

Joel Wu

Legal and ethical issues in storing and conducting research with residual blood samples collected through state legislated mandatory newborn screening programs.

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Section I: Introduction

Nearly every child born in the United States is tested for a variety of genetic diseases shortly after birth. This practice of screening newborns for genetic illnesses began in the early 1960's with the Guthrie Bacterial Inhibition Assay, a test for phenylketonuria.¹ Forty years ago, the practice of newborn screening was a new and untested practice. Today, an estimated four million infants are screened annually as part of state legislated mandatory newborn screening programs.² Newborn screening has become "...a part of common practice and accepted public policy..."³

Advances in science have led to the increased complexity and scope of newborn screening programs. Every new gene or disease that is identified leads to another potential test; each new technology that is invented leads to another potential intervention. In 1962, Massachusetts offered one optional test for one disease.⁴ As of July 2007, the California Newborn Screening program uses screening technology capable of screening for 72 disorders.⁵ Each new piece of technology presents not only potential benefits, but also potential harms.

¹ *Serving the Family From Birth to the Medical Home, Newborn Screening: A Blueprint for the Future, A call for a National Agenda on State Newborn Screening Programs*. 106(2) PEDIATRICS 389-427 (2000), <http://pediatrics.aappublications.org/cgi/reprint/106/2/S1/386> [hereinafter *Blueprint*].

² *Id.*

³ Alexander M. Capron, *Which Ills to Bear? Reevaluating the Threat of Modern Genetics*, 39 EMORY LJ 665, 689 (1990).

⁴ *Blueprint*, *supra* note 1, at 389. (Massachusetts was the first state to offer optional newborn screening for PKU).

⁵ *Important Information for Parents about the Newborn Screening Test*, California Department of Health Services, Genetic Disease Branch, Newborn Screening Section, June 2005, [cited 2007, November, 24], <http://www.dhs.ca.gov/pcfh/gdb/html/nbs/addingdisorders.htm> (listing 72 different disorders that "... can be detected as of mid-2005." The notice clarifies by stating, "Due to biological variability of newborns and differences in detection rates for the various disorders in the newborn period, the [California] Newborn Screening Program will not identify all newborns with these conditions. While a positive screening result identifies newborns at an increased risk to justify a diagnostic work-up, a negative screening disorder does

The developments of powerful computers and DNA storage, amplification, and analysis technologies have added a new dimension to newborn screening programs. The blood samples collected as a part of newborn screening programs may be used in large population-based genetic studies. Many states have begun to store blood samples collected as a part of mandatory state newborn screening programs, and many of these states are using these samples in epidemiological and public health research.

This note argues that the practices of storing and conducting research with residual dried blood samples collected as a part of mandatory state newborn screening programs, is not legally justifiable because the practice is not a proper exercise of the states' *parens patriae* and police powers. In section II, this note briefly retraces the history of newborn screening and how newborn screening became a function of the state. In section III this note reviews the current state of newborn screening programs with a specific focus on storage and research practices. In section IV, this note outlines the traditional legal framework supporting state sponsored and controlled newborn screening programs. In section V, this note argues that storage and research using blood samples collected as part of newborn screening cannot be justified under the current, traditional legal framework. In section VI, this note proposes an ethically and legally acceptable solution to the public health interest of conducting large-scale population-based public health genetic research.

Section II: The History of Newborn Screening

not rule out the possibility of a disorder. Parents should remain watchful for any sign or symptoms of these disorders in their child and consult a physician.”).

In the early 1960's, Dr. Robert Guthrie developed a screening test for phenylketonuria ("PKU").⁶ PKU is a rare metabolic disease that results in abnormally high levels of the amino acid phenylalanine in the affected individual's blood and tissues.⁷ Estimates for the incidence of PKU in the United States vary from 1 in 13,500 newborns to 1 in 19,000 infants.⁸ Untreated PKU usually results in mental retardation, microcephaly, delayed speech, seizures, behavioral abnormalities as well as other symptoms.⁹ Early detection and implementation of a phenylalanine-restricted diet reduces the morbidities associated with PKU.¹⁰ Research has shown that as time passes before appropriate intervention occurs, average intelligence scores decrease.¹¹ Without an early screening test, PKU is usually diagnosed after 6 months, the point at which irreversible developmental delays have begun to manifest.¹²

Guthrie's screening test involved two basic steps: collection and testing. The collection step involves placing a drop of a newborn's blood onto filter paper for storage and transport. The testing step involves placing a small piece of the blood-impregnated filter paper in a bacterial medium, which contains a phenylalanine-restricting chemical. If there is an excess amount of phenylalanine in the blood, the excess phenylalanine will allow bacteria to grow; if there is not enough phenylalanine, bacteria will not be able to grow.

⁶ Robert Guthrie & Ada Susi, *A simple phenylalanine method for detecting phenylketonuria in large populations of newborn infants*, 32 PEDIATRICS 338-343 (1963).

⁷ Celia I. Kaye et al., *Newborn Screening Fact Sheets*, 118 PEDIATRICS 934-963 (2006), available at <http://www.pediatrics.org/cgi/content/full/118/3/e934> [hereinafter Fact Sheets].

⁸ *Id.* at 956.

⁹ *Phenylketonuria: Screening and Management*, NIH Consensus Statement Online, 2000 October 16-18; [cited 2007, November, 24]; 17(3):1-27.

¹⁰ Fact Sheets, *supra* note 7, at e956-e957 (explaining children with PKU who receive appropriate intervention soon after a positive test have average intelligence scores, although their scores are lower when compared to parent and sibling intelligence scores).

¹¹ *Id.*

In 1962, the state of Massachusetts had implemented a voluntary newborn PKU screening program.¹³ At this point, the PKU test was optional, and was not a legislated state activity. Parents and physicians could request the PKU test for newborns at their discretion. There was no guidance as to who would have the authority and burden to implement the testing of newborns. Health professionals were slow to adopt the practice, in part because of concerns regarding the validity of the test and the efficacy of the intervention.¹⁴

At the same time, there was a growing concern that a failure to screen newborns would lead to high rates of mental retardation in children affected with PKU. Several groups worked together to increase the rates of PKU screening in newborns. The National Association of Retarded Children (“NARC”) (now The Arc US) proposed model legislation for the creation of mandatory public screening programs.¹⁵ The NARC also joined in with other groups, such as the March of Dimes, in supporting local lobbying efforts for the passage of legislation that would increase rates of PKU screening.¹⁶

Simultaneously, the Kennedy administration sponsored a public campaign in support of

¹² *Id.*

¹³ Diane B. Paul, *The History of Newborn Phenylketonuria Screening in the US*, app. 5, in PROMOTING SAFE AND EFFECTIVE GENETIC SCREENING IN THE UNITED STATES: FINAL REPORT OF THE TASK FORCE ON GENETIC TESTING, 137-160, (Neil A. Holtzman & Michael S. Watson eds, 1997) (explaining that the Massachusetts legislature formally passed law mandating newborn screening for PKU in 1963).

¹⁴ *Blueprint*, *supra* note 1, at 389, (explaining that the American Academy of Pediatrics did not initially support the practice of screening for PKU because of concerns regarding the sensitivity and specificity of the test, and concerns regarding the efficacy of interventions for PKU).

¹⁵ PRESIDENT’S COMM’N FOR THE STUDY OF ETHICAL PROBLEMS IN MED. AND BIOMEDICAL AND BEHAVIORAL RESEARCH, SCREENING AND COUNSELING FOR GENETIC CONDITIONS: A REPORT ON THE ETHICAL, SOCIAL, AND LEGAL IMPLICATIONS OF GENETIC SCREENING, COUNSELING AND EDUCATION PROGRAMS (1983).

¹⁶ *Blueprint*, *supra* note 1, at 389.

mandatory PKU screening.¹⁷ By 1973, 43 states had passed legislation mandating the screening of newborns for PKU.¹⁸

Section III: Newborn Screening Today

Today all 50 states have laws that require the screening of newborns.¹⁹ An estimated 4 million newborns are screened annually,²⁰ and an estimated 5.3 million blood samples are collected annually, through state legislated newborn screening programs.²¹ Newborn screening programs have become a major state function, providing testing, treatment, and follow-up for nearly every child born in this country. In 2001, the 50 states spent \$120 million dollars on newborn screening, with states paying \$20 to \$40 dollars per newborn.²²

The central purpose of newborn screening programs within each state is the same. In 2000, the National Task Force on Newborn Screening wrote, “Newborn screening in the United States is a public health program aimed at the early identification of conditions for which early and timely interventions can lead to the elimination or reduction of

¹⁷ *Id.* at 390 (explaining that the Presidential Advisory Commission on Retardation supported the efforts of the NARC and March of Dimes. The Presidential Advisory Commission on Retardation supported an advertising campaign promoting mandatory PKU screening).

¹⁸ *Id.*

¹⁹ UNITED STATES GENERAL ACCOUNTING OFFICE, REPORT TO CONGRESSIONAL REQUESTERS, GAO-03-449, NEWBORN SCREENING: CHARACTERISTICS OF STATE PROGRAMS (Mar. 2003), [hereinafter GAO Report], <http://www.gao.gov/new.items/d03449.pdf> (explaining that 50 states as well as Puerto Rico have laws which require newborn screening. All 50 states as well as Puerto Rico screen newborns for at least PKU and Congenital Hypothyroidism. 50 states screened for galactosemia, 44 states screened for sickle cell disease, and 32 states screen for congenital adrenal hyperplasia).

²⁰ Blueprint, *supra* note 1, at 389.

²¹ Bradford L. Therrell et al., *Status of Newborn Screening Programs in the United States*. 117 PEDIATRICS s212, s217 (2006), <http://www.pediatrics.org/cgi/content/full/117/S1/S212>, (5.3 million samples are collected because a number of states collect multiple samples for every newborn screened).

²² See GAO Report, *supra* note 18, at 3.

associated mortality, morbidity, and disabilities.”²³ However, the similarities in state newborn screening programs end there.

In 2003, the United States General Accounting Office conducted a survey of all the 50 states newborn screening programs, and found that state programs varied widely in their newborn screening policies and practices. States varied in the number and type of diseases screened. Most states screened for 8 disorders, but the number of disorders screened ranged from 4 to 36.²⁴ Every state requires newborn screening, but only Wyoming requires that the health care provider collecting the blood sample obtain consent; no other state requires consent prior to screening.²⁵ States varied in their policies regarding exemptions and confidentiality. Most states allow children to be exempted from screening for either religious reasons (33 states) or any reason (13 states.)²⁶ Five states do not allow a child to be exempted from screening for any reason.²⁷

States also varied in their policies regarding the confidentiality of information collected as part of the screening program. Over half the states have laws that indicate the information collected is confidential; however, many states also have exceptions to the confidentiality rule.²⁸ The most common exception permitting the release of information collected by newborn screening, is for use in research or statistical analysis. Of the 25

²³ Blueprint, *supra* note 1, at 389.

²⁴ GAO Report, *supra* note 18, at 8.

²⁵ *Id.* at 22.

²⁶ *Id.* at 22-23.

²⁷ *Id.* (explaining Arizona, Montana, Nebraska, South Dakota, and West Virginia do not all newborns to be exempted from screening for any reason).

²⁸ *Id.* at 24.

states that prohibit disclosure of genetic information without consent, 14 have an exception that permits disclosure for use in research.²⁹

A recent development in newborn screening has been the practice of storing and conducting research with residual blood spots collected through mandatory newborn screening programs. Many state programs store these samples and use them in research that may be either related to, or completely unrelated to, newborn screening. Investigators from within the state agencies, and from external institutions, have used blood samples from newborn screening programs in epidemiologic surveys of infectious disease,^{30, 31} population-based studies of pharmacologic and environmental exposures,^{32, 33} population based studies of birth defects, developmental disabilities and childhood cancers,^{34, 35} and population based genetic studies.³⁶

There is a great deal of inconsistency in state policy regarding the storage and use of residual blood samples. A study in 2006 reported that only 9 states have specific statutory

²⁹ *Id.* at 24-25 (explaining that the release of information collected through newborn screening programs is usually subject to several conditions, including requirements that the identify of the subjects is not revealed, and that researchers comply with applicable state and federal law.)

³⁰ Maria Barbi et al., *Use of Guthrie cards for the early diagnosis of neonatal herpes simplex virus disease*, 17 PEDIATR INFECT DIS 251-252 (1998).

³¹ Marta Gwinn et al., *Prevalence of HIV infection in childbearing women in the United States: Surveillance using newborn blood samples*. 265 JAMA 1704-1708 (1991).

³² VW Burse et al., *Preliminary investigation of the use of dried blood spots for the assessment of in utero exposure to environmental pollutants*. 61 Biochem Mol Med 236-239 (1997).

³³ CENTERS FOR DISEASE CONTROL AND PREVENTION. *POPULATION-BASED PREVALENCE OF PERINATAL EXPOSURE TO COCAINE, GEORGIA, 1994*. 45 MMWR 887-891 (1996).

³⁴ Karin B Nelson et al., *Neuropeptides and neurotrophins in neonatal blood of children with autism or mental retardation*. 49 ANN NEUROL 597-606 (2001).

³⁵ Judith Klotz et al., *Population-based retrieval of newborn dried blood spots for researching paediatric cancer susceptibility genes*. 20 PAED PERINATAL EPI 449-452 (2006).

³⁶ B Wilcken et al., *Geographical and ethnic variation of the 677C>T allele of 5,10 methyl-enetetrahydrofolate reductase (MTHFR): findings from over 7000 newborns from 16 areas world wide*. 40 J MED GEN 619-625 (2003).

requirements governing the retention of newborn screening information and specimens.³⁷ All other state programs “seem to be able to destroy or retain newborn screening samples and information as long as they are compliant with general record-retention and sample-storage laws...”³⁸ Thirty-seven programs have written policies regarding storage of samples, while 14 other states have no written policies regarding storage.³⁹ Twenty-three programs have policies governing the use of specimens, and 28 have no written usage policies.⁴⁰ Length of storage ranged from 24 programs storing samples for less than 6 months, to 8 programs that stored samples indefinitely.⁴¹

Another study in 2006 had similar findings. Of 49 states that responded to the investigator’s research, half of states stored residual blood samples for over 6 months, and more than 40% stored residual blood samples for longer than 12 months.⁴² When these programs stored samples, 74% of programs used the stored samples for evaluation of testing, 52% for clinical or forensic testing, 28% for epidemiologic studies.⁴³ Forty-one percent of the responding programs said they would consider participating in multistate epidemiologic studies by contributing unlinked blood samples they have collected through their newborn screening program.⁴⁴

³⁷ Therrell, *supra* note 21, at s219.

³⁸ *Id.*

³⁹ *Id.*

⁴⁰ *Id.*

⁴¹ *Id.*

⁴² Richard S. Olney et al., *Storage and Use of Residual Dried Blood Spots from State Newborn Screening Programs*, 148 J PEDIATRICS 618, 619 (2006).

⁴³ *Id.* at 619-620

⁴⁴ *Id.*

A study in 2002 reported that 70.6% of all state programs stored blood samples, and only 8.3% of those who stored did so without patient identifiers.⁴⁵ Forty-nine percent of those who stored blood samples aggregated data for research, and 16% of that data is publicly available.⁴⁶

Section IV: The law supporting newborn screening

The power of the states to mandate newborn screening is ultimately reserved to the states by the Constitution. The Constitution not only grants the government power, but also constrains the government's power so it cannot inappropriately limit individual rights. The Constitution does this by dividing the government's power between the three branches of the government, by dividing power between state and federal government, and by specifically limiting the power of the government over specific individual rights. The Constitution not only gives the government power to act to protect the health and safety of the community, the Constitution also limits the power of the government to restrict individual liberties.

The Constitution grants only limited power to the national government, and reserves all remaining power to each individual state. The 10th amendment states, "The powers not delegated to the United States by the Constitution, nor prohibited to the States, are reserved to the States respectively, or the people."⁴⁷ For the purposes of public health, the federal government is limited to the power to tax, to spend, and to regulate interstate

⁴⁵ Kenneth D. Mandl et al., *Newborn Screening Program Practices in the United States: Notification, Research, and Consent*, 109 PEDIATRICS 269, 271 (2002)

⁴⁶ *Id.*

⁴⁷ US CONST. amend. X.

commerce; the states hold all the remaining power.⁴⁸ As result, all newborn screening laws are state laws; there is no federal law that directly mandates or governs newborn screening.⁴⁹

Individual states hold two specific powers that “express the state’s inherent sovereignty to safeguard the community’s welfare;” 1) the police power and 2) the *parens patriae* power.⁵⁰

The police power is the expression of the government’s power to act to protect and promote the general welfare of the public. Lawrence Gostin defines the police power as “The inherent authority of the state to enact laws and promulgate regulations to protect, preserve, and promote the health, safety, morals, and general welfare of the people. To achieve these communal benefits, the state retains the power to restrict, within federal and state constitutional limits, private interests- personal interests in autonomy, privacy, association, and liberty as well as economic interests in freedom to contract and use property.”⁵¹ The police power is the power of the state to enact laws and restrict individual liberties for the public welfare. This enables the government to act to protect the interests of the community at large, common interests that are held by every member of the community.

⁴⁸ LAWRENCE O. GOSTIN, *PUBLIC HEALTH LAW*, 26 (2000).

⁴⁹ There is no federal law which directly mandates newborn screening, or mandates any specific tests or procedures. However, there is federal legislation that supports state newborn screening programs. For example, the Centers for Disease Control and Prevention and the U.S. Department of Health and Human Services offer monitoring and evaluation services to state newborn screening programs, and may propose recommendations to state programs on how to improve state newborn screening programs. States are not obligated to comply with federal recommendations; however, failure to meet certain standards may result in the denial of federal financial support. GAO report, *supra* note 18, at 3-8.

⁵⁰ Gostin, *supra* note 48, at 27.

The *parens patriae* power is the expression of the government's power to act to protect and promote the interests of individuals who are unable to protect and promote their own interests. Traditionally this includes minors and incompetent persons.⁵² This power allows states to make decisions for individuals who cannot make decisions for themselves. This allows the state to exercise power over an incompetent individual to protect that individual's interests. The standard for the exercise of this power is either a best interests standard, or a substituted judgment standard, meaning that either the government must act in the individual's best interest or consistent with what the individual would have wanted if they were capable of making a decision.⁵³ This exercise of power may result either in the loss of liberty or privacy rights by the individual in question, or in some cases such as in newborn screening, the rights of a parent to make decisions regarding their children.

Certain individual liberties are protected by the Bill of Rights, such as the right to free speech and the right to the free exercise of religion.⁵⁴ However, limitations on individual liberties are often necessary to promote the both public welfare and the welfare of minors and incompetents. Any limitation of an individual's constitutionally protected liberties by the state is constrained by Constitutional protections. The government may not restrict these liberties without first meeting Constitutional requirements for procedural and

⁵¹ *Id.* at 47-48.

⁵² *Id.*, at 52. (citing *Alfred L. Snapp & Son, Inc. v. Puerto Rico*, 458 U.S. 592, 600 (1982) (quoting J. Chitty, *Prerogatives of the Crown*, 155 (1820))). Gostin explains the original source of the *parens patriae* power lies in the Royal Prerogative of the Crown in England, which states "The King shall have the custody of the land of natural fools, taking the profits of them without waste or destruction, and shall find them their necessaries." "It was the job of the crown 'to take care of people legally unable, on account of mental incapacity, whether it proceeded from 1. nonage, 2. idiocy or 3. lunacy: to take proper care of themselves and their property.'")

⁵³ *Id.* at 52.

⁵⁴ US CONST. amend. I.

substantive due process.^{55, 56} Procedural due process requires, generally, that a person have notice and a hearing before a neutral decision maker prior to the loss of some constitutionally protected liberty interest.⁵⁷ Substantive due process requires the state to justify their action.⁵⁸ Depending on the nature of the civil right in question, different standards of constitutional review are used by the courts in determining whether a state action is justifiable. Rational basis review, the lowest standard, requires that the state action must be justified by a legitimate state interest, and that the action must be rationally related to that legitimate state interest.⁵⁹ Intermediate review requires that the state action must serve important government interests, and the state action must be substantially related to those interests.⁶⁰ Strict scrutiny, the highest level of review, requires that the state action be justified by a compelling government interest, and that the action be narrowly tailored to meet that interest.⁶¹

For the most part, state public health laws and actions have been reviewed under rational basis review.⁶² Actions justified as a proper exercise of state police power include mandatory vaccination,⁶³ isolation and quarantine,⁶⁴ as well as regulation of air and water,⁶⁵ standards for food and drinking water,⁶⁶ inspection of commercial and residential premises,⁶⁷ and sanitation laws generally.⁶⁸ The courts have found that these

⁵⁵ US CONST. amend. V.

⁵⁶ US CONST. amend. XIV.

⁵⁷ ERWIN CHEMERINSKY, CONSTITUTIONAL LAW: PRINCIPLES AND POLICIES 546 (Aspen Pub. 3rd ed. 2006).

⁵⁸ *Id.*

⁵⁹ *See generally*, Pennell v. City of San Jose, 485 U.S. 1 (1988).

⁶⁰ *See generally*, Craig v. Boren, 429 U.S. 190, 197 (1976).

⁶¹ *See generally*, Adarand Constructors v. Peña, 515 U.S. 200 (1995).

⁶² Gostin, *supra* note 48 at 77-78.

⁶³ *See generally*, Zucht v. King, 260 U.S. 174 (1922).

⁶⁴ *See generally*, Leisy v. Hardin, 135 U.S. 100 (1890).

⁶⁵ *See generally*, State *ex rel.* Corp. Comm'n v. Texas County Irrigation & Water Res. Ass'n, 818 P.2d 449 (Okla. 1991).

⁶⁶ *See generally*, Strandwitz v. Board of Dietics, 614 N.E. 2d 817, 824 (Ohio Ct. App. 1992).

⁶⁷ *See generally*, Givner v. State 124 A.2d 764, 774 (Md. 1956).

actions are rationally related to a legitimate government interest, and are therefore constitutional. These actions are properly justified under the police power because the failure of individuals to comply with certain standards results in potential harm to other members of the community.

In contrast, newborn screening programs are a state action more likely to be justified as an exercise of the states *parens patriae* power, and not the police power. First, newborn screening programs address genetic and metabolic disorders which are not communicable, and pose no risk to other members of the community.⁶⁹ The failure to participate in newborn screening poses risks only to the newborn, and not to the community at large.⁷⁰ Second, the subject of newborn screening programs are newborns, and the *parens patriae* power traditionally expresses the states interest in protecting minors. The government may seek to protect the health and life of newborns by requiring that they be screened for disease.

In the case of newborn screening, the rights of parents may be limited by the state when the state seeks to take action on behalf of the newborn that is inconsistent with the wishes of the newborn's parents. Courts have specifically upheld newborn screening programs as a Constitutional exercise of the states *parens patriae* power in two cases. Both cases

⁶⁸ See generally, 39 Am Jur 2d Health § 22 (1968).

⁶⁹ Ellen Wright Clayton, Screening and Treatment of Newborns 29 HOUS L REV 85:103, 127-128 (1992).

⁷⁰ *Id.* (explaining that failure to screen may impose costs on the community because unhealthy children absorb community health care resources, and therefore the community may have a cost-motivated interest in newborn screening. Studies have shown that newborn screening may reduce costs by preventing disease. Clayton asserts these studies are flawed in that they assume all children who are screened and test positive for disorders, receive adequate care, when often they do not. Furthermore, the costs spent in operating a newborn screening program takes money away from other potential public health interventions or public cost-saving measures. It is not clear that expanded or mandatory newborn screening programs are truly saving the community money. States must carefully evaluate the cost savings and diminishing returns of implementing and expanding newborn screening programs).

involve the state of Nebraska, where the state newborn screening laws do not allow for any exemptions from screening. In each case, parents challenged the newborn screening program, claiming that mandatory testing of their newborn violated their rights to exercise their religion and to parent their children.

In *Douglas County v. Anaya*,⁷¹ the Supreme Court of Nebraska upheld a newborn screening statute, Neb. Rev. Stat. §71-519 (2007)⁷², which required the screening of every child in Nebraska without any exceptions or exemptions. Josue and Mary Anaya, parents of a newborn born in Nebraska, challenged the constitutionality of the statute, arguing that the statute infringed on their right to freely exercise their religion, and on their fundamental right to parent their child.

Rose Anaya was born to the Anayas' in their home on July 11, 2003. There was no physician present at the birth. The Anayas' reported the birth of Rose to the Nebraska Department of Health and Human Services ("NDHHS") on July 17, 2003. NDHHS regulations at that time required that testing of newborns be completed within 48 hours of registration if the birth was not attended by a physician.⁷³ The Anayas' refused to submit Rose for screening, citing religious beliefs. The Anayas' believed that life is taken from a person when blood is removed from the body, and loss of blood may shorten the individual's life span.

On September 26, 2003, Douglas County filed a lawsuit seeking to compel the Anayas' to submit Rose for screening. In response, the Anayas' has filed a motion for judicial

⁷¹ *Douglas County v. Anaya* 694 N.W. 2d 601 (Neb. 2005).

⁷² NEB. REV. STAT. § 71-519 (2007).

exemption, arguing in part, that the statute violated the 14th amendment.⁷⁴ The district court held that that the state had a compelling interest in screening newborns for metabolic diseases, and ordered that the Anayas' submit Rose for screening.⁷⁵

The Anayas appealed to the Supreme Court of Nebraska. Their case was heard on March 25, 2005. On their appeal, the Anayas' argued that strict scrutiny should apply because the law infringes upon both their right to freely exercise their religion and their fundamental right to manage the affairs of their child.⁷⁶ The Anayas' argued that Section 71-519 fails to meet the requirements of the strict scrutiny standard because the state cannot show a compelling interest in screening Rose which justifies infringing on their rights.⁷⁷

The Supreme Court of Nebraska began its analysis by evaluating what the proper standard of constitutional review should be, based on the nature of the law and the civil rights involved. The court held that the proper standard of review is rational basis review because first because the Anayas' claim is not a proper hybrid rights claim,⁷⁸ and second because Section 71-519 is a law of neutral and general applicability.⁷⁹ ⁸⁰ Having

⁷³ *Anaya*, 694 NW 2d 601, 604 (Neb. 2005).

⁷⁴ *Id.*

⁷⁵ *Id.*

⁷⁶ *Id.*, at 604-605. The Anayas' argued that strict scrutiny should apply because they raise a free exercise claim along with another constitutional right. In *Employment Div. Ore. Dept. of Human Res. V. Smith*, 494 US 872, the US Supreme Court indicated that where a claim involves not only a free exercise claim, but also another constitutional claim such as freedom of speech or the right of parents to direct the education of their children, a "hybrid situation" may exist, and may require heightened or strict scrutiny. See also, MICHAEL W. MCCONNELL, *RELIGION AND THE CONSTITUTION*, 173-176, (2006).

⁷⁷ *Anaya*, 694 NW 2d 601, at 606.

⁷⁸ *Id.* ("We conclude that the Anayas' assertion of a hybrid rights claim does not implicate strict scrutiny review of §71-519. A party may not force the government to meet the strict scrutiny standard by merely asserting claims of violations of more than one constitutional right.")

⁷⁹ *Id.*

⁸⁰ The US Supreme Court held laws of "neutral and general applicability" do not need to be supported by a compelling interest to be found Constitutional. "In addressing the constitutional protection for free exercise

established the standard of review, the court went on to determine whether or not the law and the program passed rational basis review. The court considered evidence regarding the testing scheme and the diseases involved. The court found that, “Early diagnosis allows for prevention of death and disability in children.”⁸¹ Consequently, the court held, “The state has an interest in the health and welfare of all children born in Nebraska, and the purpose of section 71-159 is to protect such health and welfare. This is a rational basis for the law, and it is constitutional.”⁸²

Similarly, in *Spiering v. Heineman*⁸³, the US District Court for the District of Nebraska upheld the same statute for essentially the same reasons. Louise and Ray Spiering also challenged Section 71-519, arguing that the law unconstitutionally infringed on their right to freely exercise their religion and on their right to parent their child.

The Spierings’ believed in the teachings of Scientology, and subscribed to the teaching of “Silent Birth.” This teaching of Scientology maintains that parents should shield their newborns from pain during birth, and for seven days following birth. The Spierings’ believe that violation of this teaching may cause the child to suffer physical or mental injury, and contend that the collection of a blood sample is inconsistent with the Scientology teaching on Silent Birth. Regulations set forth by NDHHS require that a blood sample be collected from all newborns within 24 hours of birth when a physician

of religion, our cases establish the general proposition that a law that is neutral and of general applicability need not be justified by a compelling government interest even if the law has the incidental effect of burdening a particular religious practice.” *Church of Lukumi Babalu Aye, Inc. v. Hialeah* 508 US 520, 531 (US 1993).

⁸¹ *Anaya*, 694 NW 2d 601, at 608.

⁸² *Id.*

⁸³ *Spiering v. Heineman*, F. Supp. 2d 1129 (D. Neb. 2006).

attended the birth.⁸⁴ The regulations also indicate in circumstances where a infant is born without an attending physician present, the blood sample maybe collected 7 to 10 days after the birth.⁸⁵ Prior to the birth of their fourth child, the Spierings’ discussed this issue with their physician. Their physician indicated that he would not assist them in delaying the testing after the child’s birth. Subsequently, the Spierings’ filed a lawsuit in federal court, challenging the state’s mandatory newborn screening program.

Much like the Anayas, the Spierings argued that strict scrutiny should apply, and that Nebraska’s mandatory screening laws and regulations are unconstitutional because they fail to meet the requirements of strict scrutiny.⁸⁶ They argued that the proper standard of review should be strict scrutiny for two reasons. First, they argued that the regulatory exception allowing blood samples to be taken from newborns 7 to 10 days after birth in situations where a physician did not attend the birth amounted to a “secular exemption”.⁸⁷ ⁸⁸ Second, the Spierings’ argued that their claim presented a hybrid rights claim because it involves both the right to free religious exercise and the right to make decisions regarding their children.⁸⁹ ⁹⁰

⁸⁴ *Id.* at 1134-1135.

⁸⁵ *Id.*

⁸⁶ *Id.* at 1136.

⁸⁷ *Id.*

⁸⁸ A secular exemption implicates strict scrutiny, and occurs where the government exempts a secular activity that is inconsistent with a government interest while not exempting a similar religious activity that is inconsistent with the same government interest in the same way. A law is not a law of neutral and general applicability if there is an improper secular exemption. *See generally*, Church of Lukumi Babalu Aye, Inc. v. Hialeah 508 US 520 (US 1993); Fraternal Order of Police v. City of Newark 170 F.3d 359 (US 1999).

⁸⁹ *Spiering* F. Supp 2d 1129 at 1136.

⁹⁰ The Spierings’ also claimed that the state screening program amounts to an unreasonable search in seizure, in violation of the 4th amendment. The court rejects the argument, concluding “Put simply, (1) since parents are advised that the testing will be done, thus triggering an opportunity to object and temporarily prevent the testing (as was the case here and in Anaya), and (2) since Nebraska’s testing requirement is only enforced by court order following a hearing, no Fourth Amendment violation has been made out and none is threatened.” *Spiering v. Heineman*, F. Supp 2d 1129, 1142 (D..Neb. 2006).

The District Court began its analysis by evaluating what standard of review should apply. The court held that the proper standard of review is rational basis review because the law did not contain an improper secular exemption, and because the claim was not a proper hybrid rights claim.⁹¹ Having established the standard of review, the court went on to evaluate whether the law met the rational basis test. First, the court held that "...screening of newborns for metabolic diseases is justified by the government's legitimate interest in safeguarding the health of children."⁹² Second, the court held that "both the evidence in this case, and the scientific literature more generally, shows that there is a "fit" between the government's interest in safeguarding the health of children and Nebraska's newborn screening program."⁹³ The court gave 3 examples of this "fit." First, "Eminent national investigators have concluded that "the conditions best meeting all of the criteria [for determining the appropriateness of newborn testing] are MCAD⁹⁴, CH,⁹⁵ and PKU"⁹⁶ and Nebraska tests for these diseases."⁹⁷ Second, "All eight diseases screened for by Nebraska are among the diseases for which national experts believe newborn testing is appropriate."⁹⁸ Third, "Nebraska uses a 24-48 hour time frame for testing and that standard is consistent with national recommendations."⁹⁹ The court ultimately concluded

⁹¹ *Id.*

⁹² *Id.* at 1140.

⁹³ *Id.* at 1141.

⁹⁴ MCAD is the abbreviation for Medium-Chain Acyl-CoA Dehydrogenase deficiency, a metabolic disorder which has been found to be linked to sudden infant death syndrome and Reye syndrome. Fact Sheets, *supra* note 7 at e953-3956.

⁹⁵ CH is the abbreviation for Congenital Hypothyroidism, a hormone deficiency that is one of the most treatable causes of mental retardation. Fact Sheets, *supra* note 7 at e942-e944.

⁹⁶ *Spiering* 448 F. Supp. 2d 1129, (D..Neb. 2006), (quoting, Newborn Screening: Toward a Uniform Screening Panel, Report for Public Comment, Executive Summary at 3(2005), <ftp://ftp.hrsa.gov/mchb/genetics/screeningdraftsummary.pdf>).

⁹⁷ *Spiering* 448 F. Supp. 2d 1129 at 1141.

⁹⁸ *Id.*

⁹⁹ *Id.*

that the newborn screening laws and regulations are rationally related to a legitimate government purpose, and are constitutional.¹⁰⁰

In both cases, the courts go through a 3-step analysis. First, the courts find that the proper standard of review is rational basis review. Second, the courts find that the state has a legitimate interest in the health of children. Third, the courts find that there is a rational relationship between the state's interest in children and the newborn screening program. The courts find a rational relationship between newborn screening and the state's interest based upon scientific evidence that shows that newborn screening reduces death and disability in children. The outcome of this analysis turns on the relationship between the state's interest and the means by which the states seeks to promote its interest. There is no debate over whether the state's interest in children's health is a legitimate state interest. There is little debate over whether the proper standard of judicial review is rational basis review. The dispositive question is whether the law supporting newborn screening and the newborn screening program's regulations and practices is rationally related to the state's interest in children. In both *Anaya* and *Spiering*, the court found that the mandatory newborn screening programs were constitutional because there was a rational relationship between the practice of screening and the states interest.

Section V

Courts have upheld state mandatory newborn screening programs as a constitutional exercise of the state's power because the courts have found that newborn screening laws

¹⁰⁰ *Id.*

are rationally related to the state's legitimate interest in preventing death and disease in children. Courts have not specifically addressed the question of whether or not blood samples collected as part of newborn screening may be stored and used in research. The practice of storing and using residual dried blood spots occurs in several states and will likely increase in the future.

Under the current legal framework supporting newborn screening programs, storage and research using blood collected as a part of newborn screening programs cannot be legally justified. The practice of storing and conducting research blood samples collected as a part of newborn screening cannot be justified under the same legal framework which authorizes newborn screening for 2 reasons: first, storage of, and research using, stored blood samples cannot be justified as an exercise of the state's *parens patriae* power because storage and research is not reasonably or rationally related to the states' interest in preventing death and disease in the individual newborns who are being tested. Second, storage of and research using blood collected as part of newborn screening is not a proper exercise of states' police power because failure to participate in research is not a threat to public health and safety.

The courts have upheld newborn screening laws because the courts found that newborn screening is rationally related to a legitimate state interest: the state's interest in preventing death and disability in newborns. When the state intervenes to protect the interest of newborns, it is an expression of the state's *parens patriae* power. If either the state's action is not rationally related to the state's interest in preventing death and disease in children, or the state's action is not in the best interest of the newborns who are

being tested, then the state's action cannot be justified as an appropriate expression of the state's *parens patriae* power.

As courts have noted, scientific evidence supports a finding that certain early screening tests and interventions prevent death and disease in children. There is a reasonable, rational connection between newborn screening and the prevention of death and disability in children. When a genetic or metabolic abnormality is detected early, interventions can be implemented to prevent death and disability. Failure to detect a genetic or metabolic abnormality may lead to death and disease. The classic example is PKU and the success of PKU screening.

In contrast, there is no rational connection between storage and research, and the prevention of death and disease in individual newborns who are the subjects of newborn screening. No individual newborn directly and personally benefits from having his or her blood stored, and used in future research. There are several clear reasons why storage of blood samples and future research using blood samples do not benefit the sample donors.

The first reason is simply that research conducted in the future cannot benefit subjects in the past. A study using stored blood samples may occur weeks at the earliest, and probably months to years after the sample donor is born. The results of the study cannot benefit the donor because there is no way to retroactively apply the benefits to the donor.

For example, in studies that evaluate the validity and utility of screening tests, the results of the study are used to improve the screening test and procedures prospectively. The

benefits of the study apply to all newborns that are screened after the study is completed and the results of the study have been implemented. If the benefit of a study is a better test, there is no way to go back and retest the study subjects. Even if it were possible to retest all the study subjects, some of the study subjects would already have sustained injuries because the subjects received an inferior test, and may have been untreated.

Similarly, epidemiological studies which seek to inform screening and public health policy can only benefit future children in a general sense, and cannot benefit specific, individual children who were screened in the past, and were the subjects of the study. For example, the results of a study of the prevalence of HIV in newborns based upon stored newborn screening samples may be used to improve interventions after the study is completed. There may be more screening for HIV among newborns, and there may be more interventions available to reduce HIV infections in newborns. The results of the study would benefit future children born after the study. If the benefit is a better treatment, there is no way to go back in time and provide that better treatment to the study subject. If the treatment prevents vertical HIV transmission, there is no way to go back in time and prevent transmission to the study subjects; they would already have been infected.

If the benefit of the study is a better test, the study subjects cannot benefit because there is no way to go back and retest the study subjects, and even if that were possible, many of the study subjects would have already suffered an injury as a result of been given an inferior test. If the benefit of the study is better public health policy, such as lower environmental exposures to harmful chemicals, the study subjects cannot benefit because

there is no way to go back and prevent the past exposure and subsequent injury. If the benefit of the study is a new or better treatment or intervention, the study subjects cannot benefit because there is no way to go back and prevent the injury. If the benefit is a treatment that can reverse the injury, there must be a way to locate all the affected study subjects.

The second reason storage and research does not benefit sample donors is that generally all studies unlink the samples from any identifying information.¹⁰¹ The samples cannot be retraced back to an individual donor. If a new treatment is available, it is unlikely that the study will be able to locate the affected study subject and provide treatment.

It can be argued that storage and research is rationally related to preventing death in disease in children, in the sense that the knowledge from the research will improve the public health systems and delivery of health care to all children in the community. This argument is well taken; however, the interest has shifted from the interest of individual newborns that are being tested, to the interests of the general public. As the interest of the government shifts from protecting individual newborns to promoting the general public health, the expression of state power shifts from the *parens patriae* power to the police power.

The police power allows for restriction of individual liberties where the exercise of these liberties threaten the general welfare. Exercise of police power occurs in many circumstances including in mandatory immunization and quarantine. The purpose is to

protect the general public from harm. Storage and research would be justified by police power if failure to participate in research would threaten the health and safety of the general public. At the very least, the threat to the public health from a failure to contribute to research should equal the threat created by a failure to be immunized, a failure to maintain a clean water supply, or another similar public health hazard. Failure to participate in research does not create such a threat. The withholding of a newborn's blood sample from storage and usage in research does not threaten the health or safety of anyone in the community. Therefore, the storage and use of stored blood samples cannot be justified as an exercise of the state's police power.

Furthermore, justifying the practice of storing blood samples and conducting research as a proper exercise of the state's police power is problematic because it expands the police power of the state beyond any cognizable ethical or legal boundaries. If the mandatory collection, storage, and use of newborn blood samples in research can be authorized as a proper exercise of police power, then by the same rationale, adults may be forced to give blood and participate in public health research for the sake of public health. The harm to the public caused by a failure to be immunized or quarantined must be distinguished from the harm caused by a failure to participate in research. Once this distinction is lost, there is no ethical or legal boundary preventing all members of society, both adults and newborns, from being forced to participate in biomedical research potentially beneficial to the public's health and welfare. The notion of forced participation in biomedical research is inconsistent with prevailing international ethical and legal standards.

¹⁰¹ This is consistent with state and federal requirements regarding research with stored samples. Most states require that identifying information be stripped from samples prior to distribution for use in research.

Conclusion

The potential benefit from newborn screening based databases is immense, however, the potential for harms are also great. Under the current legal framework, the state has the power to compel newborn screening only for the benefit of the newborn. The state does not have, and should not have, the power to compel newborns to participate in public health research.

Newborn screening programs should involve only actions that directly and immediately benefit individual newborns who are the subject of the testing. Programs limited in this way are a proper exercise of the states' *parens patriae* power. Newborn screening programs should not include any actions that do not directly benefit the newborns that are being tested. This includes the practice of storing blood and genetic information, and using blood and genetic information in future research. Actions that may benefit the public health and welfare should be authorized only by standards that apply to other public health hazards.

Newborn screening should be completely segregated from research because the legal and ethical foundations for each are different. State legislated, mandatory participation in biomedical research is not only legally unjustifiable, but also ethically problematic. If researchers want to create a biobank of stored biological samples from all newborns, the

See supra notes 21, 29.

legal and ethical protections that apply to other study subjects in similar research should also apply to newborns. Researchers may accomplish this by creating an independent research program that collects and stores samples independent of the state's newborn screening program. Such a research program must incorporate basic ethical and legal protections such as informed consent and institutional review board oversight. Research programs that deal with stored sample research should also actively address questions regarding control over future use of stored samples, confidentiality of stored samples and research results, and disclosure of research results. A major question that remains unresolved is whether parents may consent for their children to participate in pediatric research involving stored biological materials. Researchers will have to address the question of whether pediatric subjects may revoke their parent's consent to participate in research when they reach the age of majority.

Newborn screening and research are two different things and should be distinguished both conceptually and legally. The rationale for each is different, and the authority for each is different. Failure to make the distinction undermines the social and legal foundation for both. The practice of storing and using blood spots collected from mandatory newborn screening programs should stop because it is both legally unjustifiable and ethically problematic.