**IN THE UNITED STATES DISTRICT COURT**
**FOR THE EASTERN DISTRICT OF MICHIGAN**

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

Plaintiffs,

vs.

MICHIGAN DEPARTMENT OF HEALTH AND HUMAN SERVICES, et al,

Defendants.

Case #. 18-cv-10472

The Honorable Thomas L. Ludington, District Judge Presiding

Magistrate Judge Patricia T. Morris

---

**ASSOCIATION OF PUBLIC HEALTH LABORATORIES' MOTION FOR LEAVE TO FILE OVERSIZE BRIEF AMICUS CURIAE IN SUPPORT OF DEFENDANTS' MOTIONS FOR SUMMARY JUDGMENT**

---

The Association of Public Health Laboratories ("APHL") requests leave to file, as amicus curiae, the attached brief in support of the defendants' motions for summary judgment.

1. By definition, an *amicus curiae* is a friend of the court, not of the parties. In this role, an *amicus curiae* should strive to provide the court with ideas, arguments, or insights that are helpful to resolution of the case but were not

addressed by the litigants themselves. *Voices for Choices v. Ill. Bell Tel. Co.*, 339 F.3d 542, 545 (7th Cir. 2003). As this Court has recognized:

> An amicus brief should normally be allowed when a party is not represented competently or is not represented at all, when the amicus has an interest in some other case that may be affected by the decision in the present case (though not enough affected to entitle the amicus to intervene and become a party in the present case), or when the amicus has unique information or perspective that can help the court beyond the help that the lawyers for the parties are able to provide.

*Hemlock Semiconductor Corp. v. Deutsche Solar GmbH*, No. 13-cv-11037, 2016 U.S. Dist. LEXIS 90640, at *63-65 (E.D. Mich. July 13, 2016) (quoting *Ryan v. Commodity Futures Trading Comm'n*, 125 F.3d 1062, 1063 (7th Cir. 1997)).

2. APHL is a non-profit, 501(c)(3) organization dedicated to promoting the value and contributions of public health laboratories and continuously improving the public health laboratory system and practice. Its expert staff represent diverse disciplines, from infectious disease, environmental health and food safety to newborn screening and public health preparedness. Through its Newborn Screening & Genetics Program, APHL develops position statements related to newborn screening and genetics, and provides input on quality control and proficiency testing issues relevant to newborn screening to the CDC's Newborn Screening Quality Assurance Program.

3. APHL's long commitment to strengthening public health laboratories enables it to provide a perspective not offered by the parties on the broader

implications this Court's ruling could have on public health and related research. That same commitment also lies at the heart of APHL's interest that will be affected by the decision. The implications of this Court's decision are not limited to the MDHHS or the Michigan Neonatal Biobank, but will affect public health laboratories and medical research nationwide.

4. APHL recognizes that its proposed *amicus curiae* brief exceeds the 25-page limit on the length of motions under Local Rule 7.1(d)(3)(A) by five pages and that this Court does not routinely grant page extensions. In light of the subject matter of this case—newborn screening and the retention and potential use of residual dried bloodspot specimens—APHL believes this Court will benefit from an explanation of the historical background, the scientific principles involved, and how the impact of this Court's resolution of the issues will extend beyond the parties presently before the court. Five additional pages were necessary both to make that explanation comprehensible and to provide appropriate citations to scientific scholarship.

5. APHL has contacted all parties to ascertain whether this motion will be opposed. The Michigan Department of Health and Human Services, the Michigan Neonatal Biobank, and each of the individual defendants consent to the filing of the brief amicus curiae; the plaintiffs have indicated that they are opposed to the filing of this brief..

WHEREFORE the Association of Public Health Laboratories respectfully requests that this Court grant APHL leave to file the attached brief *amicus curiae* instanter.

HINSHAW & CULBERTSON LLP

By: /s/ Joshua G. Vincent

Joshua G. Vincent
Hinshaw & Culbertson LLP
151 North Franklin Street
Suite 2500
Chicago, IL 60606
Tel: 312-704-3000
Fax: 312-704-3001
E-mail: jvincent@hinshawlaw.com

## CERTIFICATE OF SERVICE

I hereby certify that on April 5, 2021, I electronically filed the **Association of Public Health Laboratories' Motion For Leave to File Oversize brief *Amicus Curiae* in Support of Defendants' Motions for Summary Judgment** with the Clerk of the Court using the ECF System, which will provide electronic copies to counsel of record.

By: /s/ Joshua G. Vincent

Joshua G. Vincent
Hinshaw & Culbertson LLP
151 North Franklin Street
Suite 2500
Chicago, IL 60606
Tel: 312-704-3000
Fax: 312-704-3001
E-mail: jvincent@hinshawlaw.com

**IN THE UNITED STATES DISTRICT COURT**
**FOR THE EASTERN DISTRICT OF MICHIGAN**

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

Plaintiffs,

vs.

MICHIGAN DEPARTMENT OF HEALTH AND HUMAN SERVICES, et al,

Defendants.

Case #. 18-cv-10472

The Honorable Thomas L. Ludington, District Judge Presiding

Magistrate Judge Patricia T. Morris

---

**ASSOCIATION OF PUBLIC HEALTH LABORATORIES' *AMICUS CURIAE* BRIEF IN SUPPORT OF DEFENDANTS' MOTION FOR SUMMARY JUDGMENT**

---

HINSHAW & CULBERTSON LLP

By: /s/ Joshua G. Vincent
Joshua G. Vincent
Hinshaw & Culbertson LLP
151 North Franklin Street
Suite 2500
Chicago, IL 60606
Tel: 312-704-3000
Fax: 312-704-3001
E-mail: jvincent@hinshawlaw.com

# TABLE OF CONTENTS

# TABLE OF AUTHORITIES

**Page(s)**

**Cases**

## Statutes



## Other Authorities

## ISSUES PRESENTED

1. Does the ongoing retention and storage of residual DBS violate the Fourth Amendment proscription of unreasonable searches or seizures?

2. Does the ongoing retention and storage of residual DBS violate substantive due process by interfering with parents' fundamental rights to direct their children's medical care?

## CONTROLLING OR MOST APPROPRIATE AUTHORITY

*United States v. Jacobsen*, 466 U.S. 109 (1984)

*United States v. Jones*, 565 U.S. 400 (2012)

*Vernonia Sch. Dist. 47J v. Acton*, 515 U.S. 646 (1995)

*Kanuszewski v. Mich. HHS*, 927 F.3d 396 (6th Cir. 2019)

## STATEMENT OF INTEREST OF AMICUS CURIAE

The Association of Public Health Laboratories (APHL) is a non-profit, 501(c)(3) organization dedicated to ensuring the strength of the laboratory systems serving the public's health in the United States and globally. APHL represents state and local governmental health laboratories in the United States and is recognized internationally as a leader in laboratory science and practice. APHL works closely with federal agencies to develop and execute national health initiatives and works internationally to build effective national laboratory systems and expand access to quality diagnostic testing services. Its expert staff represent diverse disciplines, from infectious disease, environmental health, and food safety to newborn screening and public health preparedness.

APHL's Newborn Screening and Genetics Program strengthens the role of public health laboratories in congenital and genetic testing and designs strategies to address changes in the field of newborn screening (NBS). The program develops and recommends position statements related to newborn screening and genetics for the association, and provides input to the CDC's Newborn Screening Quality Assurance Program on quality control and proficiency testing issues relevant to newborn screening laboratories across the globe. The program also interacts with state, federal and association partners to implement national recommendations on newborn screening and genetics testing.

Resolution of the weighty Constitutional issues raised in this case will significantly impact APHL member laboratories nationwide and could drastically restrict vital biomedical quality improvements and research currently conducted using residual dried bloodspot (DBS) specimens. APHL believes that this Court will benefit from its insights with respect to the policy issues in this area of public health.

## STATEMENT OF FACTS

### I. Historical Background of Newborn Bloodspot Screening

NBS began with a rare but potentially devastating condition: phenylketonuria (PKU). Infants with PKU are deficient in an enzyme necessary for protein synthesis and the resulting accumulation of phenylalanine in the blood leads to mental retardation.[1] This outcome can be avoided, however, 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]

---

[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).

"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 industrialized nation."[5] "The premise of [NBS] is to detect disorders pre-symptomatically, such that effective treatments can be applied."[6] Initially, DBS were analyzed using the Guthrie Bacterial Inhibition Assay (BIA), followed by fluorometric and enzyme immunocentric assays.[7] These early assays required one-at-a-time analysis of the analytes for each disorder included in the newborn screening program.[8] The introduction of tandem mass spectrometry in the late 1990s allowed for simultaneous analysis of multiple analytes characteristic of numerous disorders.[9] Thanks to these scientific advancements, NBS has expanded to include more than 50 different life- or health-threatening conditions for which early detection and

---

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

[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)

[8] 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).

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

treatment are essential.[10] In the United States, NBS has proven to be a successful and universally accessible medical service.

Although there is not a nationally managed NBS program in the United States, in 2008 Congress enacted the Newborn Screening Saves Lives Act of 2007 to support screening efforts by providing grants improve screening and expand public education.[11] It also created the United States' Secretary of Health and Human Services' Advisory Committee on Heritable Disorders in Newborns and Children (SACHDNC), 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 regarding means of improving the NBS process.[12] The SACHDNC has approved a Recommended Uniform Screening Panel (RUSP) 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]

---

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

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

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

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

[14] Association of Public Health Laboratories, Newborn Screening: Four Facts Policymakers Need to Know, 2,

## 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 is wiped away, additional drops are collected to fill pre-printed circles on specialized filter paper (sometimes referred to as a "Guthrie card").[17, 18] After drying at room temperature for several hours, the card is transported to an appropriate laboratory for testing.

"All NBS testing in the United States must be done by laboratories licensed by their respective states and must meet the requirements of" the Clinical Laboratory Improvement Amendments of 1988 (CLIA) (Pub. L. No. 100-578, 102 Stat.

---

https://www.aphl.org/aboutAPHL/publications/Documents/NBS_2012Dec20_Newborn-Screening-Four-Facts-Policymakers-Need-to-Know.pdf.

[15] See, e.g., Texas Department of State Health Services, *Handle With Care...My Future is in Your Hands: Newborn Screening Specimen Collection Guide*, https://www.dshs.texas.gov/newborn/pdf/care/; 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), https://www.alabamapublichealth.gov/newbornscreening/assets/newbornscreeningbloodcollectionguidelines.pdf

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

[17] 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).

[18] *Ibid.*

2903).[19] 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."[20] 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.

## 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, appropriate treatment or management when a condition is detected, 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 SACHDNC Committee Report addressing the retention and use of residual DBS.[21]

---

[19] 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).

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

[21] Association of Public Health Laboratories, *APHL Position Statement on Newborn Screening Residual Dried Blood Spot Specimens* (2017),

The SACHDNC recommended that all state NBS programs have policies in place that: "specifi[y] who may access and use dried blood specimens once they arrive at the state-designated NBS laboratory, including further access after NBS tests are completed;" "address[ ] the disposition of dried blood specimens remaining after NBS;" and "are in compliance with federal research regulations, assure that parents are aware of these activities, and consider whether documentation of parents' wishes and willingness to participate are required."[22] The SACHDNC also recommended that the "Secretary of HHS... facilitate a national dialog among federal and state stakeholders about policies for the retention and use of residual NBS specimens, including model consent and dissent processes."[23] "Consent" in this context refers to "an opt-in approach to secondary use of residual dried blood specimens," and "dissent" refers to "an opt-out approach to secondary use of residual dried blood specimens that presumes consent unless explicitly refused."[24]

---

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).

[22] Therrell, Jr., *Committee report...*, *supra*, at 622-23.

[23] *Id.*, at 623.

[24] Secretary's Advisory Committee on Heritable Disorders in Newborns and Children, *Considerations and Recommendations for National Guidance Regarding the Retention and Use of Residual Dried Blood Spot Specimens after Newborn Screening: Briefing Paper*, at 4 (2011), https://www.hrsa.gov/sites/default/files/hrsa/advisory-committees/heritable-

### A. Quality Assurance and Program Accountability.

Residual DBS specimens are retained for a number of "standard program uses" such as "program evaluation and quality assurance, treatment efficacy, test refinement, and result verification activities for the laboratory and program."[25] 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.[26]

The SACHDNC has emphasized that these standard program uses "are valid components of the public health NBS program and, therefore, do not require additional consent."[27]

---

disorders/reports-recommendations/reports/briefing-residual-dried-spot-specimens.pdf.

[25] Therrell, Jr., Committee report..., *supra*, at 622.

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

[27] Therrell, Jr., Committee report..., *supra*, at 622-23.

One of the primary purposes for retention and storage of DBS specimens "is to document that a specimen was collected, received, and properly analyzed."[28] Much like an x-ray retained as part of an individual's medical record, a retained DBS specimen is a necessary component for assuring that NBS Programs are held accountable for their testing results. For example, if a child develops signs of a screened disease sometime after a negative screening result, the retained sample might be used to confirm whether the reported screening result was correct. Destruction of dried blood spots and/or their associated results makes it impossible to hold a NBS program accountable for the accuracy and completeness of their screening process and results.

Residual DBS specimens are also essential for quality assurance (QA) and quality improvement (QI). QA is more than simply quality control (QC).[29] In the NBS process, QC "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."[30] QA "is a dynamic

---

[28] *Id.*, at 622.

[29] 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

[30] *Ibid.*

process of defining the quality of performance required for each step in the testing process" and "encompasses all parameters of the NBS system."[31] 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 total testing process (which consists of the preanalytic, analytic, and postanalytic phases)."[32] Laboratories must examine or test proficiency testing samples in the same manner it tests patient specimens. 42 C.F.R. § 493.801(b).

The newborn period represents a unique time in measuring many of the biochemical analytes needed to screen for NBS disorders. In fact, several biochemical analytes utilized for the purpose of NBS are not present in infants, children, or adults. Because of this, residual DBS from newborns are the most appropriate source of quality control materials for NBS programs.

### B. Biomedical Research

The unique attributes of residual DBS collected during the neonatal period make these samples particularly valuable in biomedical research. "They provide a nearly complete representation of the population[,]... can be integrated with existing

[31] *Ibid.*

[32] 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).

public health data[,]... and contain a very wide range of biomarkers, including DNA, RNA, proteins, metabolites, and evidence of exposures to environmental or infectious agents."[33] "They cover nearly the entire population and often are the only remaining tissue sample for a particular individual."[34] And, because many of the diseases and disorders tested for in NBS are rare, a large repository of retained samples is invaluable for preserving even a modest pool of samples reflective of any particular disease or disorder. The prevalence of PKU, for example, is only 0.59 per 10,000 live births.[35] Thus, for every 100,000 samples collected, fewer than six can be expected to be positive for PKU. For every 100,000 samples collected, only 49 samples can be expected to be positive for sickle cell disease.[36]

The uses of residual DBS specimens "for test development and research has accelerated discovery and has resulted in direct public health benefits."[37]

---

[33] 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.

[34] *Id.*, at 12.

[35] 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.

[36] *Id.*

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

Repositories of DBS, like that maintained by the Michigan BioTrust at Michigan's Neonatal Biobank, "provide a unique and potentially powerful resource for 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."[38] 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."[39] 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)."[40]

"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

---

[38] 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).

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

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

allergies, and childhood cancers."[41] Studies involving severe combined immunodeficiency (SCID) have already yielded new nationwide NBS programs.[42] Indeed, medical research using newborn DBS has recently led to the development of a SARS-CoV-2 antibody assay to detect past maternal infection, measure population-level trends of COVID-19, and to monitor for resurgence of this disease.[43]

The SACHDNC has encouraged state NBS laboratories to "consider the value of the [residual DBS] specimens as a promising resource for research" as well as "the importance of protecting the privacy and confidentiality of families, and... ensuring the public's trust."[44] The privacy of individually identifiable health information contained in residual DBS specimens, when held by a covered entity (or in the case of the MDHHS laboratory, a covered component of a hybrid entity), is protected under the Health Insurance Portability and Accountability Act of 1996 ("HIPAA"). 45 C.F.R. § 160.103. In addition, all federally funded research is subject to the Federal Policy for the Protection of Human Subjects ("the Common Rule"),

---

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

[42] 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),

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

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

an ethical rule applicable to research involving human subjects. 45 C.F.R. § 46.101, *et seq.*

### C. Future Medical Care

The Sixth Circuit expressed some skepticism as to whether the retention of residual DBS samples could provide any benefit for the health of the child from whom the sample was collected. But, in fact, retained residual DBS specimens can prove useful in the retrospective diagnosis of patients. For example, properly "[s]tored DBS can be used to diagnose [congenital cytomegalovirus infection ("cCMV")] retrospectively."[45] "[A]cquired CMV infection... rarely causes harmful sequelae."[46] "Infants [with cCMV infections, by contrast,] can experience substantial morbidity, mortality, and long-term sequelae, including sensorineural hearing loss (SNHL), the most common sequela."[47] Although "[n]eonatal CMV screening would enable early detection of cCMV...[,] universal neonatal screening for CMV is currently not recommended by any public health body."[48]

---

[45] Lazzarotto, T., *et al.*, *Congenital Cytomegalovirus Infection: A Narrative Review of the Issues in Screening and Management From a Panel of European Experts*, 8(13) Frontiers in Pediatrics 1, 4 (2020).

[46] Samedi,V., *et al.*, *Comparison of Presentation, Course, and Outcome of Congenital and Acquired Cytomegalovirus Infection in Twins*, 6(1) Am. J. Perinatol. Rep., e1, e4 (2016).

[47] Lazzarotto, *et al.*, *Congenital Cytomegalovirus Infection...*, *supra*, at 2.

[48] *Id.*, at 3.

"cCMV infection is often insidious as it is most often asymptomatic or poorly symptomatic at birth while it can result in defects that appear during infancy from birth up until six years of age."[49] "Diagnosis of the infection may [also] be hampered due to its very strict diagnostic timing."[50] CMV infection can be detected in urine, saliva, or blood samples; however, because CMV can be acquired after birth, residual DBS samples make it possible to distinguish between congenital infections and infections acquired postnatally.[51]

"Due to widespread utilization in neonatal screening for other conditions, there has been much interest in using dried blood spots (DBS) taken at birth for CMV screening."[52] "[T]he use of DBS for retrospective diagnosis or screening of newborns is hampered by the destruction of samples"[53] "after a fixed, and sometimes short"[54] retention period. "The impossibility of diagnosing cCMV due to the disposal of residual DBS specimens" has been a source of frustration.[55]

---

[49] Pellegrinelli, L., *et al.*, *Diagnosing congenital Cytomegalovirus infection: don't get rid of dried blood spots*, 20(217) BMC Infectious Diseases (2020).

[50] *Ibid.*

[51] Lazzarotto, *et al.*, *Congenital Cytomegalovirus Infection...*, *supra*, at 4.

[52] *Ibid.*

[53] *Ibid.*

[54] Pellegrinelli, *et al.*, *...don't get rid of dried blood spots*, *supra*, at 4.

[55] *Ibid.*

By storing a single residual DBS specimen at the MDHHS State Laboratory for parental use, Michigan ensures that a specimen will be available to parents (or to the children after reaching majority) in the event future testing for cCMV or other disorders is desired.

## IV. Plaintiffs' Challenge and Why it Matters

Plaintiffs challenge, on Fourth Amendment and substantive due process grounds, the retention and storage of residual DBS samples collected from their children and the potential use of those samples in biomedical research. This framing involves more than simply a policy determination as to whether parental consent should be required for the storage and use of these samples or what form such consent should take.( Indeed, parents—or the child at age of majority—can direct the Michigan DHHS to destroy all remaining DBS or continue to store them but not use the DBS in medical research. (ECF # 138-5.) Instead, plaintiffs' claims implicate important issues regarding property interests in human biological materials extracted in the course of providing medical care and the scope of the parental right to make important medical decisions for their children.

The Michigan Neonatal Biobank has been storing residual DBS since 1984, and its repository now includes millions of specimens.[56] The research potential of

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

such archives is enormous—not simply because that 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 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 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

Following remand by the Sixth Circuit Court of Appeals, two issues remain to be decided by this Court:

1. Does the ongoing retention and storage of residual DBS violate the Fourth Amendment proscription of unreasonable searches or seizures?

2. Does the ongoing retention and storage of residual DBS violate substantive due process by interfering with parents' fundamental rights to direct their children's medical care?

AHPL respectfully submits that the answer to both questions is: No. Enjoining the State of Michigan from continuing to retain and store residual DBS would

significantly hinder the State's ability to maintain its NBS program and would inhibit important biomedical research. This impairment of important components of public health policy is not necessary to ensure the protection of the constitutional rights of newborns and their families. Continuation of these important public health policies is necessary to ensure continued universal access to quality medical services.

## I. Fourth Amendment

Plaintiffs contend that the retention of their children's DBS specimens violates the 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.* Plaintiffs do not distinguish between these analytically distinct questions.

### A. 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) ("state law defines property interests"); *Bd. of Regents v.*

*Roth*, 408 U.S. 564, 577 (1972) ("[p]roperty interests... are not created by the Constitution," but rather "are created and their dimensions are defined by existing rules or understandings that stem from an independent source such as state law"); *Houchens v. Beshear*, No. 20-5644, 2021 U.S. App. LEXIS 7095, at *5 (6th Cir. Mar. 9, 2021) (same). To establish that a seizure occurred at all—much less an unreasonable one—the plaintiffs are required to establish a right to possession of the residual DBS specimens under Michigan law.

Few cases have addressed ownership interests in biological samples 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) ("Only a limited number of cases in the United States have addressed the issue of whether a patient or research subject retains any right to his tissue once it has been removed at a doctor's office or hospital.") Those that have recognize that the laws governing human biological materials treat such specimens "as objects sui generis, regulating their disposition to achieve policy goals rather than abandoning them to the general law of personal property." *Moore v. Regents of Univ. of Cal.,* 51 Cal. 3d 120, 137 (1990). Whether to provide property interests in human biological materials is an issue "better suited to legislative resolution." *Id.* at 142.

The California Supreme Court recognized that this issue implicates a policy decision that must balance whatever interest individuals may have in their excised cells must be against the public interest in socially useful activities like medical research. *Id.*, at 143. The court highlighted the Office of Technology Assessment's 1987 report to Congress, which 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).

To date, neither the Michigan legislature nor Michigan courts have established that an individual holds a property interest in biological samples extracted from a person's body. To the contrary, the Michigan statute governing newborn screening reflects 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 Serv. § 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 Serv. § 333.5431(7)(b). Significantly, the

statute does not provide for the parents of an infant to take possession of residual DBS at any time. Rather, the only options are: (1) retention; or (2) disposal consistent with the requirements for disposal of medical waste. Mich. Comp. Laws Serv. § 333.5431(7); see Mich. Comp. Laws Serv. § 333.13811. Without a possessory interest in the residual DBS, the plaintiffs cannot establish a seizure under the Fourth Amendment, much less an unreasonable one.

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 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.* *Smith v. State*, 744 N.E.2d 437, 439 (Ind. 2001). Numerous other courts, including the Sixth Circuit, have similarly concluded that the retention of information derived from a lawfully collected sample does not violate the Fourth Amendment. See

*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 individuals a property interest in their biological specimens, plaintiffs cannot establish that the retention and storage of residual DBS is a seizure under the Fourth Amendment.

### B. Search—Privacy Interests

Plaintiffs' argue that the retention of residual DBS amounts to an impermissible search. So long as the Michigan BioTrust does not extract information from the retained samples specific to any identifiable individual, however, no search occurs at all, much less an unreasonable one.

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

"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.'" *Carpenter v. United States*, 138 S. Ct. 2206, 2213 (2018) (quoting *United States v. Jones*, 565 U.S. 400, 405, 406 n.3 (2012)). While later cases have 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.

The Sixth Circuit has already dismissed the plaintiffs' claims with respect to any information obtained from the initial collection and screening of the DBS samples, leaving at issue only the claims with respect to the retention and storage of residual DBS and the potential use of those samples in biomedical research. The State obtains no information at all from the mere retention and storage of residual DBS and so retention and storage cannot, on their own, constitute a search. Third-party medical researchers who obtain residual DBS for research purposes do, of course, hope to obtain information from the samples. But, so long as the residual DBS samples provided to researchers are de-identified, such researchers do not obtain information through any trespass or invasion of privacy.

Plaintiffs assert that "the infants' medical and personal privacy is both invaded and eviscerated" when residual DBS samples are provided to medical researchers. (Pl. Br. at 30.) So long as the Michigan program is structured to ensure that no personal or private information is conveyed to researchers, however, no privacy interest is affected. Consistent with the SACHDNC recommendations, the Michigan statute conditions the use of residual DBS specimens for medical research on the requirement that such "research is conducted in a manner that preserves the confidentiality of the test subjects." Mich. Comp. Laws Serv. § 333.5431(7)(b).

Under the MDHHS guidelines, a de-identification protocol is employed to ensure that residual DBS specimens provided to medical researchers do not include any information that could identify the individual from whom the specimens were collected. (ECF #138-8, p. 5.) Prior to storage at the Michigan Neonatal Biobank, residual DBS specimens are assigned an anonymous numeric code. (ECF # 138-8, p. 5; ECF #138-11, p. 2.) The MDHHS retains the only link through which these de-identified samples can be re-connected to a specific specimen source. (ECF # 138-8, p. 5.)

Plaintiffs argue in a footnote that the protections of the de-identification process are "illusory," citing to a variety of New York Times articles unrelated to neonatal DBS. APHL is not aware of any reason to believe that either the Michigan State Laboratory or the Michigan Neonatal Biobank are vulnerable to the sort of data breach plaintiffs fear. Both are required under HIPAA to "[i]mplement security measures sufficient to reduce risks and vulnerabilities." *United States ex rel. Sheldon v. Kettering Health Network*, 816 F.3d 399, 405 (6th Cir. 2016) (quoting 45 C.F.R. § 164.308(a)(1)(B).) While failure to implement appropriate security measures might expose these entities to penalties under HIPAA, speculation that these entities could someday be vulnerable to a data breach does not establish any actual or imminent Fourth Amendment violation.

"[T]he obtaining of information is not alone a search unless it is achieved by... a trespass or invasion of privacy." *Jones*, 656 U.S. at 408, n.5. As the privacy of plaintiffs' children is not invaded by the provision of de-identified DBS specimens to third-party researchers, the State's retention of those specimens for research purposes does not constitute a search for purposes of the Fourth Amendment.

**2. Any "search" that occurred was reasonable.**

Even if this Court were to conclude that medical research using de-identified DBS samples does constitute a search, "[t]hat conclusion... [would] not decide the ultimate question of the program's constitutionality." *Grady v. North Carolina*, 575 U.S. 306, 310 (2015). "The Fourth Amendment prohibits only *unreasonable* searches." *Id.*, (emphasis in original). "Where a search is undertaken by law enforcement officials to discover evidence of criminal wrongdoing, [the Supreme] Court has said that reasonableness generally requires the obtaining of a judicial warrant." *Vernonia Sch. Dist. 47J v. Acton*, 515 U.S. 646, 653 (1995). "But a warrant is not required to establish the reasonableness of *all* government searches; and when a warrant is not required (and the Warrant Clause therefore not applicable), probable cause is not invariably required either." *Id.*

"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)). Three factors are considered under the special needs analysis: (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." *Id.*, at 654, 658, and 660.

So long as de-identification protocols are followed, the privacy interest at stake is negligible at best—whatever information might be disclosed during the research process, none of that information can be linked to any particular individual. Plaintiffs do not articulate what expectation of privacy they could possibly have in any information that can be gleaned from de-identified DBS specimens. As for the "character of the intrusion," the process of obtaining the samples, a minimally intrusive heel prick, is not at issue at this stage. Rather, plaintiffs' current challenge is limited to the retention and use of residual DBS specimens already in the possession of the defendants. While the parties dispute the validity of the consent provided, all DBS samples collected from 2010 forward are, under Michigan law, stored and made available for research use in de-identified form only with parental consent. Again, plaintiffs fail to articulate anything intrusive about the retention of these samples or their availability, in deidentified form, for use in medical research.

The Supreme Court has explained that 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?" *Acton*, 515 U.S. at 661. "Rather, the phrase describes an interest that appears *important enough* to justify the particular search at hand." *Id.*, (emphasis in original).

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 a uniquely valuable asset in ongoing biomedical research. Because samples are routinely collected from newborns throughout the state, they provide a nearly complete representation of the population—including segments of the population that might otherwise be underrepresented in medical studies. The samples contain a wide array of biomarkers, including analytes that are not available in samples collected at later stages in an individual's life. While these biomarkers and analytes cannot be used to identify an individual, they are uniquely useful to public health research, and are thus essential to furthering collective knowledge. The interest in promoting public health through research using these valuable samples is more than "important enough to justify the particular search at hand"—particularly given that any intrusion into a reasonable expectation of privacy is so vanishingly negligible that it is difficult to characterize the process as a search at all.

## II. Substantive Due Process

The plaintiffs alternatively contend that the retention and storage of the residual DBS samples collected from their children for potential research use violates the parents' substantive due process rights. Purporting to quote the Sixth Circuit's opinion in this case, plaintiffs assert that "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." (Pl. Br. at 34, quoting *Kanuszewski v. Mich. HHS*, 927 F.3d 396, 420 (6th Cir. 2019)). But neither plaintiffs' quotation nor their analysis is complete.

Noting its obligation to take the plaintiffs' allegations as true in reviewing a motion to dismiss, the Sixth Circuit held: "*Taking these allegations as true*, 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." *Kanuszewski*, 927 F.3d at 420 (emphasis added). The court's conclusion that plaintiffs' pleading was sufficient to allege a facially plausible claim did not relieve plaintiffs of the obligation to produce evidence establishing that claim. Thus, as the Sixth Circuit carefully instructed, "the questions on remand [are] 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.

Plaintiffs' brief skips over the first question—whether defendants' actions interfered with their rights to direct their children's medical care—jumping straight to the question of strict scrutiny. If the plaintiffs' right to control their children's medical care was not implicated, however, then defendants' program is not subject to strict scrutiny.

The plaintiffs' substantive due process claim rests on the premise that the retention and storage of residual DBS specimens violates their fundamental right as parents to direct the medical care of their children. The difficulty with this framing is that the retention and storage of de-identified residual DBS samples for use in medical research does not affect decisions regarding the medical care of plaintiffs' children. Medical researchers are not provided information from which they would be able to identify the individuals from whom residual DBS samples were collected. They do not and cannot attempt to diagnose individuals from whom residual DBS samples were collected and do not provide medical treatment of any kind to such individuals. *Cf. 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?").

Theoretically, the residual DBS retained by the MDHHS Laboratory for parental use, which has not been de-identified, could be used in future diagnoses of

plaintiffs' children—for example, if advances in medical science lead to the ability to identify additional disorders not previously screened for. So long as defendants obtain parental consent before screening the identified residual DBS for the purpose of diagnosis, parents' rights to direct their children's medical care will remain intact.

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). The state's interest in promoting public health is indisputably legitimate and retaining neonatal DBS for use in medical research is reasonably related to that interest. Plaintiffs do not contend otherwise.

## CONCLUSION

APHL recognizes and embraces the need to protect the privacy of all individuals and to ensure the rights of parents to direct the care and upbringing of there children. So long as MDHHS and the Michigan Neonatal Biobank adhere to the de-identification protocols outlined in their guidelines, neither privacy nor the parental prerogative are at risk. Accordingly, APHL respectfully implores this Court to enter summary judgment in favor of the defendants and against the plaintiffs..

HINSHAW & CULBERTSON LLP

By: /s/ Joshua G. Vincent

Joshua G. Vincent
Hinshaw & Culbertson LLP
151 North Franklin Street
Suite 2500
Chicago, IL 60606
Tel: 312-704-3000
Fax: 312-704-3001
E-mail: jvincent@hinshawlaw.com