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**UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY
(Trenton Vicinage)**

HANNAH LOVAGLIO,

J.L. and B.L., by next friend,
Hannah Lovaglio,

ERICA JEDYNAK,

JEREMIAH JEDYNAK,

C.J., by next friends, Erica and
Jeremiah Jedynak,

Plaintiffs,

Civil Action No.: 3:23-cv-21803-
CG-RLS

**First Amended
Class Action Complaint**

v.

KAITLAN BASTON,
Commissioner of the New Jersey
Department of Health, sued in
her official capacity,

NANCY SCOTTO-ROSATO,
Assistant Commissioner for the
Division of Family Health
Services, sued in her official
capacity,

Defendants.

1. Plaintiff Hannah Lovaglio and Plaintiffs J.L. and B.L., by next friend Hannah Lovaglio, who reside at 46 S. Main Street, Cranbury, New Jersey 08523, along with Plaintiffs Erica Jedynak and Jeremiah Jedynak, and Plaintiff C.J., by next friends Erica and Jeremiah Jedynak, who reside at 203 Deerlea Lane, Boonton, New Jersey 07005 (collectively, “Plaintiffs” or “Named Plaintiffs”), seek declaratory, injunctive, and class action relief against Defendant Commissioner Kaitlan Baton, located at 55 North Willow Street, Trenton, New Jersey 08608, and Defendant Assistant Commissioner Nancy Scotto-Rosato, located at 50 East State Street, Trenton, New Jersey 08608 (collectively referred to as

“Defendants” or “New Jersey”), for the deprivation of Plaintiffs’ rights, and the rights of those similarly situated, under the Fourth and Fourteenth Amendments to the United States Constitution.

INTRODUCTION

2. Every baby born in New Jersey is screened for diseases. Shortly after birth, the baby’s heel is pricked, blood is collected on a card, and the card is sent to the New Jersey Department of Health’s Newborn Screening Laboratory, where the state tests for 62 disorders. This testing is not particularly controversial—every state does it. Plaintiffs are not challenging this heel prick or the test itself, which gives parents results in one to two weeks.

3. Plaintiffs are, however, challenging what happens after the testing is complete. When Plaintiffs filed their original complaint (Doc. 1), Defendants were secretly keeping the blood of every child born in the state for 23 years. And Defendants had no oversight or limits on how they could use that blood—or to whom they could give the blood.

4. Plaintiffs were appalled to learn about Defendants’ retention policy, so they filed this class action lawsuit on behalf of all children and

parents in New Jersey to stop Defendants from violating their collective rights under the Fourth and Fourteenth Amendments to the United States Constitution.

5. Plaintiffs also provided Defendants with an easy and straightforward fix: Just ask parents for consent. That's all this lawsuit is about—voluntary, informed consent. If the state obtains voluntary, informed consent from parents to retain their children's blood, Defendants will comply with the Constitution. It really is that simple.

6. In response to Plaintiffs' original complaint, Defendants, along with the New Jersey Attorney General Matthew Platkin, made voluntary and non-binding changes to the newborn testing program and retention policy. Among other things, Defendants shortened their retention period and now promise to disclose some information to parents.

7. These changes, however, are missing the one thing that matters: Consent. Defendants are *still* refusing to obtain parental consent before retaining the blood. As a result, nothing has changed constitutionally about this case. Defendants are still retaining the blood

of every child born in New Jersey after the testing is complete. Defendants are still refusing to ask parents for consent to retain the blood. And thus, Defendants are still violating the Fourth and Fourteenth Amendments to the United States Constitution.

8. In the end, it remains perplexing why Defendants still refuse to do the one thing that will fix their policy: Just ask parents for consent. Perhaps Defendants are worried some parents will say “no.” But Defendants cannot sidestep the Constitution just because they think some parents will make, as Defendants see it, the “wrong” choice.

JURISDICTION AND VENUE

9. This is a civil rights case brought under 42 U.S.C. § 1983, as well as the Fourth and Fourteenth Amendments to the United States Constitution.

10. This Court has jurisdiction under 28 U.S.C. §§ 1331, 2201, and 2202 because the claims arise under the United States Constitution.

11. Venue is proper in this Court under 28 U.S.C. § 1391 because all defendants reside in New Jersey and all or a substantial part of the events or omissions giving rise to the claims occurred in New Jersey.

THE PARTIES

12. Plaintiff Parent Hannah Lovaglio is a mother who lives in Cranbury, New Jersey. Hannah has two boys, Plaintiffs J.L. and B.L. (ages 5 and 1.5, when the lawsuit was filed), both of whom were born in New Jersey. Hannah brings this suit on her own behalf, as well as parent-guardian and next friend to her minor children, Plaintiffs J.L. and B.L.

13. Plaintiff Parents Erica and Jeremiah Jedynak are a married couple who live in Boonton, New Jersey. The Jedynaks have one son, Plaintiff C.J., who was born in New Jersey and turned two in December 2023, after the lawsuit was filed. The Jedynaks bring this suit on their own behalf, as well as parent-guardians and next friends to their minor child, Plaintiff C.J.

14. Defendant Kaitlan Baston is the commissioner of the New Jersey Department of Health—the agency in charge of New Jersey’s newborn screening program. She is sued in her official capacity under *Ex parte Young*, 209 U.S. 123 (1908).

15. Defendant Nancy Scotto-Rosato is the assistant commissioner for the Division of Family Health Services, which oversees the newborn

testing program in New Jersey. She is also sued in her official capacity under *Ex parte Young*, 209 U.S. 123 (1908).

STATEMENT OF FACTS

The Newborn Screening Program.

16. Since the 1970s, New Jersey has required every baby born in the state to be tested for a wide range of disorders, including cystic fibrosis, hormonal deficiencies, and other immunity and congenital disorders. N.J. Stat. § 26:2-111; N.J. Dep’t of Health, *Disorders Screened*, <https://tinyurl.com/NJ-Disorders>.

17. Within 48 hours of birth, hospitals prick the heel of each newborn and collect the blood on a paper card—creating “blood spots.”¹

¹ The following image comes from a video that New Jersey publishes on its website. N.J. Dep’t of Health, *Newborn Screening & Genetic Services*, <https://www.nj.gov/health/fhs/nbs/bloodspot/handout/> [“NJDH Video”] (link at the bottom of the page to register and watch at <https://attendee.gotowebinar.com/recording/4933247376685884930>).



18. This paper card is then sent to the Newborn Screening Laboratory, which is run by the New Jersey Department of Health at the New Jersey Public Health and Environmental Laboratories.

19. The lab is located just outside Trenton, New Jersey, and processes more than 100,000 newborn tests each year.

20. New Jersey does not require parental consent before it takes blood from newborns.

21. Rather, parents simply receive a handout about the program in the packet of paperwork every new parent receives at the hospital.

22. When Plaintiffs filed this lawsuit, this was the entire handout:

Parent Overview

All babies born in New Jersey are required by law to receive a newborn blood screen 24-48 hours after their birth. One part of newborn screening is a simple and safe blood test that provides important information about your baby's health.

The blood sample is used to screen for many rare conditions which, if left untreated, may result in serious health problems. A newborn baby can look healthy, but have a serious disease that cannot be seen right after birth. Newborn Screening helps to detect these unseen illnesses. Early diagnosis and treatment may help prevent problems and complications related to these conditions.

The New Jersey Newborn Screening Program currently tests for **60** different disorders and identifies about 150 babies a year who have one of these rare and serious illnesses.

KNOW YOUR RESULTS! Please check with your baby's doctor to find out your baby's Newborn Screening test results. Results are often available as early as your baby's one-week checkup. If a repeat test is recommended for any reason, please arrange for it to be completed as soon as possible.

Websites below are written for parents and have lots of good information about Newborn Screening:



<http://www.state.nj.us/health/fhs/nbs/>
www.BabysFirstTest.org
www.NewbornScreening.info
www.SaveBabies.org



KNOW YOUR RESULTS!

23. Parents may also find out about the screening from nurses.

24. The handout provides links to four websites as referral sources. Three of these websites are from third parties—not New Jersey. The lone link back to the New Jersey Health Department does not provide any information about the retention of the blood.

25. Under New Jersey law, however, the hospital's informational obligations are limited to ensuring that "the infant's parent is informed

of the purpose and need for newborn screening and given newborn screening educational materials” provided by New Jersey’s Newborn Screening and Genetic Services. N.J. Admin. Code §§ 8:18-1.2–1.4.

26. New Jersey also has a PowerPoint presentation on its website, which is designed to give an overview of the program to healthcare providers. *See* NJDH Video.

27. The blood draw and testing are mandatory unless a “parent or guardian objects to the testing on the grounds that testing would conflict with his or her religious tenets or practices.” N.J. Admin. Code § 8:18-1.12(a).

28. There is no requirement that anyone inform parents about their right to object on religious grounds.

29. New Jersey also gives parents a second notice about the availability of supplemental testing that parents can choose to opt-in and purchase.

30. The supplemental notice references the “Mandated Newborn Screening” and explains that “New Jersey does not test for every possible birth defect.” Any extra testing is performed by a private lab.

31. This is the supplemental notice:

**State of New Jersey
Department of Health**

NOTICE OF AVAILABILITY OF SUPPLEMENTAL NEWBORN SCREENING

Mandated Newborn Screening

New Jersey law mandates that every baby born in New Jersey receive:

- Newborn Biochemical (Bloodspot) screening
- Hearing screening
- Critical Congenital Heart Defect (pulse oximetry) screening

For more information about the NJ Newborn Screening Program see <https://www.nj.gov/health/fhs/nbs/>

Supplemental (additional, optional) screening

The purpose of this notice is to inform expectant parents that New Jersey does not test for every possible birth defect and that additional, supplemental, testing is available for defects for which the State does not screen, should you choose to pursue further screening.

- **Supplemental** screening is performed by private laboratories and may not be covered by your insurance plan.

The results of any supplemental screening tests are sent to the ordering health professional and NOT to the NJ Newborn Screening Program.

32. After the screening tests are completed, New Jersey sends the results to the hospital where the baby was born.

33. As the handout explained, *supra* ¶ 22, “Results are often available as early as your baby’s one-week checkup.”

34. Generally, the screening tests are completed within one to two weeks after the baby is born.

35. If the screening results are abnormal, New Jersey also sends the results directly to the baby’s primary care provider.

36. Regardless of whether the results are normal or abnormal, parents cannot directly access their child’s newborn screening results.

37. Under Defendants’ policy, the Laboratory only keeps the blood for fourteen days before placing all blood spots into storage boxes and transferring the boxes to a storage area.

New Jersey Unlawfully Keeps the Unused Blood.

38. After New Jersey completes the newborn screening tests, there is some unused blood left on the paper card—called a “residual dried blood spot.”

39. New Jersey does not destroy the unused blood; instead, it holds onto it.

40. In fact, as reported by several news outlets and a prominent newborn screening website to which the New Jersey Department of Health refers parents, at the time this lawsuit was filed, New Jersey had a policy of storing all unused blood in a temperature-controlled room for 23 years after testing.²

² See, e.g., Nikita Biryukov, *Newborn Screening Program Used to Aid Criminal Investigation, Public Defender Says*, N.J. MONITOR (July 13, 2022, 7:44 AM), <https://tinyurl.com/NJ-Monitor-BabyBlood>; Matt Delaney, *New Jersey Health Officials Gave Police Access to Baby DNA for Criminal Probes, Lawsuit Says*, WASH. TIMES (Aug. 10, 2022), <https://tinyurl.com/Wash-Times-BabyBlood>; Baby’s First Test, *New Jersey*,

41. No New Jersey statute requires unused blood to be destroyed.

42. No statute authorizes New Jersey to retain the blood either.

43. Instead, the New Jersey Department of Health has unilaterally determined that it can keep and store the unused blood from every baby born in New Jersey.

44. When Plaintiffs filed this lawsuit, New Jersey never told parents that it would store their baby's blood after the newborn screening testing is completed.

45. Instead, Defendants secretly kept the blood for however long it wanted.

46. New Jersey does not—and never has—asked parents for consent to keep their baby's blood after the newborn screening testing is completed.

47. New Jersey never obtains a warrant to retain unused blood.

<https://www.babysfirsttest.org/newborn-screening/states/new-jersey>
(last visited Oct. 17, 2023).

New Jersey Gives Blood to Third Parties.

48. New Jersey does not just keep the unused blood for itself. Rather, it has been caught giving baby blood to third parties.

49. Following a lawsuit filed by the New Jersey Office of the Public Defender, it was revealed that New Jersey gave unused blood from its baby blood stockpile to law enforcement officers on at least five occasions.

50. The officers did not have a warrant to take the blood.

51. On information and belief, New Jersey also gives or sells blood from its baby blood stockpile to other third parties. This could include, but is not limited to, researchers, companies, or other government agencies.

52. When Plaintiffs filed this lawsuit, New Jersey did not tell parents anything about when—or to whom—it gives away or sells their children's blood.

Plaintiffs Were Appalled to Learn that New Jersey Is Secretly Keeping Their Children's Blood.

53. Plaintiff Parent Reverend Hannah Lovaglio is the pastor of a church in New Jersey. Hannah has been married for eight years. Hannah

and her husband love New Jersey and have enjoyed raising their family here. To Hannah, it's the perfect place: Far enough from New York City that it feels like a small-town community, but close enough to still experience all of NYC's restaurants, museums, and culture.

54. Starting a family was not easy for Hannah. But, with the help of in vitro fertilization, Hannah now has two boys. Both of Hannah's boys were born in New Jersey. When this lawsuit was filed, her oldest son, J.L., was five years old; her younger son, B.L., was a year-and-a-half.

55. Hannah and her husband are considering whether to have more children in New Jersey. Hannah still has several frozen embryos that are stored in New Jersey.

56. If and when Hannah and her husband have their next child, their child will be subject to New Jersey's unconstitutional blood-retention policy.

57. At birth, New Jersey took blood from both of Hannah's boys through the state's newborn screening program. The newborn testing for both of Hannah's boys came back as normal.

58. New Jersey retained the unused blood from Hannah's boys after the newborn screening tests were completed—and still has the blood.

59. New Jersey never asked Hannah whether it could keep her children's unused blood after the testing was completed.

60. Nor did New Jersey ask Hannah whether it could use her children's blood for other purposes, such as giving or selling the blood to third parties.

61. When Hannah learned about New Jersey's secret retention of her children's blood, she was appalled. As Hannah sees it, when your baby is born and you're in the hospital, the only concern is for the baby's health and the mother's health—that's it.

62. So while Hannah would have consented to the initial drawing of her children's blood to test for the 62 diseases in the newborn screening program, she would not have agreed to allow New Jersey to keep her children's blood for any length of time following that testing.

63. Like any mom, Hannah recognizes that her top priority is protecting her children. That includes protecting and keeping track of her

children, their health and medical needs, and everything else about them—including their blood, which contains their DNA and genetic information.

64. But now Hannah worries about how New Jersey may be abusing its possession of her children's blood.

65. Hannah's concerns are not hypothetical. New Jersey has already given some blood to law enforcement officers without a warrant.

66. And other states, with similar schemes, have been caught using babies' blood in alarming ways. In Texas, for example, a lawsuit revealed that the state was turning over blood to the Pentagon to create a national (and someday, international) registry.

67. Plaintiff Parents Erica and Jeremiah Jedynak are married and live in Boonton, New Jersey. The Jedynaks love New Jersey and have enjoyed raising their family here. They have a son, C.J., who was born in New Jersey and, after this lawsuit was filed, turned two in December 2023.

68. Erica and Jeremiah are also considering whether to have more children in New Jersey.

69. If and when Erica and Jeremiah have their next child, their child will be subject to New Jersey's unconstitutional blood-retention policy.

70. At birth, New Jersey took blood from the Jedynaks' son through the state's newborn screening program. The newborn testing for the Jedynaks' son came back as normal.

71. New Jersey retained the unused blood from the Jedynaks' son after the newborn screening tests were completed—and still has the blood.

72. New Jersey never asked the Jedynaks whether it could keep their child's unused blood after the testing was completed.

73. Nor did New Jersey ask the Jedynaks whether it could use their child's blood for other purposes, such as giving or selling his blood to third parties.

74. Erica was horrified and disgusted when she learned that New Jersey was keeping her son's blood in a state facility for what she describes as "a creepy database."

75. To Erica, keeping the blood of an innocent newborn, who has done nothing wrong, is immoral.

76. Indeed, while the families were still in the hospital during the initial 24 to 48 hours after birth—a time that most parents feel is sacred and special as they meet and begin to care for their new baby—New Jersey took part of the Jedyunks' son and Hannah's children with the intent to keep it and possibly use it against the children decades later.

In Response to this Lawsuit, Defendants Made Voluntary and Non-Binding Changes to the Newborn Screening Program and Retention Policy.

77. On November 2, 2023, Plaintiffs filed their original complaint against Defendants. (Doc. 1.)

78. In response, Defendants reached out to Plaintiffs to try and resolve the case without litigation.

79. The parties then worked together for almost six months trying to reach an agreement. But once it became clear to Plaintiffs that Defendants wanted to keep retaining blood from the newborn screening program without parental consent, Plaintiffs informed Defendants that further negotiations would not be productive.

80. The parties then informed the Court that negotiations failed, and the case could continue. (Doc. 23.) Defendants were scheduled to finally respond to the original complaint on June 25, 2024. (Doc. 24.)

81. On June 20, 2024, however, Defendants made a surprise announcement. (Doc. 25.)

82. The Department of Health made a public statement that announced changes to its retention policy of blood from the newborn screening program.

83. Among other changes, Defendants voluntarily shortened the retention policy from 23 years to either 2 years or 10 years. If a test is negative, Defendants now claim they will retain the negative blood spots for only two years post testing. If a test is positive, Defendants now claim they will now retain a positive blood spot for ten years post testing.

84. In either situation, Defendants *still* do not ask parents for consent before retaining the blood.

85. On July 25, 2024, Defendants made another voluntary and non-binding policy change.

86. These changes are simple policy changes that could be changed in the next hour. These changes were not, for example, made in compliance with the Administrative Procedures Act, with a public comment period, etcetera. Rather, these policy changes could change again if Defendants simply issued a new press release.

87. This time, Defendants revised the handout about the program in the packet of paperwork every new parent receives at the hospital. *See supra* ¶ 22 (showing the version of this card that was given to parents when this lawsuit was filed and until Defendants voluntarily changed the card in response to the lawsuit).

88. This is the front of the new card that Defendants created in response to this lawsuit:

Effective November 1, 2024

DO NOT USE THIS FORM AFTER 09/30/2023

BABY'S LAST NAME (*PRINT*) SN 23100001

Instructions to Submitter:

After entering the newborn's name, remove this copy and give it to the parents of this newborn.

Parents and Legal Guardians,

Newborn Screening is an important public health service that can protect your baby. Babies may look healthy but have certain rare health problems, which can be found by taking a small amount of blood from a baby for testing. The Newborn Screening program currently conducts tests for more than 60 disorders.

Five blood drops have been taken from your baby's heel and sent to the New Jersey Newborn Screening Laboratory for initial testing, which will be completed in the next few days. You have received the brochure "These Tests Could Save Your Baby's Life," which is also available at https://www.nj.gov/health/fhs/nbs/documents/the_tests_for_screening_eng.pdf. This brochure has more information about Newborn Screening.

Please take this notice to your baby's doctor, who can get a copy of your baby's test results by contacting the Newborn Screening Laboratory.

Por favor lleve esta carta al doctor de su bebé.

 **State of New Jersey
NEWBORN
SCREENING**

**New Jersey
Department of Health**
<http://www.newbornscreening.nj.gov>

PARENT COPY

89. This is the back of the new card that Defendants created in response to this lawsuit:

Effective November 1, 2024


In accordance with Department of Health (DOH) policy, the sample taken from your baby will be securely stored for 2 years to ensure the integrity of your baby's tests results (for example, to rule out false positive or false negative results). If we do not hear otherwise from you, we will destroy the sample after 2 years.

At your request, the blood sample from your baby's Newborn Screening can be:

1. Destroyed at any time after initial testing, including before your child is 2 years old.
2. Stored for additional time, up to 8 years beyond the initial 2-year retention period.

DOH uses blood samples from the Newborn Screening program only for the following purposes: (1) newborn screening for your baby; (2) routine quality assurance and quality control for DOH's lab; and (3) developing new tests for disorders. Any blood samples used for the second or third purposes will be de-identified—that is, unlinked from your baby's identifying information.

The sample taken from your baby will not be released in identified form (that is, with identifying information about your baby) to non-law enforcement third parties without your consent. DOH will release your baby's identified blood samples to law enforcement (for example, if your child went missing) only with your consent or consistent with the Attorney General's binding Law Enforcement Directive (available at www.nj.gov/oag/dcj/agguide/directives/). De-identified samples will be released to third parties only as allowed by federal law.



Scan the QR code below to access the full Newborn Screening bloodspot retention policy, or to fill out and submit either a destruction form or an extended-retention form. These forms are also available at: www.nj.gov/health/phel/documents/destruction-form.pdf and www.nj.gov/health/phel/documents/extended-retention-form.pdf.

90. On this card, Defendants include a “QR Code” that links to a Newborn Screening Bloodspots Destruction Request Form.

91. If parents fill out this form, Defendants say they will destroy their child's bloodspot that Defendants are retaining.

92. This card is given to parents in the hospital, along with other paperwork, within the first 24 to 48 hours that the child is born.

93. Other lawsuits, including a nearly identical challenge to Michigan's retention policy, have explained why this “opt-out” option is

not the same as voluntary, informed consent under the Fourth Amendment, such as an “opt-in” option. *See, e.g., Kanuszewski v. Mich. Dep’t of Health & Hum. Servs.*, 684 F. Supp. 3d 637, 647 (E.D. Mich. 2023), *appeal docketed*, No. 23-1733 (6th Cir. Aug. 16, 2023).

94. For instance, as the District Court in Michigan put it, there’s a variety of reasons why a new parent may not ask the state to stop violating their rights, such as “the product of the opacity of the system, the infants’ nascent existence in the world, or the result of the overwhelmed state of their new parents.” *Id.*

95. For blood with negative test results, Defendants say they will obtain parental consent to continue retaining the blood after two years.

96. If parents give consent, Defendants will retain the blood for ten years. In other words, Defendants *will* obtain consent to continue the retention of blood, post testing, for years three through ten.

97. Defendants have an Extended Retention Form that allows parents to opt-in to retention for years three to ten.

98. If parents do not give consent through the Extended Retention Form, Defendants say they will destroy the blood after two years.

99. After ten years, Defendants claim they will destroy all blood samples no matter the original test results.

100. According to Defendants, they will destroy all current blood spots they have for children that are now older than two years old.

101. Defendants will continue the retention of all blood spots they have for children younger than two years old. Defendants will not ask parents for consent to continue this retention.

102. Defendants say this mass destruction will take place starting November 1, 2024.

103. According to the new card, some of the policy changes will also become effective on November 1, 2024.

104. The new card also gives a primary reason for the retention: “the sample taken from your baby will be securely stored for 2 years to ensure the integrity of your baby’s tests results (for example, to rule out false positive or false negative results).”

105. Other states, including Virginia, have a less restrictive way of preserving newborn blood in the event someone needs to rule out a false positive or a false negative result—or in the tragic situation that blood is needed to identify a child.

106. Through the Virginia Child ID Blood Spot program, parents have the option, at the time of the child's birth, to have the hospital collect and give parents a sample of the newborn's blood.

107. Parents can then properly safeguard the blood without the risk of government or third-party abuse.

108. On July 25, 2024, Defendants also updated a page on the Department of Health's website: <https://www.nj.gov/health/phel/public-health-lab-testing/newborn-screening-lab/parents.shtml>.

109. Defendants now have a short section about “Newborn Screening Specimen Retention,” with three links:

Newborn Screening Specimen Retention

Currently, all NBS specimens are retained for 23 years. Effective November 1, 2024, this is changing and NBS specimens will be saved for two years. At that time, all specimens older than two years will be destroyed.

[Notice of Change to Newborn Screening Program’s Retention Policy](#)

[Parent Information about NBS Specimen Retention](#)

[Newborn Screening Retention Policy, Effective November 1, 2024](#)

110. The website does not directly tell parents that they can request the destruction of blood spots retained by Defendants.

111. Rather, a parent would have to click one of the three links and find the explanation and reference to the Destruction Request Form in one of those three documents.

112. Defendants also announced that they “will use retained bloodspots only for the following purposes: (1) newborn screening for a child; (2) routine laboratory quality assurance and quality control; and (3) the development of new tests for disorders.”

113. Defendants, however, confirm that they will still release blood spots to third parties in various situations.

114. Defendants will still release blood spots to state and local law enforcement agencies “as consistent with the Attorney General’s Directive.”

115. Also on June 20, 2024, the New Jersey Attorney General, Matthew Platkin, issued Attorney General Law Enforcement Directive No. 2024-03.

116. The Attorney General confirmed that Defendants have released blood retained from the newborn screening program to law enforcement agencies.

117. Moving forward, the Attorney General claims that law enforcement agencies will only be able to obtain blood from the newborn screening program “in genuinely exceptional circumstances.”

118. While calling these circumstances “rare,” the Attorney General goes on to explain that law enforcement agencies will *still* be able to access blood retained from the newborn screening program, but that such agencies “shall first seek approval from the Director of the Division of Criminal Justice.”

119. These requests, the Attorney General says, must “be made in writing and must explain why this is an exceptional circumstance that necessitates seeking information from the Program and why less intrusive means will not suffice.”

120. The Attorney General then goes on to detail the three different processes through which law enforcement officers can access the blood retained by Defendants.

121. Unlike some other states, the Attorney General did *not* categorically bar law enforcement officers from obtaining blood retained by Defendants from the newborn screening program.

122. The Attorney General admits that his voluntary and non-binding policy change is in fact voluntary and non-binding: “This directive shall take effect immediately, and shall remain in force and effect unless and until it is repealed, amended, or superseded by Order of the Attorney General.”

123. Attorney General Platkin has rescinded and amended directives that previous attorneys general have issued.

124. Nothing prevents Defendants, or the Attorney General, from rescinding, amending, or changing their policy changes tomorrow, in a year, or in five years.

125. Nothing prevents the next administration, the next Commissioner of the New Jersey Department of Health, the next Assistant Commissioner for the Division of Family Health Services, or the next Attorney General from rescinding, amending, or changing any of these policy changes at any time and for any reason whatsoever.

States Can Achieve Quality Control By Using Samples From Other Sources and By Obtaining Consent Before Birth.

126. Any government interest in retaining the blood spots without voluntary, informed consent before birth is minimal or nonexistent.

127. The Centers for Disease Control and Prevention's Newborn Screening Quality Assurance Program (NSQAP) provides newborn screening laboratories with quality assurance services. Newborn Screening Quality Assurance Program, U.S. Centers for Disease Control and Prevention, <https://tinyurl.com/NSQAP-Guidance>. As part of those services, NSQAP supplies laboratories with dried blood

spot materials that mimic newborn specimens. These reference materials help laboratories assess their ability to produce accurate results by, among other things, ensuring that testing accurately detects disorders and minimizes false positive reports.

128. As stated on NSQAP's website, all newborn screening laboratories in the United States—which surely includes New Jersey's laboratory—use the NSQAP's quality assurance services. Even if Defendants are not getting samples from NSQAP, the number of laboratories using NSQAP's materials means the materials meet most, if not all, quality assurance standards.

129. Any claim that the unique properties of newborn blood necessitates the use of newborn blood to calibrate testing and improve diagnostic capabilities falls flat. While newborn blood does differ from the blood of older infants and adults, “blood collected from any source, including cord blood,” can be modified to promote quality assurance in newborn screening laboratories. W. Harry Hannon et al., *Newborn Screening Quality Assurance*, in *Genetics and Public Health in the 21st*

Century 243, 245 (Muin Khoury et al., eds., Oxford University Press 2000).

130. To the extent that there is any remaining government interest in keeping blood spots beyond the initial screening, nothing prevents Defendants from obtaining voluntary, informed consent for the retention of blood spots before birth.

131. When medical providers give parents up-front information about newborn screening, parents have greater trust in and understanding of both the initial testing and any subsequent storage and research.

CLASS ACTION ALLEGATIONS

132. Named Plaintiffs reallege and incorporate by reference the allegations in paragraphs 1–131 as if fully stated here.

133. Named Plaintiffs seek to maintain this action on behalf of themselves and all others similarly situated under Federal Rule of Civil Procedure 23(b)(2).

134. New Jersey's conduct towards Named Plaintiffs is part of a broader policy and practice, in which the state retains and uses the

blood of every child born in New Jersey—without notice or informed consent.

135. Named Plaintiffs represent two putative classes.

136. Plaintiff Children J.L. and B.L., by next friend, Hannah Lovaglio, and Plaintiff C.J., by next friends Erica and Jeremiah Jedynak, represent the first putative class (the “Children’s Class”) with the following proposed class definition:

All persons born in New Jersey on or after November 2, 2000, whose blood has been or will be retained by New Jersey’s newborn screening program.

137. Plaintiff Parents Hannah Lovaglio and Erica and Jeremiah Jedynak represent the second putative class (the “Parents’ Class”) with the following proposed class definition:

All parents or legal guardians of minors born in New Jersey on or after November 3, 2005, whose blood has been or will be retained by New Jersey’s newborn screening program.

138. Plaintiff Children J.L. and B.L., by next friend, Hannah Lovaglio, and Plaintiff C.J., by next friends Erica and Jeremiah Jedynak, and the members of the Children’s Class have suffered, and will continue to suffer, constitutional violations under the Fourth Amendment to the

United States Constitution for the unlawful retention of blood from the newborn screening program.

139. Plaintiff Parents Hannah Lovaglio and Erica and Jeremiah Jedynak, and the members of the Parents' Class have suffered, and will continue to suffer, constitutional violations under the Fourteenth Amendment to the United States Constitution for the unlawful retention of blood from the newborn screening program.

140. Both classes satisfy all requirements under Rule 23(b)(2), including the numerosity, commonality, typicality, and adequacy requirements of Rule 23(a)(1)–(4).

141. Both classes satisfy the numerosity requirement of Rule 23(a)(1). In New Jersey, there are over 100,000 babies born each year. That means New Jersey is stockpiling *millions* of blood spots from the newborn screening program.

142. Both classes satisfy the commonality requirement of Rule 23(a)(2). Common questions of law and fact will predominate over any individual issues.

143. Common questions of fact for both the Children's Class and the Parents' Class include, but are not limited to:

- a. Why does New Jersey not obtain parental consent to retain the residual blood from the newborn screening program?
- b. How is New Jersey using the residual blood from the newborn screening program?
- c. What third parties has New Jersey given residual blood from the newborn screening program to?
- d. Does New Jersey make a profit from selling residual blood from the newborn screening program?
- e. Where does New Jersey store the residual newborn blood?
- f. Who is allowed access to the blood retained from the newborn screening program?
- g. How is New Jersey storing the blood?
- h. Why did New Jersey keep the blood for 23 years?

- i. Why does New Jersey keep the blood for any length of time post-testing?
- j. What justification, if any, does New Jersey have to stockpile the residual blood from the newborn screening program?
- k. Why does New Jersey not use less restrictive means, many of which other states use, to achieve the same goals or justifications for retention?

144. Common questions of law for the Children’s Class include, but are not limited to:

- a. Whether the retention of blood from the newborn screening program, after the initial testing is completed, constitutes a “continued seizure” that requires a new justification for New Jersey to keep the blood.
- b. Whether the retention of blood from the newborn screening program, without informed consent, a warrant, or a valid warrant exception violates the Fourth Amendment.

- c. Whether notice and the ability to request Defendants to end the continued seizure of the blood—i.e., to “opt-out”—constitutes voluntary consent under the Fourth Amendment.
- d. Whether voluntary consent under the Fourth Amendment requires Defendants to ask parents to “opt-in” to the continued seizure of the blood before Defendants retain the blood for any length of time after the newborn screening testing is complete.
- e. At what time—e.g., in the hospital, during a prenatal visit, or at some other time—do Defendants need to obtain consent from parents for that consent to be considered informed and voluntary.

145. Common questions of law for the Parents’ Class include, but are not limited to:

- a. Whether parents have the fundamental right to raise their children without undue state interference.

- b. Whether parents have the fundamental right to direct the care, custody, and control of their children.
- c. Whether parents have the fundamental right to direct the medical care of their children.
- d. Whether the retention of the blood from the newborn screening program, without obtaining consent from the parents or legal guardians to do so, violates the substantive due process rights of parents under the Fourteenth Amendment.

146. Under Rule 23(a)(3), the attributes of Named Plaintiffs are typical of the claims of the respective class members in both the Children's Class and Parents' Class. In fact, the claims, facts, and injuries are identical. New Jersey, under the same policy or practice: (a) unlawfully retained blood from Plaintiffs J.L., B.L., and C.J. and every person in the Children's Class, and (b) violated the same fundamental rights of Plaintiffs Hannah, Erica, and Jeremiah and every parent or legal guardian in the Parents' Class.

147. Named Plaintiffs, like all class members, have an interest in obtaining declaratory and injunctive relief that will require New Jersey to either (a) obtain voluntary, informed consent to keep the blood spots, or (b) return or destroy the blood spots. There is nothing materially different about the relief Named Plaintiffs seek on their own behalf and the relief they seek for members of the Children's Class and Parents' Class.

148. Named Plaintiffs will fairly and adequately represent both the Children's Class and Parents' Class, satisfying Rule 23(a)(4). Named Plaintiffs are represented by Robert Frommer, Brian Morris, and Christen Hebert at the Institute for Justice and by CJ Griffin of Pashman Stein Walder Hayden, P.C.

149. The Institute for Justice is a nonprofit, public-interest law firm that, since its founding in 1991, has successfully litigated constitutional issues nationwide. The Institute for Justice also has extensive experience litigating civil rights class actions raising claims under the Fourth and Fourteenth Amendments around the country, including in Philadelphia, Pennsylvania; Seattle, Washington; Pagedale,

Missouri; Brookside, Alabama; New York, New York; Los Angeles, California; and Chicago, Illinois.

150. The classes will also be represented by CJ Griffin of Pashman Stein Walder Hayden, P.C., who has decades of experience litigating in state and federal courts in New Jersey. CJ is the director of Pashman Stein's Public Interest Center and even has experience litigating the unauthorized use of residual baby blood against New Jersey.

151. As a result, both classes satisfy Rule 23(a)(1)-(4).

152. Both classes also meet the requirement of, and are brought in accordance with, Rule 23(b)(2) of the Federal Rules of Civil Procedure. By keeping blood from the newborn screening program absent parental consent, New Jersey has acted, or refused to act, on grounds generally applicable to members of both the Children's Class and the Parents' Class.

153. Also, insofar as a Rule 23(b)(2) class must be ascertainable, this action satisfies that requirement for both the Children's Class and the Parents' Class. For instance, records within

New Jersey's custody or control would identify members of both classes in a manageable process requiring little, if any, individual factual inquiry.

154. Lastly, to the extent that the Court reads a cohesiveness requirement into Rule 23(b)(2), both classes satisfy that element. Here, there are no individual factual issues that prevent these claims from proceeding on a class-wide basis.

155. The classes are entitled to the requested declaratory and injunctive relief. Thus, a class action is an appropriate method for adjudication of this case under Rule 23(b)(2).

CONSTITUTIONAL VIOLATIONS

Count I

42 U.S.C. § 1983—Fourth Amendment

**(Unlawful Seizure Claim of Plaintiffs J.L. and B.L.,
by next friend Hannah Lovaglio, and Plaintiff C.J., by next
friends Erica and Jeremiah Jedynak, for themselves
and those similarly situated)**

156. Plaintiff Children reallege and incorporate by reference the allegations in paragraphs 1–155 as if fully stated here.

157. The Fourth Amendment to the United States Constitution provides that “[t]he right of the people to be secure in their persons, houses, papers, and effects, against unreasonable searches and seizures, shall not be violated[.]”

158. The right of the people to be secure in their persons includes property and privacy interests in the possession of their blood and genetic information.

159. The Fourth Amendment is incorporated against the states through the Fourteenth Amendment to the United States Constitution.

160. Warrantless searches and seizures are per se unreasonable unless one of the narrow exceptions to the warrant requirement applies.

161. The initial drawing and collection of baby blood through the newborn screening program is a seizure under the Fourth Amendment.

162. New Jersey's purpose for the initial drawing and collection of baby blood, and thus, the initial seizure, is to test for 62 diseases.

163. New Jersey has no property interest in the blood collected for the newborn screening program. Instead, Plaintiff Children, via their parents, maintain their property and privacy interests in the blood.

164. The retention of the baby blood following testing is a continuing seizure within the meaning of the Fourth Amendment.

165. If a person or property has been seized, and the justification for that seizure has ended, the government must either:

- a. End the seizure and return the property, or
- b. Secure a new justification to continue the seizure.

166. Once New Jersey completes the testing on the baby blood, which takes one to two weeks, the justification for initially collecting the baby blood has ended.

167. More specifically, once New Jersey completes the newborn screening tests, the justification for the initial seizure of the blood—i.e., the health of the baby—has run its course.

168. New Jersey does not end its seizure of the baby blood once the testing is complete.

169. New Jersey does not return the baby blood once the testing is complete.

170. New Jersey does not secure a new justification for the continued seizure of the baby blood once the testing is complete.

171. New Jersey has no lawful justification for its continuing seizure of blood from the newborn screening program.

172. Without a new lawful justification to keep and stockpile the baby blood, New Jersey's continuing seizure violates the Fourth Amendment.

173. No exception to the Fourth Amendment's warrant requirement applies to New Jersey's retention of blood spots after the newborn screening testing is completed.

174. As a result, New Jersey's retention of baby blood for 2 years, 10 years, 23 years, or any amount of time post-testing, violates the Fourth Amendment to the United States Constitution.

175. Plaintiffs J.L. and B.L., by next friend Hannah Lovaglio, Plaintiff C.J., by next friends Erica and Jeremiah Jedynak, and the Children's Class are entitled to declaratory relief stating that retaining blood from the newborn screening program absent voluntary, informed consent violates the Fourth Amendment.

176. Plaintiffs J.L. and B.L., by next friend Hannah Lovaglio, Plaintiff C.J., by next friends Erica and Jeremiah Jedynak, and the Children's Class are also entitled to injunctive relief.

177. The Court should permanently enjoin New Jersey from retaining any blood spots absent voluntary, informed consent. To that end, the Court should require that, within a year of judgment, New Jersey must either:

- a. Obtain voluntary, informed consent to continue retaining each blood spot for specific disclosed purposes;

- b. Return each blood spot to the person from whom that blood was drawn or to their parent or legal guardian, if that person is below the age of eighteen (18) years; or
- c. Destroy the blood spot.

178. The Court should also permanently enjoin Defendants from retaining blood from the newborn screening program after testing is completed absent voluntary, informed consent.

179. To that end, moving forward, this Court should order New Jersey to either:

- a. Obtain voluntary, informed consent from the parent or legal guardian, meaning that parents are informed of the specific uses that the blood can be used for, before New Jersey retains any blood spot after the newborn screening tests are completed, and the parents voluntarily opt-in to the retention of the blood;
- b. Return all blood spots for which New Jersey does not first obtain voluntary, informed consent to retain the

blood for specified uses once the newborn screening tests are completed; or

- c. Destroy all blood spots for which New Jersey does not obtain voluntary, informed consent to retain the blood for specified uses once the newborn screening tests are completed.

180. Unless Plaintiffs J.L. and B.L., by next friend Hannah Lovaglio, Plaintiff C.J., by next friends Erica and Jeremiah Jedynak, and the Children's Class obtain the declaratory and injunctive relief requested, they will suffer continuing and irreparable harm.

Count II

42 U.S.C. § 1983—Fourteenth Amendment

(Substantive Due Process Claim of Plaintiffs Hannah Lovaglio, Erica Jedynak, and Jeremiah Jedynak, for themselves and those similarly situated)

181. Plaintiff Parents reallege and incorporate by reference the allegations in paragraphs 1–155 as if fully stated here.

182. The due process guarantee of the Fourteenth Amendment to the United States Constitution provides that no state

shall “deprive any person of life, liberty, or property, without due process of law[.]”

183. The Due Process Clause protects against state infringement of, among other things, those fundamental rights and liberties that are deeply rooted in our Nation’s history and traditions or are implicit in the concept of ordered liberty. State action that infringes on fundamental rights is reviewed under strict judicial scrutiny.

184. Plaintiff Parents have a fundamental due process right to raise their children without undue state interference.

185. As part of that right, parents have the fundamental due process right to direct the care, custody, and control of their children.

186. In *Troxel v. Granville*, 530 U.S. 57, 66 (2000) (plurality op.), the Supreme Court noted that parents’ right to direct “the care, custody, and control of their children” is fundamental. Indeed, the Court recognized that the right to make decisions about raising one’s children “is perhaps the oldest of the fundamental liberty interests recognized by [the Supreme] Court” and is “established beyond debate as an enduring American tradition.” *Id.* at 65–66.

187. What’s more, the parental right over the “care, custody, and control of their children” includes the right to make medical decisions for their children. The Third Circuit has explicitly said as much. *See Gruenke v. Seip*, 225 F.3d 290, 306–07 (3d Cir. 2000) (recognizing that a public school violated substantive due process when it pressured a student into taking a pregnancy test absent her mother’s knowledge or consent).

188. Here, after the newborn testing is completed, there is a choice about whether to retain a child’s blood for any amount of time post-testing.

189. Defendants, however, have taken that choice away from every parent in New Jersey.

190. Instead, Defendants are making that choice *in lieu of* parents when Defendants automatically retain the blood of every child after the testing is complete.

191. In doing so, Defendants strip parents of their fundamental rights without a compelling reason to do so.

192. And Defendants have unilaterally decided what *they think* is in the best interest of New Jersey children.

193. New Jersey's stockpiling of blood from the newborn screening program absent voluntary, informed consent violates Plaintiff Parents' fundamental right to raise their children without undue state interference.

194. New Jersey's stockpiling of blood from the newborn screening program absent voluntary, informed consent violates Plaintiff Parents' fundamental rights to make decisions about the care, custody, and control of their children.

195. New Jersey's stockpiling of blood from the newborn screening program absent voluntary, informed consent violates Plaintiff Parents' fundamental right to make medical decisions for their children.

196. There is no compelling reason to allow New Jersey to stockpile blood from the newborn screening program without obtaining voluntary, informed consent.

197. Not only does New Jersey's stockpiling of blood from the newborn screening program lack a compelling interest, it is not narrowly tailored to serve any government interest.

198. For instance, a simple and less-restrictive alternative exists: Simply obtain voluntary, informed consent to keep the baby blood for specific disclosed purposes.

199. Unless Plaintiff Parents Hannah Lovaglio, Erica Jedynak and Jeremiah Jedynak, along with the Parents' Class, obtain the declaratory and injunctive relief requested, they will suffer continuing and irreparable harm.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs request relief as follows:

- A. An entry of judgment holding Defendants liable for their unconstitutional conduct;
- B. Certification of both classes under Rule 23(b)(2);
- C. Appointment of Named Plaintiffs as representatives of their respective classes; and

D. Appointment of the Institute for Justice as class counsel, and appointment of CJ Griffin as local class counsel.

E. A judgment declaring, on a class-wide basis, that Defendants' retention of blood from the newborn screening program without first obtaining voluntary, informed consent violates the Fourth Amendment;

F. A judgment declaring, on a class-wide basis, that Defendants' retention of blood from the newborn screening program without first obtaining voluntary, informed consent violates the Fourteenth Amendment;

G. An injunction, as described in paragraph 177, that permanently enjoins Defendants from keeping any blood spots absent voluntary, informed consent;

H. An injunction, as described in paragraph 179, that permanently enjoins Defendants from retaining and stockpiling blood spots from the newborn screening program after the testing is completed absent voluntary, informed consent.

I. An award of reasonable attorneys' fees and costs; and

J. Such other relief as this Court deems appropriate.

LOCAL CIVIL RULE 11.2 CERTIFICATION

Plaintiffs, by their undersigned counsel, certify that to the best of their knowledge and belief, the matter in controversy is not the subject of any other action pending in any court or of a pending arbitration or administrative proceeding in this District.

Dated: August 2, 2024.

Respectfully submitted,

/s/ CJ Griffin

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