### 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.

Case No.: 18-cv-10472

Hon. Thomas L. Ludington, District Court Judge

Hon. Patricia T. Morris, Magistrate Judge

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Plaintiffs,

٧.

FIRST AMENDED COMPLAINT

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MICHIGAN DEPARTMENT OF HEALTH AND HUMAN SERVICES; NICK LYON, sued in his official and individual capacities; DR. SANDIP SHAH, sued in his official and individual capacities; DR. SARAH LYON-CALLO, sued in her official and individual capacities; HARRY HAWKINS, sued in his official and individual capacities; MARY KLEYN, sued in her official and individual capacities; MICHIGAN NEONATAL BIOBANK, INC also known as MICHIGAN NEONATAL BIOREPOSITORY; DR. ANTONIO YANCEY, sued in his official and individual capacities,

**JURY DEMANDED** 

Defendants

FIRST AMENDED COMPLAINT FOR INJUNCTIVE AND DECLARATORY RELIEF WITH POSSIBLE MONEY DAMAGES FOR CONSTITUTIONAL VIOLATIONS

#### INTRODUCTION

- 1. Since the 1960s, the State of Michigan has operated a program which has seized blood samples from its youngest citizens, as newborn Michiganders less than 48 hours old, to test for various diseases.
- 2. The idea—early testing for newborns—is a noble public policy idea but the method by which Michigan has opted to implement the program—and then morph the objectives into more—violates the United States Constitution.
- 3. In short, the State of Michigan failed to obtain express or informed consent from the newborn and/or his/her legal guardian, or to secure a warrant from a neutral, detached magistrate before taking the blood into the permanent custody of and permanent detention by the state government.
- 4. Parents, including these parents in this legal action, had no knowledge of blood or blood spots being drawn from their newborn child while their precious new addition to their family was in the care of hospital staff which were then being turned over the government for its permanent custody and/or permanent seizure, and use by said government or those third parties granted possession/custody.

- 5. It has been well-established that drawing a person's blood for analysis constitutes a search within the meaning of the Fourth Amendment. *Birchfield v North Dakota*, 136 S Ct 2160, 2173 (2016).
- 6. The Fourth Amendment of the United States Constitution guarantees the right of persons to be secure against unreasonable searches and seizures by the government, including the State of Michigan, its agencies, and those that work for or in cahoots with those agencies.
- 7. And in the absence of consent, a court order, or an exception the warrant requirement, the search and seizure is *per se* unreasonable and unconstitutional.
- 8. It has been well-established that citizens, even our youngest, have the constitutionally protected liberty interest in approving or refusing unwanted medical procedures under the doctrine of informed consent, *Cruzan v Director, Missouri Dep't of Health*, 497 U.S. 261, 278 (1990).
- 9. These blood tests are constitutionally invasive as the tests "require piercing the skin" and "extract a part of the subject's body," see *Birchfield, supra.*
- 10. Moreover, once the alleged testing is finished, the sued state agency and its officials do not destroy the taken samples but instead *indefinitely* store the leftover blood spots in a temperature and humidity-

controlled facility on or near the campus of Wayne State University and/or a warehouse in Lansing for future unspecified uses, including selling the samples to businesses and researchers.

- 11. These Defendants operate or have putative control over the Infants' blood samples after the completion of the newborn screening tests under the program names of Michigan BioTrust for Health and/or the Michigan Neonatal Biobank.
- 12. According to recent disclosures seeking records of requests from any or all law enforcement agency or agencies seeking blood sample(s) or spot(s) and/or information deriving/extracted from blood sample(s) or spot(s) held by the Michigan BioTrust for Health, the Michigan Department of Health and Human Services indicated that twenty-two (22) forensics requests were proffered.
- 13. There are no state statutory protections against the State of Michigan, its agencies, its officials, police officers, or accessible users against these persons/entities for using the blood samples for other purposes, which has resulted in Defendant MICHIGAN NEONATAL BIOBANK, INC attempting to commoditize these seized "assets" to big pharma businesses and others. See **Exhibit R**.

- 14. This entire process violates the United States Constitution and must be ordered stopped in the absence of consent, the samples illegally taken be destroyed (in the absence of retroactive consent), and appropriate reimbursement of losses to be paid by those who stole the blood of millions of newborn children.
- 15. To be clear, the problem with this entire process is that State of Michigan and its private entity partners have forgotten to get actual informed consent; in other words, a group of state actors have has stolen the right of parental informed consent.

### **PARTIES**

- 16. Plaintiffs ADAM KANUSZEWSKI and ASHLEY KANUSZEWSKI are the parent-guardians and next friend to their minor children:
  - a. D.W.L., date of birth 01/17/2008
  - b. R.F.K., date of birth 04/22/2013
  - c. C.K.K., date of birth 02/10/2016
- 17. Plaintiff SHANNON LAPORTE is the parent-guardian and next friend to her minor children:
  - a. M.T.L., date of birth 10/19/2008
  - b. E.M.O., date of birth 02/06/2017

- 18. Plaintiff LYNNETTE WIEGAND is the parent-guardian and next friend to her minor children:
  - a. L.R.W., date of birth 11/21/2011
  - b. C.J.W., date of birth 07/17/2013
  - c. H.J.W., date of birth 12/24/2014
  - d. M.L.W., date of birth 01/30/2017
- 19. The plaintiff-children identified via acronyms above are collectively referred to as the "Infants"; their parent-guardians are collectively referred to as the "Parents."
- 20. Plaintiffs in this action are the Infants themselves and each parent as parents-guardians of one or more children born in the State of Michigan.
- 21. Defendant MICHIGAN DEPARTMENT OF HEALTH AND HUMAN SERVICES is a state agency/department formed under the laws of the State of Michigan with its principal office is located at 333 S. Grand Avenue, Lansing, Michigan.
- 22. Defendant NICK LYON is the director of MICHIGAN DEPARTMENT OF HEALTH AND HUMAN SERVICES and is sued in his official and individual capacities while acting under the color of law.

- 23. Defendant DR. SANDIP SHAH is the director of the Bureau of Laboratories within the MICHIGAN DEPARTMENT OF HEALTH AND HUMAN SERVICES, and is on the Board of Directors of Defendant MICHIGAN NEONATAL BIOBANK, INC, and is sued in his official and individual capacities while acting under the color of law.
- 24. Defendant DR. SARAH LYON-CALLO is the state epidemiologist and director of the Bureau of Epidemiology and Population Health and serves as manager of Michigan BioTrust for Health, and is sued in her official and individual capacities while acting under the color of law.
- 25. Defendant HARRY HAWKINS is a manager of the Newborn Screening program within the MICHIGAN DEPARTMENT OF HEALTH AND HUMAN SERVICES and is sued in his official and individual capacities while acting under the color of law.
- 26. Defendant MARY KLEYN is a manager of the Newborn Screening Section within the MICHIGAN DEPARTMENT OF HEALTH AND HUMAN SERVICES and is sued in her official and individual capacities while acting under the color of law.
- 27. Defendants NICK LYON, DR. SANDIP SHAH, DR. SARAH LYON-CALLO, HARRY HAWKINS, and MARY KLEYN are collectively referred to herein as the STATE OFFICIALS DEFENDANTS.

- 28. Defendant MICHIGAN NEONATAL BIOBANK, INC (also known as MICHIGAN NEONATAL BIOREPOSITORY) is a domestic non-profit entity formed under the laws of the State of Michigan and is, by operation of law, a state actor subject to the limitations and prohibitions of the United States Constitution; its principal office is located at 440 Burroughs St, Detroit, Michigan on or near the campus of Wayne State University.
  - a. Defendant MICHIGAN NEONATAL BIOBANK, INC is a legal entity seemingly separate and distinct from non-party Wayne State University and is legally separate and distinct from Defendant MICHIGAN DEPARTMENT OF HEALTH AND HUMAN SERVICES.
  - b. Defendant MICHIGAN NEONATAL BIOBANK, INC has its own board of directors consisting of Dr. Antonio Yancey (Wayne State Univ); Scott Jewell, Ph.D. (Van Andel Institute); Sonia Hassan, M.D. (Wayne State Univ); Ed Goldman (Univ of Michigan); Defendant Sandip Shah (Michigan DHHS); and Nigel Paneth, Ph.D. (Michigan State Univ), see <a href="https://mnb.wayne.edu/about/board">https://mnb.wayne.edu/about/board</a>
  - c. Defendant MICHIGAN NEONATAL BIOBANK, INC is primarily funded by in-kind gifts from Wayne State University, a Michigan

public university, grants (directly or indirect) from Defendant MICHIGAN DEPARTMENT OF HEALTH AND HUMAN SERVICES (see Exhibit Q, p. 42 and Exhibit P), and the sale of newborn blood samples to companies, researchers, and others. See Exhibits C, I, P, Q (p. 42), and R.

29. Defendant DR. ANTONIO YANCEY is the director of the MICHIGAN NEONATAL BIOBANK and is sued in his official and individual capacities while acting under the color of law.

### **JURISDICTION**

- 30. This is a civil action brought pursuant to 42 U.S.C. § 1983 seeking injunctive and declaratory relief together with monetary damages against Defendants for past and ongoing violations of the Fourth and Fourteenth Amendments of the United States Constitution.
- 31. This Court has jurisdiction pursuant to 28 U.S.C. § 1331, which authorizes federal courts to decide cases concerning federal questions; 28 U.S.C. § 1343, which authorizes federal courts to hear civil rights cases; and 28 U.S.C. § 2201, which authorizes declaratory judgments via the Declaratory Judgment Act.
- 32. Venue is proper in this Court as Defendants conducts business and/or committed constitutional violations in the Eastern District of Michigan.

### **GENERAL ALLEGATIONS**

- 33. Since at least 1987 (but perhaps earlier), certain Defendants (or their predecessors) have, individually or in conspiratorial agreement, routinely and unlawfully caused the illegal collection of samples of blood from all or nearly all newborn babies in Michigan at the time of birth and stored those samples or "spots" indefinitely for purposes of testing and later research unrelated to the purposes for which the infants' blood was originally drawn, without the knowing and/or informed consent of the Parents.
- 34. The currently named Defendants continue to do so today, individually and by joint operation.
- 35. At the time the birth of each Infant, a health professional in charge of the care of each newborn infant or at the birth of an infant was conscripted by Defendant MICHIGAN DEPARTMENT OF HEALTH AND HUMAN SERVICES and the STATE OFFICIALS DEFENDANTS to cause a needle or other skin-piercing device to breach the outside skin of the newborn Infants to extract five or six samples of blood, known as blood spots.
- 36. The Infants' blood spots are seized 24-48 hours post-birth on a filter paper collection device created and compelled for use by Defendant MICHIGAN DEPARTMENT OF HEALTH AND HUMAN SERVICES and the STATE OFFICIALS DEFENDANTS, see **Exhibit B**.

- 37. This filter paper collection device is known the Dried Blood Spot ("DBS") card.
- 38. The health professional in charge of the care of a newborn infant or at the birth of an infant was legally coerced to cause a needle or other skin-piercing device to breach the outside skin of the newborn Infants to extract five or six blood spots because his or her failure to do so would have or could have caused in the health professional being charged and jailed pursuant to MCL 333.5431(5) as a criminal misdemeanor.
- 39. The STATE OFFICIALS DEFENDANTS directed or otherwise approved of the conscripted doctors' conduct and the conduct of those under their command within the Defendant MICHIGAN DEPARTMENT OF HEALTH AND HUMAN SERVICES who commit violations of the US Constitution, see e.g. **Exhibits D, E, and F**.
- 40. Each uninformed Parent was, at the time of the extraction of blood spots, unaware that health professional, as a conscripted government agent, was taking their Infant's blood for the purpose of providing the blood spots to the state government when the statute only requires certain "health

professional[s]" to "administered to the infant a test" for certain diseases, see MCL 333.5431(1).1

- 41. Despite the STATE OFFICIALS DEFENDANTS all having knowledge and/or active part in the ongoing non-consensual seizing, testing, storing, and later selling of blood spots of newborn Michigan infants, no Defendant sought to obtain general and/or informed consent from any Parent <a href="mailto:before">before</a> causing a needle or other skin-piercing device to breach the outside skin of the newborn Infants to extract five or six blood spots for any purpose.
- 42. The Parents did not reasonably understand, were not reasonably told, or did not give pre-procedure informed consent to Defendant MICHIGAN DEPARTMENT OF HEALTH AND HUMAN SERVICES or any STATE OFFICIALS DEFENDANTS to authorize its agents and/or the

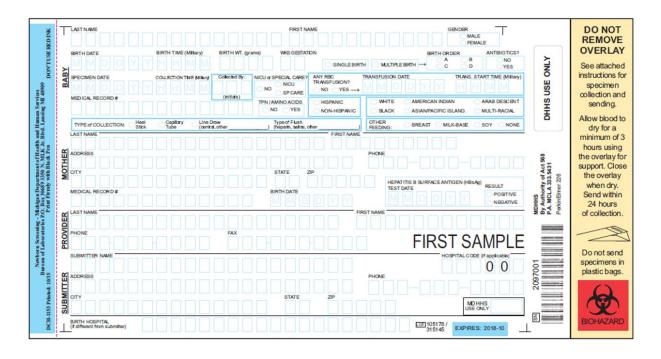
<sup>&</sup>lt;sup>1</sup> Interestingly, Michigan law only requires the health care professional to "administered to the infant a test" to detect certain diseases in newborns. MCL 333.5431(1). Michigan law does not require the State of Michigan or its laboratories to be the entity that ultimately performs the tests. However, the State, by these Defendants, have misused and misapplied the statute in an unconstitutional manner to <u>require</u> a massive dragnet scheme, undertaken without consent, for the extraction of blood spots and turning over those samples to the government for all newborn infants, and later causing the indefinite seizure and storage of the blood spots as if the State's own property. So, while the statute itself might (and that is not a foregone conclusion) pass constitutional muster, its interpretation and application by these state actors does not.

conscripted health professionals to take their respective Infants' blood for the purpose of providing the blood spots to the government.

- 43. Additionally, the Parents did not give any general or informed consent to Defendant MICHIGAN DEPARTMENT OF HEALTH AND HUMAN SERVICES or any STATE OFFICIALS DEFENDANTS to transfer, convey, handover, or reassign the Infants' blood samples to a private, non-profit entity known as Defendant MICHIGAN NEONATAL BIOBANK (including its Board of Directors and/or Defendant DR. ANTONIO YANCEY) for the private entity's own disposition.
- 44. Collectively Defendants, by and through its conscripted or regular agents/officials/employees, illegally and unlawfully pierced the skin of the Infants for the purpose of extracting a part of each Infants' body for testing in a government laboratory without a warrant signed by a neutral and detached magistrate, consent of the Parents, or constitutionally sufficient authorization under law.
- 45. At no point were the Parents ever presented with the option to simply opt-out of the blood draw <u>before</u> their Infants' blood draw occurred, the seizure of blood spots occurred via the DBS cards, the medical testing was undertaken on the Infants, or otherwise.

- 46. At some point during the hospital stay for the birth of the Infants, the Parents might have been presented with a card giving the Parents an option of whether they want their Infants' <u>already</u> illegally seized and tested blood to be donated to medical research.
- 47. However, when any such card was presented, the extraction of the blood spots had <u>already occurred</u> and the Parents were denied the opportunity to first make the informed choice of whether to allow for the medical tests, via a blood draw, in the first place.
- 48. On information and belief, the Parents did not provide general or informed consent, and if they did so sign such a document they had an insufficient understanding of matters they asked/forced to sign and thus were not given proper informed consent.
- 49. In the alternative, any consent alleged to be obtained by any Defendant was not proper *informed* consent as required by law.
- 50. In addition to the blood spot samples, Defendants, individually or collectively, required the conscripted healthcare profession to submit certain data about the blood spots and also other private personal information including the Infants' names, genders, weight, gestation time, and whether transfused with red blood cells and whether part of a single or multiplenewborn birth (i.e. twins, triplets).

51. A sample of that form looks like this:



- 52. The Parents are also charged a fee, usually more than \$100.00, for the cost of Defendant MICHIGAN DEPARTMENT OF HEALTH AND HUMAN SERVICES and all STATE OFFICIALS DEFENDANTS undertaking the seizing, storage, and testing of the blood spots of their respective Infants (hereinafter "Blood Money").
- 53. On information and belief, a portion of the collected Blood Money is distributed, in part, as public grants to Wayne State University, which then funnels those funds to Defendant MICHIGAN NEONATAL BIOBANK as a private entity. See **Exhibit Q**.
- 54. After searching and seizing the blood drops from Infants 24-48 hours post-birth without consent as described above, Defendant MICHIGAN

DEPARTMENT OF HEALTH AND HUMAN SERVICES and the STATE OFFICIALS DEFENDANTS demands delivery of and are transmitted the blood spots which become in the possession of the Bureau of Laboratories with the Defendant MICHIGAN DEPARTMENT OF HEALTH AND HUMAN SERVICES under the custody and control of the STATE OFFICIALS DEFENDANTS.

- 55. By and through its laboratory technicians within Defendant MICHIGAN DEPARTMENT OF HEALTH AND HUMAN SERVICES and under the authority of the STATE OFFICIALS DEFENDANTS, tests, which were not consented to be undertaken, are conducted to detect and learn of any maladies, disorders, or diseases of Infants.
- 56. A list of maladies, disorders, or diseases sought to be detected is attached as see **Exhibit A**.
- 57. None of the maladies, disorders, or diseases sought to be detected in **Exhibit A** are contagious or can spread by communitive human contact; in other words, an Infant either has one of these diseases by operation of their heredity and cannot spread the same to third parties like the flu.
- 58. No STATE OFFICIALS DEFENDANTS and no laboratory technician at Defendant MICHIGAN DEPARTMENT OF HEALTH AND

HUMAN SERVICES obtained or secured the informed and/or lawful consent of the Infants or their Parents to conduct these tests.

- 59. No STATE OFFICIALS DEFENDANTS and no laboratory technician at Defendant MICHIGAN DEPARTMENT OF HEALTH AND HUMAN SERVICES provided reasonable notice or explanation to the Infants or their Parents to seek informed consent to conduct these medical tests.
- 60. Regardless of whether those blood spots had tested positive for any of the 50+ maladies, disorders, or diseases, Defendant MICHIGAN DEPARTMENT OF HEALTH AND HUMAN SERVICES retained the remaining blood spots indefinitely via a complicated arrangement with Defendant MICHIGAN NEONATAL BIOBANK.
- 61. After the Newborn Screening Program testing is complete, the Infants' blood spots are kept and then transferred to Defendant MICHIGAN NEONATAL BIOBANK under the custody and control of Defendant DR. ANTONIO YANCEY.
- 62. On information and belief, every Infant in this legal action has their seized blood spots on the above-described DBS cards stored by Defendant MICHIGAN DEPARTMENT OF HEALTH AND HUMAN SERVICES in Lansing, Michigan and/or Defendant MICHIGAN NEONATAL BIOBANK in Detroit, Michigan.

- 63. Despite claiming that the Infants' identities are decoupled from the blood spot samples for "privacy," Defendant MICHIGAN NEONATAL BIOBANK readily and publicly admits that it is easily possible to request and break the blind causing the private medical and genetic information of the Infants to be revealed.
- 64. As of current, there are no statutory legal protections on who may access, use, or utilize the private medical and genetic information of the Infants which is obtainable through blood and blood-based testing, see MCL 333.5431.
- 65. Defendant MICHIGAN NEONATAL BIOBANK readily admits that—

dried blood spot samples have been used to detect a number of other conditions and substances. It is possible to measure, for example, lead and mercury levels and alcohol and tobacco exposure, and to look for environmental or genetic links to many childhood disorders. <u>New technologies make it possible to measure thousands of genes, gene transcripts, proteins, metabolites, infectious agents, drugs, and toxins from small samples when stored under optimal conditions.</u>

#### Exhibit O.

66. As part of their marketing to parents in this state, Defendant MICHIGAN DEPARTMENT OF HEALTH AND HUMAN SERVICES and the STATE OFFICIALS DEFENDANTS, individually or collectively, explained the Newborn Screen Program has been granted "the highest level of

protection, a 'Certificate of Confidentiality' from the United States

Department of Health and Human Services", from which it claims that the

State "will use that Certificate to resist any demands for information that

could identify you" with two exemptions. **Exhibit J**.

- 67. As an additional example, Defendant MICHIGAN DEPARTMENT OF HEALTH AND HUMAN SERVICES and the STATE OFFICIALS DEFENDANTS offer a public document which asks "Do law enforcement officials or insurance companies have access to the BioTrust?"
- 68. The answer provided says "No" and that "[t]he BioTrust has been designated a medical research project by the MDHHS Chief Medical Executive. Under state law, the samples, data and other information included as part of this medical research project are protected and <u>are not subject to forced disclosure to third parties." Exhibit K.</u>
  - 69. Those assurances are false.
- 70. Blood samples on several occasions were provided pursuant to state court orders, **Exhibit L**, and being sold to third party businesses and researchers, **Exhibits N and R**.
- 71. As such, Defendant MICHIGAN DEPARTMENT OF HEALTH AND HUMAN SERVICES and the STATE OFFICIALS DEFENDANTS do

not resist any such demands for information, including those from courts and law enforcement.

- background With Defendant 72. the of the MICHIGAN DEPARTMENT OF HEALTH AND HUMAN SERVICES and the STATE OFFICIALS DEFENDANTS providing blood samples and data to third parties, the Defendant MICHIGAN DEPARTMENT OF HEALTH AND HUMAN SERVICES and the STATE OFFICIALS DEFENDANTS have also entered in an agreement to convey, handover, and/or assign the Infants' blood samples to a private, non-profit entity known as Defendant MICHIGAN NEONATAL BIOBANK (including its independent Board of Directors and/or Defendant DR. ANTONIO YANCEY) for the private entity's own decisions on disposition.
- 73. There is no legal contract, state statute, or administrative rule limiting the range of uses of the Infants' blood spots by Defendant MICHIGAN NEONATAL BIOBANK (including its independent Board of Directors and/or Defendant DR. ANTONIO YANCEY).
- 74. Any past adherence to the commands of the Defendant MICHIGAN DEPARTMENT OF HEALTH AND HUMAN SERVICES and the other individual state defendants named herein by Defendant MICHIGAN

NEONATAL BIOBANK has been merely by grace and business judgment acquiescence.

- 75. Defendant MICHIGAN NEONATAL BIOBANK and Defendant DR. ANTONIO YANCEY indefinitely store the Infants' blood in a temperature and humidity-controlled facility in an area in or near Wayne State University known as Tech Town as willful participants in joint action with the State and/or its agents, including for and on behalf of Defendant MICHIGAN DEPARTMENT OF HEALTH AND HUMAN SERVICES and the other individual state defendants named herein.
- 76. The DBS cards containing the seized dried blood spots of Infants are stored in archival boxes inside Tech Town and are under the custody and control of Defendant MICHIGAN NEONATAL and Defendant DR. ANTONIO YANCEY.
- 77. On information and belief, the current DBS inventory exists of over five million residual newborn blood spot specimens representing nearly every Michigan birth since at least October 1987, but on information and belief as early as 1984.
- 78. Since the blood spots contain deeply private medical and genetic information, see Exhibit O, the Parents are concerned and fear about the misuse of that information and fear the possibility of discrimination against

their Infants and perhaps even relatives through the use of such blood samples and research activity thereon.

- 79. That hear is well-founded and actual as the sharing of blood spots containing deeply private medical and genetic information has recently resulted in the arrest of an alleged killer but has already resulted in the wrongful arrest of persons who were not guilty of any crime, see *AP Explains: A Look at DNA-Sharing Services and Privacy*, N.Y. TIMES, Apr 27, 2018, available at <a href="https://nyti.ms/2FttAqu">https://nyti.ms/2FttAqu</a> (printout attached as **Exhibit M**).
- 80. As part of a recent *Freedom of Information Act* request upon Wayne State University, it has been revealed that Defendant MICHIGAN NEONATAL BIOBANK actively <u>sells</u> punches, of various sizes to universities <u>and businesses</u> at different rates, **Exhibit N**.
- 81. In fact, Defendant MICHIGAN NEONATAL BIOBANK has begun a process mass selling samples to commercial research outfits around the county. See **Exhibit R**.
- 82. The Parents are concerned and fear that Michigan statutory law provides no legal protections from invasion or use by courts, law enforcement, state actors, for profit business, and/or private actors who gaining access to the blood spot collections and DBS cards held by Defendant MICHIGAN NEONATAL BIOBANK.

83. Any alleged public understanding as to the use of the blood spots has exceeded the limited uses presented by Defendants for vaguely defined "research."

### COUNT I FOURTEENTH AMENDMENT VIOLATION 42 U.S.C. § 1983 LIBERTY DUE PROCESS RIGHT (EXCLUDING DEFENDANT BIOBANK AND DR. ANTONIO YANCEY)

- 84. The prior allegations are alleged word for word herein.
- 85. The Fourteenth Amendment provides that no State shall "deprive any person or life, liberty, or property, without due process of law."
- 86. The US Supreme Court has held a competent person had the constitutionally protected liberty interest in refusing unwanted medical procedures, *Cruzan v Director, Missouri Dep't of Health*, 497 U.S. 261, 278 (1990).
- 87. Here, the Parents were never given the choice to decide whether to accept or reject the medical procedure of the testing as to all or some of the 50+ maladies, disorders, or diseases *prior* to a piercing device breaching the outside skin of the Infants to extract five or six blood drops and seize those blood spots for medical testing and use by the government.
- 88. By conscripting medical professionals to take the Infants' blood for government seizures and use without informed consent of the Parents

throughout the use of MCL 333.5431(2), Defendants deprived the Infants their liberty interest in their guardians self-making personal and private medical procedure decisions without due process of law.

- 89. Infants have experienced constitutional harm, including harm to their liberty rights under due process, by the illegal and unlawful processes and procedures undertaken and/or the same is a policy, custom, and/or practice of Defendants.
- 90. The conduct of Defendants was reckless and undertaken with complete in indifference to the federal rights of Infants to be free from violations of the Fourteenth Amendment to the United States Constitution.

# COUNT II FOURTEENTH AMENDMENT VIOLATION 42 U.S.C. § 1983 LIBERTY DUE PROCESS RIGHT (ALL DEFENDANTS)

- 91. The prior allegations are alleged word for word herein.
- 92. All Defendants have improper used incomplete informed consent which inadequately, vaguely, unclearly, ambiguously and/or imprecisely failed to provide all pertinent information under the doctrine of informed parental consent in an intentional attempt to claim obtainment of consent needed to conduct medical test and/or medical procedure on the Infants.

- 93. That incomplete informed consent is false consent and is not legal sufficient to constitute informed parental consent to authorize all the activities undertaken by Defendants under the guise of the Newborn Screening Program.
- 94. All Defendants have purposely and intentionally sought incomplete consent during the birthing hospital stay when the Parents failed to have a clear head and mind to make an informed decision on whether to grant consent, in any form, to Defendants.
- 95. Any claimed consent that any Defendant purported to receive from any Plaintiff failed to be sufficiently clear and informative to constitute informed consent.
  - 96. In other words, Defendants obtained false consent.
- 97. Moreover, the public representations made by Defendants was that, at most, the State was doing research using the blood of Infants.
- 98. Later when transferring the blood samples from Defendant MICHIGAN DEPARTMENT OF HEALTH AND HUMAN SERVICES to the Defendant MICHIGAN NEONATAL BIOBANK, who then sells the samples to third-party businesses, or third-party bio-sample brokers (see **Exhibit R**) for use by for profit companies, any consent alleged to have been obtained

has been far exceeded than any alleged consent received by these Defendants.

- 99. By undertaking the taking of the Infants' blood for government seizure and use without proper informed consent of the Parents, Defendants deprived the Infants their liberty interest in their guardians self-making informed personal and private medical procedure decisions without due process of law.
- 100. In the face of the lack of any legal restrictions in the form of statutes, administrative rules, written agreements with the Parents, or other legal-enforceable standards, the blood of the Infants can be imminently and actively used by Defendants contrary to the doctrine of parental informed consent and/or contrary to the desired personal and private medical directives of the Parents.
- 101. The conduct of Defendants was reckless and undertaken with complete in indifference to the federal rights of Infants to be free from violations of the Fourteenth Amendment to the United States Constitution.

### COUNT III FOURTH AMENDMENT VIOLATION - 42 U.S.C. § 1983 INITIAL EXTRACTION AND SEIZURE FOR TESTING (EXCLUDING DEFENDANT BIOBANK AND DR. ANTONIO YANCEY)

102. The prior allegations are alleged word for word herein.

- 103. The search of an Infant for the seizure of their blood spots for testing purposes, without the prior consent of the Infants or their Parents, is an unlawful and unconstitutional search and/or seizure under the Fourth Amendment to the United States Constitution when done at the direction of or acquiesced to by Defendant MICHIGAN DEPARTMENT OF HEALTH AND HUMAN SERVICES and the STATE OFFICIALS DEFENDANTS.
- 104. Defendant MICHIGAN DEPARTMENT OF HEALTH AND HUMAN SERVICES and the STATE OFFICIALS DEFENDANTS failed to have any consent or a warrant signed by a neutral and detached magistrate to legally cause a needle or other skin-piercing device to breach the outside skin of the newborn to extract five or six blood drops and seize those blood spots for testing and use by the government.
- 105. Defendants' actions, done under the color of law, intentionally and wantonly deprived the Infants of their right to be free from unlawful search and seizure as it applies to their own blood.
- 106. All Infants have experienced constitutional harm by the illegal and unlawful processes and procedures undertaken and/or the same is a policy, custom, and/or practice of Defendants.

107. The conduct of Defendants was reckless and undertaken with complete in indifference to the Infants' federal rights to be free from violations of the Fourth Amendment to the United States Constitution.

# COUNTS IV & V FOURTH AMENDMENT VIOLATION - 42 U.S.C. § 1983 PLUS CIVIL CONSPIRACY UNDER § 1983 INDEFINITE SEIZURE AND STORAGE (ALL DEFENDANTS)

- 108. The prior allegations are alleged word for word herein.
- 109. The indefinite search-and-seizure of the blood of the Infants, for no reasonable and rationale basis when undertaken without the actual and informed consent of the Infants or their Parents, is an unlawful and unconstitutional search-and-seizure under the Fourth Amendment to the United States Constitution.
- 110. Defendants failed to have any consent or a legally-obtained judicial warrant signed by a neutral and detached magistrate to indefinitely test, keep, store, and use the blood of the Infants via a third party, namely Defendant MICHIGAN NEONATAL BIOBANK.
- 111. Parents, as the legal decisionmakers of their respective Infant(s), did not give any general or informed consent to Defendant MICHIGAN DEPARTMENT OF HEALTH AND HUMAN SERVICES or any STATE OFFICIALS DEFENDANTS to transfer, convey, handover, or reassign the

Infants' blood samples to a private, non-profit entity known as Defendant MICHIGAN NEONATAL BIOBANK (including its Board of Directors and/or Defendant DR. ANTONIO YANCEY) for the private entity's own disposition of the samples.

- 112. Defendants' actions, done under the color of law, intentionally and wantonly deprived the Infants of their right to be free from unlawful and ongoing seizures as it applies to their own blood.
- 113. Defendants' actions were done individually and also via a plan with shared general conspiratorial objectives to deprive the Infants of their constitutional rights to be free from illegal search-and-seizure under the Fourth Amendment in the form of an overt act of indefinitely causing the leftover blood from the Newborn Screening program to be not destroyed but instead seized and stored indefinitely by the Michigan BioTrust for Health and/or Defendant MICHIGAN NEONATAL BIOBANK in either Lansing, Detroit, or both locations.
- 114. For purposes of this case, the Infants, by their Parents, allege that Defendant DR. ANTONIO YANCEY is a state actor or is otherwise liable via civil conspiracy under 42 U.S.C. § 1983 by his role as director of Defendant MICHIGAN NEONATAL BIOBANK.

- 115. For purposes of this case, the Infants, by their Parents, allege that Defendant MICHIGAN NEONATAL BIOBANK is a state actor or is otherwise liable via civil conspiracy under 42 U.S.C. § 1983 despite being formed as a non-profit domestic corporation.
- 116. Infants have experienced constitutional harm by the illegal and unlawful processes and procedures undertaken and/or the same is a policy, custom, and/or practice of Defendants.
- 117. The conduct of Defendants was reckless and undertaken with complete in indifference to the federal rights of Infants to be free from violations of the Fourth Amendment to the United States Constitution.

### RELIEF REQUESTED

- 118. WHEREFORE, Plaintiffs, individually and collectively, respectfully request this Court to
  - a. Enter an order, pursuant to the Declaratory Judgment Act, declaring the conduct of Defendants acting under the color of law as being unconstitutional in violation of the Fourth and/or Fourteenth Amendments to the United States Constitution;
  - b. Enter an order, pursuant to the Declaratory Judgment Act, declaring the use of coercive criminal penalties to turn over the Infants' blood instead of the medical professionals themselves

- conducting the required tests is not a valid substitute for constitutionally-required and/or informed consent;
- c. Enter an order, pursuant to the Declaratory Judgment Act, declaring a certain provision of the Newborn Testing Statute, MCL 333.5431(2)², is unconstitutional in that it unlawfully self-authorizes the search and/or seizure of blood samples and spots of newborns (including these Infants) by the State without consent or a warrant, thereby violating the Fourth Amendment to the United States Constitution;
- d. Enter an order, pursuant to the Declaratory Judgment Act, declaring certain provisions of the Newborn Testing Statute, MCL 333.5431(2)³, are unconstitutional in that it mandates both medical procedures and the automatic waiver the right to informed consent owed to the Infants and the Parents in violation of their liberty rights, thereby violating the Fourteenth Amendment to the United States Constitution;

<sup>&</sup>lt;sup>2</sup> "The department may require that the tests be performed by the department."

<sup>&</sup>lt;sup>3</sup> The informed consent requirements of sections 17020 and 17520 do not apply to the tests required under subsection (1). The tests required under subsection (1) shall be administered and reported within a time and under conditions prescribed by the department. The department may require that the tests be performed by the department.

- e. Enter an order, pursuant to the Declaratory Judgment Act, declaring any consent that Defendants claim to have obtained has been exceeded and thereby is unconstitutional in that violates the Fourteenth Amendment to the United States Constitution;
- f. Enter an order for prospective injunctive relief to halt the illegal processes and procedures of Defendants in violation of the Fourth and Fourteenth Amendments to the United States Constitution;
- g. Enter an order for prospective injunctive relief to halt continued possession and retention of all blood samples and spots of the Infants by any or all Defendants which they, individually or collectively, caused to be seized, transferred, and stored indefinitely without informed consent;
- h. Issue a prospective injunction, commanding Defendants to destroy all data collected or extracted regarding the Infants, and return to the Parents all blood samples and spots of the Infants, which Defendants have caused to be seized and stored indefinitely without informed consent;

- i. Issue a prospective injunction, commanding Defendants to advise the Parents for what purposes Defendants are or have been used the blood samples and spots of the Infants and permanently enjoin any on-going or planned use of the Infants' blood samples and spots which Defendants have caused to be seized and stored indefinitely without informed parental consent;
- j. Enter an order for damages in the amount of all damages, including nominal damages and full refunds of all expropriated fees taken from the Parents, with interest, obtained by Defendants by its illegal actions, to the extent not prohibited pursuant to the Eleventh Amendment to the United States Constitution;
- k. Enter an order for an award of punitive damages for each Infant and/or their Parent to the extent not prohibited pursuant to the Eleventh Amendment to the United States Constitution;
- I. Enter an order for an award of actual reasonable attorney fees and litigation expenses pursuant to 42 U.S.C. § 1988 and all other applicable laws, rules, or statutes; and
- m. Enter an order for all such other relief the court deems equitable and/or just.

### **JURY DEMAND**

119. For all triable issues, a jury is hereby demanded.

Date: April 30, 2018 RESPECTFULLY SUBMITTED:

/s/ Philip L. Ellison

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### **CERTIFICATE OF SERVICE**

I, the undersigned attorney of record, hereby certify that on the date stated below, I electronically filed the foregoing with the Clerk of the Court using the ECF system which will send notification of such filing to all counsel or parties of record.

Date: April 30, 2018 RESPECTFULLY SUBMITTED:

/s/ Philip L. Ellison

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