

UNITED STATES DISTRICT COURT
WESTERN DISTRICT OF TEXAS
SAN ANTONIO DIVISION

FILED

MAR 12 2009

CLERK, U.S. DISTRICT COURT
WESTERN DISTRICT OF TEXAS
BY
DEPUTY CLERK

ANDREA BELENO, on behalf of her infant son and on behalf of the class similarly situated,

GEOFFREY N. COURTNEY, on behalf of two children of his and on behalf of the class similarly situated,

MARYANN OVERATH, on behalf of two minor children of hers,

KEITH A. TAYLOR, on behalf of his infant daughter, and

NANCY PACHECO,

Plaintiffs

v.

TEXAS DEPARTMENT OF STATE HEALTH SERVICES,

DAVID L. LAKEY, M.D., in His Official Capacity as Commissioner of the Texas Department of State Health Services,

TEXAS A&M UNIVERSITY,

NANCY W. DICKEY, M.D., in Her Official Capacity as President, Texas A&M Health Science Center & Vice Chancellor for Health Affairs, and

RODERICK E. McCALLUM, in His Official Capacity as Interim Dean, Texas A&M Health Science Center School of Rural Public Health

Defendants

CIVIL ACTION

NO. _____

SA09CA0188 **FB**

COMPLAINT

Plaintiffs complain that Defendants have unlawfully and deceptively collected blood samples from their children at time of birth and stored those samples indefinitely for undisclosed research purposes, without Plaintiffs' knowledge or consent, and would show:

STATEMENT OF CLAIM

1. Plaintiffs bring this civil action for declaratory and injunctive relief on behalf of themselves, their infant children, and the class, alleging discriminatory and unlawful deprivation of their children's constitutional rights by Defendants (and of the class) under color of law and in violation of the Fourth and Fourteenth Amendments to the U.S. Constitution. Plaintiffs also bring forward supplemental claims under Texas constitutional law and common law privacy.

JURISDICTION AND VENUE

2. This Court has jurisdiction over Plaintiffs' federal claims, pursuant to Article III of the United States Constitution and 28 U.S.C. § 1331 and over their state claims, pursuant to 28 U.S.C. §§ 1332 and 1367.

3. This Court is the proper venue, pursuant to 28 U.S.C. § 1391, because most of the events complained of occurred within this Court's jurisdiction. Plaintiff Geoffrey Courtney resides in Bexar County. Plaintiffs Andrea Beleno and Maryann Overath are residents of Travis County. Plaintiff Keith Taylor lives in Harris County. Defendants Texas Department of State Health Services (TDSHS) and Dr. David Lakey have their principal office in Travis County.

PARTIES

Plaintiffs

4. Plaintiff Andrea Beleno is a resident of Austin, Texas, and the mother of an infant, born on November 4, 2008.

5. Plaintiff Geoffrey Courtney resides in San Antonio, Texas, and is the father of children born December 12, 2003 and May 31, 2007 respectively.

6. Plaintiff Maryann Overath lives in Austin, Texas, and is the mother of children born December 23, 1993 and December 6, 1998 respectively.

7. Plaintiff Keith Taylor is a resident of Houston, Texas, and the father of an infant daughter, born January 10, 2009.

8. Plaintiff Nancy Pacheco lives in Austin, and is expecting her first child in August 2009. She participates in the case for prospective relief only, although, for convenience, she is included in "Plaintiffs" generally.

Defendants

9. Defendant David L. Lakey, M.D., is sued in his official capacity as Commissioner of the Texas Department of State Health Services (TDSHS) and, together with the Department, may be served process at the TDSHS offices, 1100 West 49th Street, Austin, TX 78756.

10. Defendant Nancy W. Dickey, M.D., is sued in her official capacity as President of the Texas A&M Health Science Center & Vice Chancellor for Health Affairs and may be served with process at the Office of the President, the Texas A&M University System Health Science Center, 301 Tarrow, 7th Floor, College Station, TX 77840-7896. Defendant Texas A&M may also be served by serving her as its Vice Chancellor for Health Affairs.

11. Defendant Roderick E. McCallum, is sued in his official capacity as Interim Dean, Texas A&M Health Science Center School of Rural Public Health and may be served with process at the Texas A&M University System Health Science Center, address above.

12. In all actions described herein, Defendants were acting under color of law. At all relevant times, Defendants were charged with, responsible, for upholding the Constitutions and laws of the United States and Texas.

STATEMENT OF FACTS

13. Since 2002, Defendants have routinely and unlawfully collected blood samples from all babies in Texas at time of birth and stored those samples or "spots" indefinitely at the Texas A&M Health Science Center School of Rural Public Health for purposes of undisclosed research

unrelated to the purposes for which the infants' blood was originally drawn, without the knowledge or consent of the infants' parents. And Defendants continue to do so.

14. Although Defendants claim they do this for research purposes, they have never disclosed specifically the purposes or methodologies of such research other than that they are unrelated to the purposes for which the infants' blood was originally drawn. Nor is there any compelling state justification for such secretive and non-consensual activity.

15. Defendants, without any authority or legal justification, have added this practice onto the state's 44-year-old mandated newborn screening program in which hospitals, birthing centers, and midwives draw blood from a baby's heel — no parental consent is required — so the state can test for a variety of birth defects. Babies, who show detectable disorders, often can be treated early to prevent disabling disorders from developing.

16. Plaintiffs do not object to the state's mandated newborn screening program so long as safeguards are in place to destroy an infant's samples within a reasonable period of time. They object to Defendants expropriating an infant's blood sample indefinitely, without their knowledge or consent, effectively making it their property for undisclosed non-consensual purposes, unrelated to the purposes for which the infants' blood was originally drawn. .

17. Moreover, since the blood spots contain deeply private medical and genetic information, Plaintiffs are concerned about the potential for misuse of that information and fear the possibility of discrimination against their children and perhaps even relatives through the use of such blood samples and research activity thereon.

18. Under Defendants' current policy and practice, researchers can use the infants' samples, which consist of five blood spots on a card, for cancer research, lab equipment calibration, and other undisclosed matters indefinitely, without the knowledge or consent of their parents, which are unrelated to the purposes for which the infants' blood was originally drawn.

19. Not only does this violate the law, but it violates standard, mandatory medical research protocols of first obtaining informed consent from subjects before they are studied, using a method that explains all the privacy facets of the study. For example, the appropriate standards and protocols with regard to minor children in this instance are set out in 45 CFR §§46.116, 46.408, regulations promulgated by the U.S. Department of Health and Human Services, and include providing, among other things:

- (a) A description of the research's purpose and procedure;
- (b) Disclosure of privacy implications of the research;
- (c) Whom to call if questions arise about the research;
- (d) Parental consent; and,
- (e) A statement of no reprisals for declining to participate in the research

21. Defendants observe no accepted professional protocols whatsoever in this regard. Nor have they disclosed what kind of financial interests or transactions are involved, such as taxpayer expense or whether the samples are sold.

21. Prior to 2002, Defendants engaged in the same practice, but claim they kept the infant blood spots for a period of limited duration. Plaintiff Maryann Overath had two children born prior to 2002, but she has no assurance or confidence that Defendants have actually destroyed her children's blood sample. Nor does she have any idea whatever what kind of research was performed on her sons' blood samples and spots.

FIRST CAUSE OF ACTION

FEDERAL AND STATE EARCH AND SEIZURE PROTECTIONS

22. Defendants' actions, stated above, violated the rights of Plaintiffs' children and of the class under the Fourth Amendment to the U.S. Constitution and Article I, Section 9 of Texas Constitution, and continue to do so.

23. Defendants' actions, done under color of law and official authority, intentionally, and with complete, deliberate, conscious and callous indifference to the constitutional rights of Plaintiffs' children and of the class, deprived them of their right to be free from unlawful search and seizure, and continue to do so.

SECOND CAUSE OF ACTION

FEDERAL LIBERTY AND PRIVACY PROTECTIONS

24. Defendants' actions, stated above, violated the rights of Plaintiffs' children and of the class under the Fourteenth Amendment to the U.S. Constitution, and continue to do so.

25. Defendants' actions, done under color of law and official authority, intentionally, and with complete, deliberate, conscious and callous indifference to the constitutional rights of Plaintiffs' children and of the class, deprived them of their fundamental federal liberty and privacy interests, and continue to do so.

THIRD CAUSE OF ACTION

TEXAS FUNDAMENTAL RIGHT OF PRIVACY

26. Defendants' actions, stated above, violated the fundamental privacy rights of Plaintiffs' children and of the class under the Bill of Rights to the Texas Constitution and under the Texas common law, and continue to do so.

CLASS ACTION

27. Pursuant to Federal Rules of Civil Procedure 23(a) and (b), Plaintiffs Andrea Beleno and Geoffrey Courtney brings this action for all other persons similarly situated whose joinder in this action is impracticable because the class is so numerous. The anticipated number of class members is in the millions since there are approximately 370,000 live births in Texas annually. Indeed, Defendants have stored 4.2 million samples since July 2002.

28. There are questions of law or fact common to the members of the class that predominate over questions of law or fact affecting only individual members. The questions of law or fact common to all members of the class are whether Defendants' have violated the federal and Texas constitutional rights of the class and their Texas common law right to privacy.

29. The claims of Plaintiffs Beleno and Courtney are typical of the class and representative of all persons in the class who were injured by Defendants' actions, and will be so injured in the future.

30. The maintenance of this action as a class action is superior to other available methods of adjudication in promoting the convenient administration of justice. Plaintiffs do not seek damages for the class.

31. Plaintiffs Beleno and Courtney and their counsel will fairly and adequately protect the interests of the other class members. Plaintiffs' counsel is capable of zealously representing class interests and is qualified to litigate this type of action. Plaintiffs Beleno and Courtney and their counsel will adequately assert and support the legal claims that form the basis of this action. Plaintiffs and the class will benefit equally by virtue of this action, if the Court recognizes and vindicates their federal and state rights.

32. This class action may be properly maintained under Federal Rule of Civil Procedure 23(b)(2) because Defendants' conduct, pursuant to their procedures, policies, and/or practices, denied Plaintiffs' children and the class members their constitutional and common law rights and final declaratory relief will settle the legality of Defendants' challenged procedures, policies, and actions for the class as a whole.

ATTORNEYS' FEES

33. Plaintiffs are entitled to recover attorneys' fees and costs, pursuant to 42 U.S.C. §1988.

DECLARATORY RELIEF

34. This suit involves an actual controversy within the Court's jurisdiction, and the Court may declare the rights of Plaintiffs and the class under the Constitutions and laws of the United States and Texas, and grant such necessary and proper relief.

INJUNCTIVE RELIEF

35. Plaintiffs' claim for injunctive relief is authorized by Federal Rule of Civil Procedure 65 and by the general legal and equitable powers of this Court.

36. Because Plaintiffs and class members will continue to suffer harm due to Defendants' disregard of their fundamental federal and state rights, injunctive relief is necessary to prevent Defendants from continuing to collect and/or store blood samples and spots from newborn babies without informed parental consent.

37. Plaintiffs and the class will suffer irreparable harm, if injunctive relief is not granted.

38. There are no adequate, measurable damages available to Plaintiffs and the class for the deprivation of their fundamental rights in this case, making injunctive relief necessary.

39. Plaintiffs and the class seek injunctive relief, commanding Defendants to stop collecting blood samples and spots from newborn infants and keeping such indefinitely without informed parental consent and further commanding Defendants to destroy all blood samples and spots of Plaintiffs' children and those of the class, which Defendants have gathered without informed parental consent and guarantee to the Court within times periods prescribed by the Court that they have done so. Plaintiffs also ask the Court to compel Defendants to disclose for what purpose they used the blood samples and spots of Plaintiffs' children and of the class and disclose all financial transactions

40. Plaintiffs do not object to the state's mandated newborn screening program so long as safeguards are in place to destroy an infant's samples within a reasonable period of time.

PRAYER FOR RELIEF

Therefore, Plaintiffs respectfully prays that this Court:

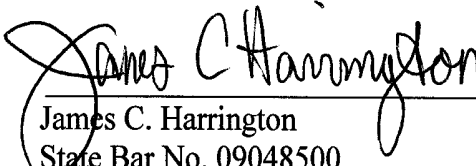
- A. Enter declaratory judgment for the Plaintiff individuals that:
 1. Acting under authority of law, Defendants intentionally, and with complete and deliberate indifference to the rights of Plaintiffs' children, unlawfully deprived them of their right to be free from unlawful search and seizure, guaranteed by the Fourth Amendment to the United States Constitution and Article I, Section 9 on the Texas Constitution; and,
 2. Acting under authority of law, Defendants intentionally, and with complete and deliberate indifference to the rights of Plaintiffs' children, unlawfully deprived them of their liberty and privacy interests, guaranteed by the Fourteenth Amendment to the U.S. Constitution and by the Texas Constitution and Texas common law;
- B. Issue an injunction, commanding Defendants to forthwith destroy all blood samples and spots of Plaintiffs' children, which Defendants have gathered and stored indefinitely without informed parental consent and guarantee to the Court within ten days of the order that they have done so;
- C. Issue an injunction, commanding Defendants to advise Plaintiffs for what purposes Defendants used the blood samples and spots of Plaintiffs' children and disclose all financial transactions involved with the use of such samples and blood, within ten days of the order;
- D. Certify this action as a class action, and thereafter:
 1. Enter the same declaratory relief as to class, as prayed for above for the Plaintiff individuals;
 2. Issue an injunction, commanding Defendants to stop collecting blood samples and spots from newborn infants and keeping such indefinitely without informed parental consent;
 3. Issue an injunction, commanding Defendants to forthwith destroy all blood samples and spots gathered since 2002 without informed parental consent or otherwise secure informed consent from affected parents to maintain such blood samples and spots, and guarantee to the Court with ninety days of the order that they have done so;
 4. Issue an injunction, establishing a procedure by which Defendants re-acquire informed consent from those children whose parents give consent, when such child reaches the age of 18 and becomes an adult, or otherwise destroy such blood samples and spots, and guarantee to the Court within thirty days of the

order that they have established such a procedure; and,

5. Issue an injunction, commanding Defendants to advise each class member for what purposes Defendants used the blood samples and spots of the class member and disclose all financial transactions involved with the use of such samples and blood, within ninety days of the order;
- H. Order Defendant to pay Plaintiff's attorneys' fees and costs; and,
- I. Grant all other and additional relief to which Plaintiffs may be entitled in this action, at law or in equity.

Dated: March 12, 2009

Respectfully submitted,



James C. Harrington
State Bar No. 09048500

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