biobanks and researchers entities will benefit from a decision by this Court that eliminates such uncertainty by providing clear regarding how possessory interests in biological materials like residual DBS should be determined.

To date, neither the Michigan legislature nor Michigan courts have established that individuals hold a property interest in biological samples extracted from their body. To the contrary, the Michigan statute governing newborn screening suggest a legislative determination *not* to grant infants or their parents a property interest in the residual DBS. The Michigan legislature has directed the Department of Health and Human Services to "develop a schedule for the retention and disposal of [DBS] used for the tests after the tests are completed." Mich. Comp. Laws § 333.5431(7)(a). The legislature further directed the DHHS to "[a]llow the blood specimens to be used for medical research

during the retention period." Mich. Comp. Laws § 333.5431(7)(b). Te statute provides for: (1) retention of the residual DBS; or (2) disposal consistent with the requirements for disposal of medical waste.[43] Mich. Comp. Laws § 333.5431(7); *see* Mich. Comp. Laws § 333.13811. Unless they can show a possessory interest in the residual DBS, plaintiffs cannot establish a seizure under the Fourth Amendment.

To the extent plaintiffs are challenging the State's retention of medical data derived from the initial screening as an unreasonable seizure, the claim is even less tenable. In *Smith v. State*, 744 N.E.2d 437 (Ind. 2001), for example, the Indiana Supreme Court rejected a challenge to the State's retention of a defendant's DNA profile. Although the court agreed that the defendant "had a legitimate expectation of privacy in his body and blood samples at the time they were taken" in connection with a prior investigation, the court

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[43] Given the necessity for proper handling of human biological samples, whether to grant individuals a possessory interest in tissues, fluids, or other biological matter extracted from their bodies is a question requiring careful consideration.

rejected the defendant's claim that the information derived from those samples "must be destroyed after the investigation that analyzed it concluded." *Id*. Once the DNA in those samples was used to create a profile, the court held, the profile became the property of the state crime lab. *Id*. at 439. Numerous other courts, including this one, have similarly concluded that the retention of information derived from a lawfully collected sample does not violate the Fourth Amendment. *See*, *e.g.*, *Wilson v. Collins*, 517 F.3d 421, 427 (6th Cir. 2008); *Boroian v. Mueller*, 616 F.3d 60, 68 (1st Cir. 2010) (collecting cases).

Unless and until the State of Michigan chooses to grant or recognize a property interest in individuals' biological specimens, plaintiffs cannot establish that the retention and storage of residual DBS is a seizure under the Fourth Amendment.

II. Substantive Due Process

Though acknowledging that the Supreme Court has never specifically defined the scope of a parental right to direct a child's medical care, this Court concluded that "parents' substantive due process right 'to make decisions concerning the care, custody, and

control' of their children includes the right to direct their children's medical care." *Kanuszewski*, 927 F.3d at 418 (quoting *PJ ex rel. Jensen v. Wagner*, 603 F.3d 1182, 1197 (10th Cir. 2010) and *Troxel v. Granville*, 530 U.S. 57, 72 (2000)). Accordingly, this Court identified two questions to be decided on remand:

> Specifically, the questions on remand will be whether the evidence demonstrates that Defendants' actions interfered with the parents' right to direct their children's medical care; and, to the extent they did interfere with the parents' fundamental rights, whether those actions survive strict scrutiny.

Id. at 421.

Since this Court issued its decision, however, the Supreme Court issued its opinion in *Dobbs v. Jackson Women's Health Organization*, ___U.S.___ , 142 S. Ct. 2228 (2022). In *Dobbs*, the Court emphasized that, while the Fourteenth Amendment "has been held to guarantee some rights that are not mentioned in the Constitution, …any such right must be 'deeply rooted in this Nation's history and tradition' and 'implicit in the concept of ordered liberty.'" *Id.*, 142 S. Ct. at 2242. In the wake of *Dobbs*, this Court found no "'deeply rooted' tradition of preventing

governments from regulating the medical profession in general or certain treatments in particular, whether for adults or their children." *L.W. v. Skrmetti*, 83 F.4th 460 (6th Cir. 2023). To the contrary, this Court noted state and federal governments' "critical role in regulating health and welfare, which explains why their efforts receive 'a strong presumption of validity.'" *Id*. In light of both *Dobbs* and *Skrmetti*, this Court should revisit its previous holding that parents have a substantive due process right to direct their children's medical care.

Even if a substantive due process right exists here, the first of the two questions specified by this Court demonstrates that any such rights were not violated. The storage and retention of residual DBS at a biobank like Michigan's has no effect at all on the medical care of the individuals from whom the samples were obtained. Storage and retention of the plaintiff children's residual DBS did not involve diagnosis, treatment, or counseling of those children. *See Pegram v. Herdrich*, 530 U.S. 211, 228 (2000) ("'Treatment decisions' …are choices about how to go about diagnosing and

treating a patient's condition: given a patient's constellation of symptoms, what is the appropriate medical response?").

And while plaintiffs' residual DBS was never used for any post-screening purpose, such a use likewise would have no effect on the parents' control over their children's medical care. Those who use the residual DBS, whether for quality control or research, are not provided information from which they could identify the individuals from whom the samples were collected. They do not and diagnose individuals from whom samples were collected and do not provide medical treatment or recommendations of any kind to such individuals.

Because the defendants' retention and storage of residual DBS for research use does not interfere with plaintiffs' rights to direct the care of their children, defendants are not required to satisfy strict scrutiny. To survive the more deferential rational basis standard, defendants' retention and storage of residual DBS samples for use in medical research need only be "reasonably related to a legitimate government interest." *EMWomen's Surgical Ctr., P.S.C. v. Friedlander*, 978 F.3d 418, 438 (6th Cir. 2020). Plaintiffs

do not dispute that retaining neonatal DBS for use in newborn screening and medical research is reasonably related to the state's indisputably legitimate interest in promoting public health.

CONCLUSION

For the foregoing reasons, amici respectfully urge this Court to reverse the judgment of the district court.

Respectfully submitted,

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CERTIFICATE OF COMPLIANCE

This brief complies with the type-volume limitation of Federal Rule of Appellate Procedure 29(b)(4) because it contains 6,429 words, excluding the parts of the brief exempted by Federal Rule of Appellate Procedure 32(f) and 6th Circuit Rule 32(b)(1).

This brief complies with the typeface and type-style requirements of Federal Rule of Appellate Procedure 32(a)(5)-(6) because it has been prepared in proportionally spaced typeface using Microsoft Word, in 14-point size.

/s/ Kimberly A. Jansen

CERTIFICATE OF SERVICE

I hereby certify that on December 4, 2023, the foregoing was electronically filed with the Clerk of the Court for the United States Court of Appeals for the Sixth Circuit using the appellate CM/ECF system. All participants in the case are registered CM/ECF users and will be served by the system.

/s/ Kimberly A. Jansen