Necessity's Sharp Pinch:
Parental and States' Rights in Conflict
in an Era of Newborn Genetic Screening

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I. An Introduction to Newborn Genetic Screening

Approximately four million infants are screened each year in the United States for a variety of genetic disorders.1 This routine testing of newborns seems relatively uncomplicated and has, in fact, become "a part of common practice and accepted public policy with little thought having been given to the implications."2 The primary goal of newborn genetic screening is the prevention of mental retardation and other irreversible clinical conditions, including death, through the discovery of metabolic disorders.3 Thus, newborn screening is a vital state public health program to prevent and limit not only chronic diseases, but also the morbidity and mortality attributable to selected inherited diseases.4

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4 See Robert M. Nelson, et al., Ethical Issues With Genetic Testing in Pediatrics 107 PEDIATRICS 1451-
Little controversy has erupted over these mandatory testing statutes. The tests traditionally used are highly accurate, and increasingly, with early detection, physicians may begin treatment of a rare disorder at the earliest possible opportunity.5 Furthermore, states have been generally consistent when developing criteria for selecting which disorders to include in their newborn screening programs.6 For instance, when developing screening policies the following must be considered: who will pay for the screening program,7 who should be screened, how often the disorder occurs in the population, whether an effective screening test exists to identify the disorder, who benefits from the screening program, what are the potential risks of screening, whether the disorder is treatable, and who will have access to the test results.8 However, there are no national newborn screening standards; thus, each state has its own policy. As a result, the number of conditions screened today varies considerably from state to state.9

Moreover, across the nation the law varies in addressing the increasing number of sensitive issues involved in newborn screening. Some of these issues include: deciding what tests to include in the screening program, preserving patient and family rights, ensuring privacy of genetic information, as well as guaranteeing that all newborns have equal access to screening nationwide. These concerns require that the law keep pace with advances in the technologies of genetic testing. The standardization of all state programs would ensure that each disorder selected for screening meets set criteria, including treatment for the disease. A national standard would also promote fairness, ensuring that every infant has the opportunity to screening and equal access to early detection and treatment of genetic disorders.

This note poses the following arguments: first, that mandated testing should be implemented only when children can derive substantial benefit from early detection, and, second, that existing laws should be amended to ensure parents’ participation in the

5 Id.
7 The issues of cost, financing and insurance coverage will not be discussed in this note. For a detailed overview of these areas, as well as the Task Force recommendations to improve financing of newborn screening programs, see Task Force, supra note 1, at 420.
9 See Task Force, supra note 1.
screening process. In addition, to balance the public interest justifications involved in newborn genetic screening statutes, new policies must address the interests of all parties, particularly in guaranteeing the right to privacy and confidentiality of parents and children. Finally, this note provides brief comparisons of current state laws and explores whether a nationwide standard should be implemented to provide guidance for state programs and to regulate the process.

Currently, some newborn genetic screening is required by law in every state; however, these laws are inconsistent when compared to one another. For example, the number of disorders screened ranges from seven in one state (Kansas) to seventy-five in another (California). Remarkably, only two states, Florida and Wyoming, allow for an exemption to the newborn genetic screening requirements if parents object on any grounds. Thirty-three states allow for an exemption for parents to object on religious grounds. At least twelve states have confidentiality requirements related to newborn screening laws. Finally, at least six states and the District of Columbia have laws related to obtaining consent from the parents of children before performing genetic tests.

The status of newborn screening laws and regulations must be more carefully evaluated by Congress, state legislatures, and the medical community. Because of the state-to-state differentiation of screening requirements, whether a newborn is screened for a particular disorder depends on the state in which he or she is born. Moreover, it

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12 Id. As of March 2005, Nebraska, Michigan, Minnesota, Montana, and South Dakota do not allow for the religious exception. Id.
13 Id. These states include Arizona, Colorado, Florida, Hawaii, Iowa, Louisiana, New Jersey, North Dakota, Ohio, South Carolina, Virginia and Wisconsin. Id.
14 Id. These states include Hawaii, Ohio, Nebraska, Texas, Wisconsin and Wyoming. Kansas requires informed consent in order to monitor infants with genetic disorders. Id.
15 See, e.g., Ellen Wright Clayton, Screening and Treatment of Newborns, 29 Hous. L. Rev. 85 (1992). For example, if a child is born with biotinidase deficiency, but happens to be born in a state that does not screen for it, then she will likely suffer from seizures and mental retardation if the condition is undetected. Id. However, if she is born in a state that does screen for the disorder,
is likely that current legislation does not provide adequate protections for the parents' and child's right to privacy. Additionally, it is important that parents and the public increase their awareness of and responsibility for newborn genetic screening legislation so that the correct balance is achieved between vital privacy concerns and the public good that may accrue from increased screening of newborns.

A. The History of Newborn Genetic Screening

In 1960, a low-cost method was introduced to screen newborns for a single gene disorder called Phenylketonuria (PKU), which affects an estimated one in fourteen-thousand individuals in the United States and, if not promptly diagnosed and treated, leads to severe mental retardation or death. The National Association for Retarded Citizens (now The Arc) proposed model legislation for creation of public programs to address low detection rates, and also conducted an extensive grassroots lobbying effort to support passage of mandatory PKU screening legislation. In 1963, Massachusetts

then those complications could be prevented with administering extra biotin to the infant. Id. The right to privacy includes confidentiality; every screening program should have policies to ensure confidential storage and appropriate use of specimen. See Newborn Screening: Toward a Uniform Screening Panel and System, Report for Public Comment, available at http://www.mchb.hrsa.gov/screening/ (last visited Feb. 19, 2006).

In addition to family education, public awareness should include additional training for medical professionals. At a minimum, for example, states should require that health care professional provide expectant parents with information about mandatory and otherwise available newborn genetic screening processes. Any information provided to expectant parents must clearly indicate the opportunity to object if such rights are granted under the state statute or regulation.

Pressure to regulate this screening test came from the National Association for Retarded Children (NARC, now The Arc US), the Children's Bureau, and the Joseph P. Kennedy, Jr. Foundation. See American Association on Mental Retardation, Newborn Screening in the 21st Century: Current Status and Considerations (Apr. 2, 2002) (White Paper from the Health Promotion and Prevention Committee of the AAMR), available at http://www.aamr.org/Reading_Room/pdf/newborn_screening.pdf. Children born with PKU appear normal at birth; symptoms can be prevented if the baby is treated with a special diet that is low in phenylalanine begun within the first 7 to 10 days of life. Id. Through routine newborn screening, almost all affected newborns are now diagnosed and treated early, allowing them to grow up with normal intelligence. Id. The inherited disorder occurs in all ethnic groups, although it is more common in individuals of Northern European and Native American ancestry than in those of African-American, Hispanic, or Asian ancestry. See March of Dimes, Medical References: PKU, available at http://www.marchofdimes.com/professionals/681_1219.asp (last visited Nov. 20, 2005).


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,
became the first state to mandate the testing of every newborn for PKU. Today, every state and the District of Columbia require the screening for this particular treatable disorder.

The screening of newborns for identification of specific diseases is compelled by statute or by regulation in every state, including the District of Columbia. Each state requires its own number of newborn genetic screening tests, varying from four to thirty-six. According to the National Newborn Screening and Genetics Resource Center, all states routinely test for up to thirty metabolic and genetic diseases including PKU, Congenital Hypothyroidism (CH), Galactosemia (GAL), and sickle cell disease (SS, SC etc.). The broad rationale for mandatory testing is that state intervention is necessary to protect the health and safety of its citizens.

COUNSELING AND EDUCATION PROGRAMS (1983) [hereinafter PRESIDENT’S COMM’N].


22 See National Newborn Screening and Genetics Resource Center’s Status Report, supra note 10.

23 Id. As of October 21, 2005, all states screen for these four conditions; this list will soon include sickle cell disease (including HB S/C and HB S/A). Id. For up-to-date information on the status of conditions tested by state, see the National Newborn Screening and Genetics Resource Center, at http://genes-r-us.uthscsa.edu/.

24 See GAO MARCH 2003 REPORT, supra note 6; see also National Newborn Screening and Genetics Resource Center’s Status Report, supra note 10.

25 See GAO MARCH 2003 REPORT, supra note 6. Most states screen for PKU, hypothyroidism, galactosemia, biotinidase deficiency, congenital hypothyroidism, and maple syrup urine disease; states may also screen for diseases with no known cure like hemoglobinopathies and cystic fibrosis. See All About Newborn Screening website, available at http://www.aboutnewbornscreening.com/.

26 Phenylketonuria (PKU) is a disorder that causes the body to be unable to break down the amino acid phenylalanine, which is found in the protein of foods. Additional information about PKU, available at http://www3.ncbi.nlm.nih.gov/htbin-post/Omim/dispmim?141900.

27 Congenital Hypothyroidism is a thyroid hormone deficiency, which can lead to poor growth and mental retardation. Additional information about Congenital Hypothyroidism, available at http://www.magicfoundation.org/conghyp.html.


29 See the National Newborn Screening and Genetics Resource Center, at http://genes-r-us.uthscsa.edu/; National Newborn Screening and Genetics Resource Center’s Status Report, supra note 10.

30 See generally, GAO MARCH 2003 REPORT, supra note 6.
for the benefit of the child.\textsuperscript{31}

Finally, some states provide additional and voluntary screening for certain disorders to selected populations, either through pilot programs or by request.\textsuperscript{32} For example, since 1999, through two pilot studies offered as part of the New England Newborn Screening Program, Massachusetts has offered screening for an additional twenty metabolic disorders, including cystic fibrosis (CF).\textsuperscript{33} The Massachusetts Department of Public Health cites three reasons to justify the program: first, that it is important to the anticipated evaluation of newborns to bring early treatment for possibly serious medical conditions; second, and more interestingly, to evaluate the laboratory testing used to screen for the disorders; and third, to find out the rate of occurrence of any given disorder in Massachusetts.\textsuperscript{34} It is estimated that more than 98 percent of parents who have babies in the state consent to the pilot program, which must undergo periodic review to include additional disorders should research support the inclusion.\textsuperscript{35} This high rate of voluntary participation of the Massachusetts pilot programs illustrates how the aforementioned justifications can be achieved to a very high degree without state impositions of strict or mandatory screening requirements that, absent the right to decline, may threaten individual liberties.

\textbf{B. Changing Technology}

Over the last 40 years, by virtue of widespread research in the area of genetics, rapid changes in technology have contributed to advances in screening for various inheritable disorders.\textsuperscript{36} As a result, many legal and ethical issues have yet to be resolved.

\begin{itemize}
\item[32] For example, see the Mississippi Department of Public Health Newborn Screening website, \textit{at} \url{http://www.msdh.state.ms.us/msdhsite/_static/41,0,101.html}. Mississippi started its program by screening for 5 disorders; today it screens every newborn for 40 disorders. \textit{Id.}
\item[35] \textit{Id.}
\end{itemize}
For example, some states are implementing testing using tandem mass spectrometry (TMS), thus the criteria for selecting disorders must be re-evaluated.\textsuperscript{37} A clear advantage of TMS is that it measures various components of the blood, urine, or plasma in approximately two minutes for 20-30 metabolic disorders.\textsuperscript{38} It has further proven to be a reasonable and cost-effective screening instrument by the American Association on Mental Retardation Board of Directors.\textsuperscript{39}

Nearly half of all U.S. states use TMS in their screening programs.\textsuperscript{40} Despite its popularity, however, significant controversy has erupted over the appropriate use of TMS in newborn screening.\textsuperscript{41} The most salient issue raised is the ability of TMS to identify disorders for which treatments are currently unavailable.\textsuperscript{42} Obviously, testing for disorders that are currently untreatable raises questions of necessity and failed rationale for newborn screening legislation; beyond the likely and perhaps serious emotional impact such news would have on the parents. Additional issues center on TMS's accuracy and effectiveness, as well as whether the incidence and severity of the disorders detected by TMS justifies screening.\textsuperscript{43} Here again, the arguments question if

\textsuperscript{37} Id. A tandem mass spectrometer is an analytical instrument used to electronically weigh molecules. A mass spectrometer functions analogously to sorting change. Id. For example, based on their unique weight coins may be sorted into pennies, nickels, dimes and quarters. Id. In newborn genetic screening laboratories, TMS is used to analyze the compounds (amino acids and acylcarnitines) from the infant's blood sample. Id. In inherited metabolic diseases, specific enzymes are not functioning properly to break down these compounds, which then accumulate in the blood and tissues and eventually become poisonous, id. It is important to note that not every state uses TMS. Id.

\textsuperscript{38} Id.

\textsuperscript{39} Id.

\textsuperscript{40} See, GAO MARCH 2003 REPORT, supra note 6, at 10.

\textsuperscript{41} Id.

\textsuperscript{42} Louis J. Elsas, II, M.D., F.F.A.C.M.G., Medical Genetics: Present and Future Benefits, 49 Emory L.J. 801, 811 (2000); see also, Donald H. Chace et al., The Role of Tandem Mass Spectrometry in Reducing the Number of False Positive and False Negative Results in the Diagnosis of Metabolic Disease from Dried Blood Spots, in EARLY HOSPITAL DISCHARGE: IMPACT OF NEWBORN SCREENING (K. Pass & H. Levy eds., Council of Regional Networks for Genetics Services, Emory University Medical School, Atlanta, Ga.), March 31, 1995, at 272-83. One of the weaker arguments is that more states have not utilized TMS for political reasons; specifically, that switching from one privately-run laboratory to another as the site where current newborn screening results are analyzed may be disruptive. See American Association on Mental Retardation, Newborn Screening in the 21st Century: Current Status and Considerations (Apr. 2, 2002) (White Paper from the Health Promotion and Prevention Committee of the AAMR), available at http://www.aamr.org/Reading_Room/pdf/newborn_screening.pdf.

\textsuperscript{43} See GAO MARCH 2003 REPORT, supra note 6 (outlining how the national Task Force was organized by the American Academy of Pediatrics). The Task Force received funding from the MCHB, HRSA, and the US Department of Health and Human Services. Id. Co-sponsors
an effective treatment should be available before testing for any specific disorder is required. Furthermore, a national Task Force on Newborn Screening has recommended that all states test for 29 different disorders, despite the fact that the incidence of 12 of the 29 disorders is thought to be less than 1 in 100,000 live births. This makes evidence of the disorder’s frequency, quality of the screening test, and safety and cost-effectiveness of treatment difficult to analyze due to the rarity of the disorder. Finally, the states’ basis for mandatory testing of all newborns, resting on an argument of protecting the health and safety of its citizenry, is thrown into stark relief in the light of the low frequency of many of the disorders.

II. Is Mandatory Screening In the Best Interest of the Child?

The interests of children and parents should be of central importance to any mandated screening programs because screening principally and substantially affects them. Consider, for example, the clinical implications of an abnormal genetic screening test for a child. At the most basic level, the presence of an abnormal test result may simply be incorrect. In some cases, an abnormal test result indicates that the child is or may become ill at some point in the future. Specifically, the mere presence of some genetic deviation may be rendered virtually meaningless because, in the cases of some of the various testable disorders, the child with such an “abnormality” might experience no noticeable illness whatsoever.

Consider a child who, in the course of a state genetic screening program, tests positive for a disorder that is currently untreatable or one that may not manifest itself in

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45 Id.
47 Id. at 96.
48 Id. citing Jay Taureen, Meningitis, in RUDOLPH'S PEDIATRICS, 559-60 (Abraham M. Rudolph et al. eds., 19th ed. 1987) (indicating, for example, that a positive test for bacteria in the spinal fluid indicates that a child has meningitis).
49 Id. citing Friedrich Vogel & Arno G. Morulsky, HUMAN GENETICS: PROBLEMS AND APPROACHES 626 (2d ed. 1986) (stating that a positive screening test for PKU does not mean the child will suffer from mental retardation if the child in fact has only hyperphenylalaninemia).
any significant way during that child’s lifetime. For example, screening could detect conditions that are considered to be adult onset diseases, such as a possibility of Alzheimer’s disease, Huntington’s disease, and breast cancer. As a general proposition, if early knowledge (of the presence of a genetic deviation suggesting a risk of a late-in-life onset of such a disease) has limited or even no positive benefit for the child or his/her parents, then what is the over-riding justification for mandatory testing? Is the states’ interest sufficient to render subordinate the interests of the individuals most affected?

Identifying a child’s illness or potential illness does him or her no good unless treatment is actually available and administered. On the other hand, for those conditions that are currently not treatable but where identification might provide parents with information to plan for child’s quality and length of life as well as for future child-bearing decisions, the voluntary screening of genetic disorders seems favorable. For example, Massachusetts, which requires genetic screening only for currently treatable disorders, includes screening for CF in its voluntary pilot program, along with other non-curable but detectable genetic diseases. Children who have CF are born with the disorder, but often do not show visible signs of disease for weeks, months or even years later. While there is currently no cure for CF, medical treatment can include replacing

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50 Michele A. Lloyd-Puryear & Irene Forsman, Newborn Screening and Genetic Testing, 31 J. OBSTET. GYNECOL. & NEONATAL NURS. 200, 206 (2002). However, the authors note that DNA-based screening as the primary method of newborn screening is not likely to occur until knowledge of the technology increases; the only exception appears to be DNA-based analysis for sickle-cell disease. Id.


52 See generally Mayo Clinic Overview on Cystic Fibrosis, at http://www.mayoclinic.com/health/cystic-fibrosis/DS00287. Cystic fibrosis is a life-threatening disorder that causes severe lung damage and nutritional deficiencies. Id. CF is an inherited (genetic) condition affecting the cells that produce mucus, sweat, saliva and digestive juices. Id. Respiratory failure is the most dangerous consequence of CF. Id. Each year approximately 3,200 white babies are born in the United States with CF. Id. The disease is much less common among black and Asian-American children. Id. Most babies born with CF are diagnosed by age 3, although mild forms of the disease may not be detected until much later in life. Id. In all, about 30,000 American adults and children are living with the disorder. Id.
digestive enzymes soon after birth, use of antibiotics, and careful monitoring to improve growth and quality life. The Commonwealth argues that because the testing is accurate the voluntary program will continue to succeed. Additionally, the program will prove to be worthwhile because the benefits of early intervention of some incurable genetic disorders outweigh the potential risks.

But all of this raises some ominous questions about the value and potential dangers of state legislated mandatory testing of each and every newborn: can the law be used to limit the potentially negative social consequences of labeling (labeling by future health insurers or simply labeling as social stigma)? Will children identified as “different” by newborn screening suffer discrimination as a result of their genetic deviation? Even when a disorder requires no intervention, mere entry of the diagnosis into a medical record or database may become available to others by virtue of mistake, poor data handling protocols and practices or even as a result of future legislation and, thus, impact the child and parents later in life. All of this is risked because, at present, states offer the simple justification that newborn genetic screening is necessary to protect the public health and welfare.

III. Parent Participation and Protection of Rights

Four critical issues emerge as a result of mandatory newborn screening programs: the questions of informed consent; parental education; the right to privacy; and the protection and confidentiality of genetic information or data. As new genetic tests become available, states’ mandatory testing programs will almost certainly infringe on parents’ right to choose whether to have the test performed on their child. As previously mentioned, all but two states permit parental refusal of newborn screening for religious or personal reasons. The principal justification offered for mandatory screening is the claim that society’s obligation to promote child welfare through early detection and treatment of selected conditions supersedes parental prerogatives to refuse any minor medical intervention.

53 Id.
54 New England Newborn Screening Program, supra note 33.
55 Id.
56 Informed consent is the right to say yes or no to screening after consideration of all available information.
57 See Nelson, supra note 4, at 1451.
A. Informed Consent

Parents have a fundamental right to make decisions concerning the care, custody, and control of their children. Therefore, at minimum, it should be required that parents be told that their newborn is being tested. Anything less fails to acknowledge the parents' interest to make decisions concerning the upbringing of their children. Furthermore, parents must be informed about the implications of screening and should be given the option to reject testing if they wish because the potential adverse consequences of screening are too great and the benefits too small in any particular case to justify mandatory testing.

A little more than a decade ago, issues of informed consent received considerable attention from the Committee on Assessing Genetic Risks of the National Science Foundation's Institute of Medicine. In a 1994 report, the committee outlined policy guidelines and legislative recommendations intended to avoid involuntary and ineffective testing and to protect confidentiality. After considering a variety of potential social and health-related impacts, the committee recommended that all screening, including that for newborns, be voluntary. The Committee cited results of the voluntary newborn screening programs of Maryland and the District of Columbia, and noted that these programs achieved compliance rates equal to or better than those of mandatory programs. For example, in a study of newborn screening in Maryland involving informed consent, the majority of women preferred that permission be asked

60 Claydon, supra note 46, at 148.
61 Id.
The report recommended the establishment of a new body for policy oversight. Id. A broad representative national advisory committee and a working group on genetic testing could set standards for professional practices and determine when new genetic tests are ready for wide scale use. Id.
65 Id.
66 Id. Although the committee said it would prefer that all screening be voluntary, it noted that if a state requires newborn screening for a particular condition, the state should do so only if there is strong evidence that a newborn would benefit from effective treatment at the earliest possible age. Id.
before screening, and the informed refusal rate was only 5 per 1000 infants.\footnote{Faden et al., supra note 58, at 1347.}

Supporters of the informed consent model argue that it is the best method of ensuring patient autonomy, a standard and essential practice in any medical procedure.\footnote{See The Genetic Science Learning Center at the University of Utah, Policy Issues in Newborn Genetic Screening, http://gslc.genetics.utah.edu/units/disorders/newborn/arpolicy.cfm [hereinafter Policy Issues in Newborn Genetic Screening] (last visited Feb. 21, 2006).} Informed consent increases awareness by helping parents understand why their newborn is being screened. However, states argue that certain genetic tests may be in the best interest of the child; therefore, parents’ objections should not hinder the screening process.\footnote{Puryear et al., supra note 50.} Furthermore, it is logistically difficult to obtain informed consent for newborn screening due to time constraints, varied birth settings and the large number of newborns to be screened.\footnote{Clayton, supra note 46, at 144. For example, many state statutes do not address the parental component of newborn screening even when they give parents an opportunity to opt out of the screening. Id. See also, OR. REV. STAT. § 433.285(3) (1992) (allowing parents to opt out for religious reasons).}

State policies regarding informing parents and parental consent vary widely. For instance, all states require newborn screening for at least four conditions but most states do not call for parental consent, and worse, in many states parents do not receive any information.\footnote{See Newborn Genetic Screening Privacy Laws, supra note 11.} Currently, 28 states require consent to either perform or require genetic testing, or to obtain, retain or disclose genetic information through genetic-specific privacy laws.\footnote{Id. Both Wyoming’s newborn screening statute and Maryland’s newborn screening regulation expressly require informed consent. Id. However, neither state’s statute nor the regulation defines informed consent. Id.} For example, Wyoming’s statute expressly requires parents to give written consent for newborn screening and Maryland has a voluntary newborn screening program.\footnote{Id. The states that actually obtain written consent from parents before screening are: Hawai‘i, Ohio, Nebraska, Texas, Wisconsin and Wyoming. Id.} At least six states and the District of Columbia have laws related to obtaining consent from the parents of children prior to performing genetic tests.\footnote{See KAN. STAT. ANN. § 65-180 (2005).} One state, Kansas, requires informed consent in order to monitor infants who have tested positive for a genetic disorder, allowing for verification of the tested disease.\footnote{See Kan. Stat. Ann. § 65-180 (2005).}
consent provisions, including Delaware, Illinois, Louisiana, Massachusetts, Michigan, Nevada, New Hampshire, New Jersey, New Mexico, New York, Oregon and Vermont. The exemption is likely due to the states' interest in protecting the health and welfare of newborns. This loophole raises a potentially troubling public policy idiosyncrasy, one that would likely be addressed with greater public awareness.

Additionally, the right to refuse genetic screening varies among the other states. For example, several state newborn screening statutes or regulations allow exemptions from screening for religious reasons, and a small number of states allow exemptions for any reason. Unlike other medical procedures where informed consent is mandatory, in many cases parents are never informed that they have the right to refuse, and the testing proceeds in the midst of the parents' lack of knowledge and absent their consent. Standardization through the establishment of national guidelines should be incorporated to address the most basic form of critical informed consent requirements. Finally, the addition of screening tests for conditions with no treatment interventions or where the efficacy of treatment intervention is unknown, will directly impact the ethical, legal, and social demands to obtain documentation of the parents' permission for newborn screening.

Lawsuits are beginning to surface in the states that do not allow parents to refuse newborn genetic screening tests. For example, in the recent case Douglas County

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76 See Newborn Genetic Screening Privacy Laws, supra note 11.
77 See Newborn Genetic Screening Privacy Laws, supra note 11. Currently, 33 states allow exemption if the screening is contrary to the parents' religion. Id.
78 Id. Currently, 13 states provide an exemption for any reason: Alaska, Colorado, D.C., Florida, Iowa, Louisiana, Maryland, Nevada, New Hampshire, New Mexico, North Carolina, Vermont, Wyoming. Id.
80 See Task Force, supra note 1, at 403.
81 See American Civil Liberties Union of Nebraska, at http://www.aclunebraska.org/religious_liberty.htm#1 (last visited Feb. 26, 2006). In December 2004, ACLU Nebraska filed a case in Federal Court, arguing that the state does not have the right to mandate medical screening unless there is a clear and present need. Id. The State refused to grant Louise and Ray Spiering a delay in the time for administering their newborn's testing based on religious beliefs. Id. This case is pending in federal court to decide the issue of whether the state law is unconstitutional as an infringement on the freedom of religion. Id.
82 See Newborn Genetic Screening Privacy Laws, supra note 11. The states that do not allow a religious exemption include Nebraska, Michigan, Minnesota, Montana, and South Dakota.
v. Anaya, the Nebraska Supreme Court unanimously upheld the state law that requires newborn genetic screening, rejecting the parents’ argument that the law violated their rights guaranteed under the First and Fourteenth Amendments. The parents in this case argued that the Nebraska law infringed upon their Constitutional rights to freely exercise their religion and to make parental decisions concerning the upbringing of their children. The Court ruled in favor of the State, concluding that the State has an interest in the health and welfare of all children born in the State and the purpose of the law is to protect that interest.

B. Parental Education

A central question in newborn screening is how to provide educational material about screening programs to parents and health care providers. Ideally, parent education and informed consent should both be central components of newborn screening programs. However, most state screening programs provide accommodations for parents who explicitly refuse testing. The central argument is that screening and potential detection is in the best interest of the newborn and parents' objections should not hinder the process.

States have not enacted legislation requiring the dissemination of educational materials to parents regarding newborn screening. Nevertheless, it is reported that almost all states have available some information and education for parents on their

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83 694 N.W.2d 601 (Neb. 2005). This is the first appellate court ruling in the United States on the issue of whether the State has the authority to require a newborn health screening over a parent's religious objection.
84 Id. at 608; see also, NEB. REV. STAT. § 71-519 (2004 & Supp. 2005) (requiring the testing of at least five metabolic diseases for all infants born in the State of Nebraska). The facts in Anaya are relatively simple. The birth of Rosa Ariel Anaya to Josue and Mary Anaya occurred in the Anayas' home without a physician present. Anaya, 694 N.W.2d at 604. Approximately one week later, the birth was reported to the Department of Health and Human Services (DHHS), which discovered that the metabolic testing required by law had not been performed. Id. at 604. DHHS sent a certified letter to the Anayas explaining the statute and included a brochure detailing the newborn genetic screening process. Id. The Anayas refused to have their daughter tested, stating that the testing was in direct conflict with their sincerely held religious beliefs, because according to their religion, blood removed from the body may shorten a person's lifespan. Id.
86 Anaya, 694 N.W. 2d at 561.
87 Puryear et al., supra note 50, at 204.
88 Id.
89 See Policy Issues in Newborn Genetic Screening, supra note 68.
genetic screening programs. In most states, typical information for parents includes how the blood specimen is obtained, the disorders considered under the state program, and how parents will be notified of testing results. A problem arises when parents may not actually receive the necessary educational materials, or, when parents are unaware of the program or how to learn about it. Rather than providing materials directly to the parents, the state usually provides materials to other third parties charged with the responsibility for its distribution, including hospital staff, midwives, pediatricians, nurses, primary care providers, and local health department personnel. These individuals are expected to share the information with the parents in a timely manner.

Improving parent understanding may increase the number of parents who comply with recommendations for further testing and follow-up. Moreover, increased parent education may also help parents with anxiety associated with false positives, ambiguous results and repeated tests. Educating parents about the screening process is especially important given that genetic research and technology is advancing at such a rapid pace. Newborn screening affects parents’ relationships with their children as well as parents’ own decision making about future childbearing in a variety of ways. Regardless of whether the effects of such screening appear to the outside observer to be beneficial or harmful, these consequences have legal implication because they represent intrusions into matters that society has generally concluded the family, and not the state, is to decide.

C. The Parents’ Right to Privacy

Another concern surrounding the mandatory testing laws is the possibility for violation of the parents’ right to privacy, especially where the constitutionality of laws that require newborns to be tested for these rare disorders is only beginning to be challenged. In other words, where the screened genetic disorders in the newborn are inherited genetic traits, rather than by random mutation, the parents’ right to privacy may be infringed as a consequence of a positive test result in their child. Therefore, a recorded genetic disorder in the newborn's medical history implies the same disorder as genetically present in one or both of the child's parents. All of this occurs absent the state having ever obtained any consent for such a test from the originating source or

90 See GAO MARCH 2003 REPORT, supra note 6, at 12.
91 See GAO MARCH 2003 REPORT, supra note 6, at 13. Forty-nine U.S. states provide educational materials for parents; but, only thirteen states distribute the information prior to testing and in almost half of the states this information is provided only in English. Id.
92 See Clayton, supra note 46, at 120-21.
93 Id. at 121.
sources (i.e. either parent). As a result, it becomes quite a simple matter to trace from
the newborn backward to the parent to identify an individual with a genetic disorder
who has never consented to the test. In other words, by screening for one, others have
been identified as possessing or potentially possessing a disorder identified by the state
as warranting testing to protect the public interest.

The chief justification offered for mandatory screening is the claim that society’s
obligation to promote welfare through early detection and treatment of selected
conditions in children supersedes parental prerogatives to refuse minor medical
intervention. However, parents traditionally have a protected broad discretion for
making health care decisions for their children. Although parents generally do not
want to decline effective treatments for life-threatening conditions, they should continue
to be allowed to pursue a variety of options in other than life-threatening circumstances,
including options that their physician might otherwise not advise.

Furthermore, it is argued that the great majority of parents will continue to
support and voluntarily participate in newborn screening when they are adequately
informed of both the risks and benefits. For example, 98% of new mothers
participate in the pilot program launched in Massachusetts when invited to do so, which
may be an indication of the high degree of willingness where the parents understand the
benefits of genetic testing. With continued broad public support, approaches
involving informed consent or parental permission will certainly fulfill the important
goals of the programs while enhancing program quality and respecting traditional and
heretofore protected parental rights to be informed participants in the health care
decisions for their children.

94 See Faden et al., supra note 58.
95 The Constitution protects the rights of parents to enjoy a relationship with their children. See
(1972)); In re Adoption of Children by G.P.B., 736 A.2d 1277, 1281-82 (N.J. 1999); New Jersey
Div. of Youth & Family Services v. A.W., 512 A.2d 438, 452 (N.J. 1986). Parents have a
constitutionally protected, fundamental liberty interest in raising their biological children. See
inviolability of the family unit. See Stanley, 405 U.S. at 651; New Jersey Div. of Youth & Family Services
v. A.W., supra, 512 A.2d at 442-43.
96 See Nelson, supra note 4, at 1451.
97 Id.
98 Philip R. Reilly, ABRAHAM LINCOLN’S DNA AND OTHER ADVENTURES IN GENETICS 265
(2000).
99 Id.
D. Confidentiality

Provisions regarding the confidentiality of screening results are included in many state newborn screening statutes and regulations and state genetic privacy laws, but are often subject to various exceptions.\textsuperscript{100} To illustrate, the State of Washington includes genetic information in the definition of protected health information under the state’s health privacy statute.\textsuperscript{101} The most common exceptions allow for disclosure of information for research purposes, for use in law enforcement, and for establishing paternity.\textsuperscript{102} While few newborn screening statutes provide penalties for violation of confidentiality provisions,\textsuperscript{103} many states’ genetic privacy statutes provide criminal sanctions and penalties for violating their provisions, including those related to confidentiality.\textsuperscript{104}

In Massachusetts, the Newborn Screening Program was created to test all newborns within 48-to-72 hours after birth for ten treatable diseases.\textsuperscript{105} The genetic information is stored according to the name on the birth certificate in a central data bank, and the state uses the information to link identified “at-risk” families with needed services.\textsuperscript{106} According to the state, despite the easily identifiable personal information, the names are never released to third parties.\textsuperscript{107} Even though the data that is released is non-identifiable, one could argue it is not truly anonymous and the stored genetic samples could potentially be used for further genetic testing in the future. For example, the government may wish to access the data bank to determine future needs of special education or other similar issues that may affect a particular community.

Yet another example of how states use genetic information is the State of Michigan, which allows for the blood sample taken from the newborn to be used for

\begin{itemize}
\item \textsuperscript{100} See Newborn Genetic Screening Privacy Laws, supra note 11. At least 12 states have confidentiality requirements related to newborn screening laws (Arizona, Colorado, Florida, Hawaii, Iowa, Louisiana, New Jersey, North Dakota, Ohio, South Carolina, Virginia and Wisconsin).
\item \textsuperscript{101} Id. See also the Washington State Legislature website at http://apps.leg.wa.gov/RCW/default.aspx?cite=70.02.010.
\item \textsuperscript{102} GAO March 2003 Report, supra note 6, at 21.
\item \textsuperscript{103} See Michigan Department of Community Health, Newborn Screening, at http://www.michigan.gov/mdch/0,1607,7-132-2942_4911_4916-64851—00.html [hereinafter Michigan Newborn Screening].
\item \textsuperscript{104} Newborn Genetic Screening Privacy Laws, supra note 11.
\item \textsuperscript{106} Commonwealth of Massachusetts, Bureau of Family and Community Health: FIRSTlink, http://www.mass.gov/dph/fch/firstlink/ (last visited Feb. 20, 2006).
\item \textsuperscript{107} Id.
\end{itemize}
subsequent scientific or medical research with specific controlling provisions to protect the confidentiality of the source.\textsuperscript{108} After the sample is cleared of any linkage to the babies' identification, it may be used for research related to newborn screening at the time of collection, assessment of new technology, quality control, minimal risk research, and epidemiological studies in the area of public health.\textsuperscript{109} No parental consent is required; however, the State must approve all research proposals.\textsuperscript{110} The newborn screening laboratory has policies and procedures to assure that privacy and confidentiality are maintained.\textsuperscript{111} For example, staff education emphasizes the need for confidentiality and penalties for violations are enforced, newborn screening data are protected from third party access, and information about newborn screening is not provided to insurers.\textsuperscript{112}

These examples provide two different glimpses of how states have addressed the issue of confidentiality as it relates to the collection and storage of genetic information. Nevertheless, the overriding question remains as to whether the value of this genetic information for research purposes or otherwise, obtained under pretenses of the promotion of the health and welfare of the public, outweighs the privacy interests of the child and his or her parents.

IV. Need for a Nationwide Standard

Currently, no federal guidelines exist as to the set of disorders that should be included in state screening programs, with the exception of federal recommendations that newborns be screened for a mere three specific disorders.\textsuperscript{113} Without a national standard, newborns in this country do not have equitable access to genetic screening and its potential benefits. Furthermore, absent thorough and comprehensive oversight, the risks posed by having 50 or more standards seem ominous and grossly inefficient.

State newborn screening programs have functioned and expanded differently over the last four decades as a result of a variety of state infrastructures and financing mechanisms, as well as inconsistent statutory requirements defining the scope of

\textsuperscript{108} \textit{See} Michigan Newborn Screening, \textit{supra} note 103; \textit{see also}, MICH. COMP. LAWS § 333.5431 (2001 & Supp. 2005).


\textsuperscript{110} \textit{Id}.

\textsuperscript{111} \textit{Id}.

\textsuperscript{112} Michigan Newborn Screening, \textit{supra} note 103.

\textsuperscript{113} \textit{See} Task Force, \textit{supra} note 1. According to the U.S. Preventive Services Task Force, the three recommended diseases to screen for include sickle cell diseases, PKU, and congenital hyperthyroidism. \textit{Id}.
mandated services. Since there is currently no federal guidance or oversight, each state is responsible for designing and implementing its own newborn screening program. Thus, each system has evolved in the context of the individual state’s economic, demographic, social, geographic, and political manifestations. While this allows some flexibility among state newborn screening programs, it has also led to a wide degree of variation among programs, resulting in disparate access to screening services from state to state. This inconsistency has drawn concern from many groups and, as a result, an influential federal advisory group recently announced its recommendation that all newborns be screened for 29 rare medical conditions.

According to the panel, the 29 core disorders identified are appropriate for newborn screening because (1) a screening test is available and (2) there is a currently available efficacious treatment as well as an adequate knowledge of natural history. The panel stresses that the first decision to screen should be based on the availability of a highly accurate and specific test that can be performed within 24 to 48 hours after the birth of the child.

V. Conclusion

A consistent national agenda is needed to ensure that state-based newborn screening systems understand and keep pace with new technology. State policymakers and program managers should not be expected to make genetic screening policy decisions independent of substantial considerations for the privacy interests of newborns, parents and the general public. The process of setting a national agenda for

115 See, GAO MARCH 2003 REPORT, supra note 6.
117 Kolata, supra note 116, at A1. The panel also recommended “secondary targets,” conditions that are part of the core panel’s differential diagnosis and conditions that are “not appropriate for newborn screening,” because either no test is available or there is poor performance with regard to multiple other evaluation criteria such as efficacious treatment, understanding of the natural history and whether the test resulted to a clinically significant condition, for example. Id.
119 Id.
state newborn screening systems requires the involvement of experts in science, medicine, public health, law and ethics, as well as the contributions from a broad spectrum of public-at-large and government officials from the federal, state, and local level. As with all policy debates in the United States, everyone’s contribution is vital to increase awareness and understanding of the issues and implications resulting from these advances, all of which are necessary to stimulate the creation of a nationwide standard of newborn screening programs. These steps are always best taken in advance of and prior to establishment of any legislation with such potentially wide-reaching and invasive effects as found in those involved in genetic testing of individuals, newborn or otherwise.

The process for these deliberations must take into account the need for: education of the public; privacy concerns; confidentiality and discrimination; recent changes in the public health and health care delivery systems; the impact of new and increasingly rapid advances in science and technology; and the potential cost-effectiveness of revised policies and programs. Such a national agenda can serve as a guide for states seeking to strengthen their newborn screening systems, and provide more equitable access to this public health preventive program for all children born in the United States.

At a minimum, all state screening programs should reflect current technology and should test for the same disorders. Furthermore, parents should be informed about screening procedures and have the broad, if not unlimited, right to decline screening, as well as the right to keep the results private and confidential in perpetuity with knowledge that breaches of such privacy and confidentiality carry appropriate penalties for the mishandling parties. Parents must be informed about the benefits and risks associated with newborn screening. Finally, ample evidence exists to support the proposition that with proper education and informed consent, voluntary programs, like the one in Massachusetts provide a more than satisfactory mechanism for achieving the objectives of protecting the public welfare without abridging sacrosanct individual rights.