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ARTICLE

SCREENING AND TREATMENT OF NEWBORNS

*Ellen Wright Clayton**

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I. INTRODUCTION

With the advent of new genetic technologies and the Human Genome Initiative, interest in the problems posed by genetic diagnostics in general, and by genetic screening in particular, has surfaced. Many recent works focus on the problems posed by the "new genetics" in the contexts of prenatal diagnosis, carrier detection, employment, and insurance.¹ In the midst of all this discussion, the routine testing of newborns for genetic disorders 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 relative lack of concern about newborn screening is understandable. The fact that a routine test can detect diseases that could have serious consequences if untreated but which

1. Prominent examples in legal literature include MARK A. ROTHSTEIN, *MEDICAL SCREENING AND THE EMPLOYEE HEALTH COST CRISIS* 70-80 (1989); Lori B. Andrews & Ami S. Jaeger, *Confidentiality of Genetic Information in the Workplace*, 17 AM. J.L. & MED. 75 (1991); Jon Beckwith, *Foreword: The Human Genome Initiative: Genetics' Lightning Rod*, 17 AM. J.L. & MED. 1 (1991); Larry Gostin, *Genetic Discrimination: The Use of Genetically Based Diagnostic and Prognostic Tests by Employers and Insurers*, 17 AM. J.L. & MED. 109 (1991); Abby Lippman, *Prenatal Genetic Testing and Screening: Constructing Needs and Reinforcing Inequities*, 17 AM. J.L. & MED. 15 (1991); Dorothy Nelkin & Laurence Tancredi, *Classify and Control: Genetic Information in the Schools*, 17 AM. J.L. & MED. 51 (1991); *The Randolph W. Thrower Symposium: Genetics and the Law*, 39 EMORY L.J. 619 (1990) (including articles by Lori B. Andrews, George J. Annas, Alexander M. Capron, Rebecca S. Eisenberg, Louis J. Elsas, II, John C. Fletcher & Dorothy C. Wertz, and John A. Robertson, as well as a bibliography of genetics and the law). In scientific and medical literature, see NEIL A. HOLTZMAN, *PROCEED WITH CAUTION: PREDICTING GENETIC RISKS IN THE RECOMBINANT DNA ERA* (1989); Peter T. Rowley, *Genetic Screening: Marvel or Menace?*, 225 SCIENCE 138 (1984); Benjamin S. Wilfond & Norman Fost, *The Cystic Fibrosis Gene: Medical and Social Implications for Heterozygote Detection*, 263 JAMA 2777 (1990).

2. Alexander M. Capron, *Which Ills to Bear?: Reevaluating the "Threat" of Modern Genetics*, 39 EMORY L.J. 665, 689 (1990).

could be alleviated by early intervention³ makes the use of routine testing on newborns seem inevitable.⁴ A growing number of commentators applaud this practical exclusion of parents from the decision-making process and assert that newborn screening is so desirable that states should require it as a matter of law.⁵

This Article argues that society should resist efforts to require that newborns be tested for an ever-increasing number of conditions. Part II of this Article examines why interdisciplinary research is essential in developing appropriate laws governing newborn screening. Part III presents an overview of the screening process by describing not only what screening can and cannot do, but also the general organization of current programs. Part IV draws upon several different areas of discourse that suggest reason for concern. First, a large body of empirical research is presented that demonstrates that newborn screening causes psychological and other harm to infants and their families. These consequences have not previously been considered by legal commentators. Second, this section suggests that the diagnosis of disease in the neonatal period, regardless of accuracy, can have adverse social and legal consequences for families and children. Part IV finally considers the rather remarkable role of the state in this process and contends that state intervention, under the guise of public health, in domains traditionally reserved for the family is not justifiable under constitutional principles. This section recognizes that economic and political forces motivating the state's decision to undertake newborn screening raise questions about the desirability of the state as a major participant in these programs. Looking more to the future, Part V argues that focusing on biological, and particularly genetic, causes of disease can fundamentally alter the ways in which society thinks about the nature of disease and the allocation of responsibility for health among individuals and society. Part VI concludes that society should screen neonates only when children can

3. For example, a child with congenital hypothyroidism, who with treatment from infancy has normal intelligence rather than severe mental retardation, clearly receives a benefit.

4. See Capron, *supra* note 2, at 687 (noting that most states have enacted mandatory newborn screening requirements).

5. See, e.g., Ruth R. Faden, *Autonomy, Choice, and the New Reproductive Technologies: The Role of Informed Consent in Prenatal Genetic Diagnosis*, in *WOMEN AND NEW REPRODUCTIVE TECHNOLOGIES: MEDICAL, PSYCHOSOCIAL, LEGAL, AND ETHICAL DILEMMAS* 37, 45 (J. Rodin & A. Collins eds., 1991); John C. Fletcher & Dorothy C. Wertz, *Ethics, Law, and Medical Genetics: After the Human Genome is Mapped*, 39 *EMORY L.J.* 747, 790 (1990).

derive substantial benefit from early detection and that legislatures should amend existing laws to ensure that parents can participate in the screening process.

II. INTERDISCIPLINARY METHOD IN LAW AND MEDICINE

In attempting to decide what society should do about newborn screening, this Article draws upon a variety of disciplines, ranging from empirical research in the social sciences to health policy, politics, and doctrinal legal analysis. An initial question that the reader may ask is whether the person who attempts to address a social problem through legal means can legitimately use this array of material. In response, this Article will demonstrate why a rigorous empirical understanding of the impact of medical practices on individuals and institutions as well as an appreciation of the historical and political forces that led to the formation and maintenance of those practices is essential to the development of appropriate legal rules governing newborn screening.

Law is not a self-sufficient enterprise existing in a vacuum, if for no other reason than that the object under discussion is usually something other than the law itself. Lawyers generally talk about business, medicine, and the family but rarely reflect on their own enterprise. In dealing with these other fields, lawyers can take one of two positions. They can either adopt the traditional position of an observer, using the techniques of the law to analyze the object field or to address the problems that it generates, or they can engage in a dialogue with the participants in the field of interest.

The last forty years have been labelled the period of "[l]aw and . . . ," in which scholars have explicitly recognized the relation of law to other disciplines.⁶ From the beginning, some members of the legal "academy"—ranging from those who studied law and society using the principles of sociology in developing a generally liberal legal agenda⁷ to the proponents of law and economics, who often operated at the other end of the philosophical and political spectrum⁸—engaged in a rich dis-

6. See generally Arthur A. Leff, *Law and*, 87 YALE L.J. 989 (1978).

7. See, e.g., David M. Trubek, *Back to the Future: The Short, Happy Life of the Law and Society Movement*, 18 FLA. ST. U. L. REV. 4, 6 (1990).

8. This is not to say that all those who use the tools of law and economics are necessarily political conservatives. See, e.g., Ian Ayres, *Fair Driving: Gender and Race Discrimination in Retail Car Negotiations*, 104 HARV. L. REV. 817 (1991). However, certainly the majority of its most vocal founders and advocates have that political leaning. See, e.g., RICHARD A. POSNER, *ECONOMIC ANALYSIS OF LAW* (3d ed.

course that led to true cross-fertilization of the disciplines involved. Thus, the methodology of one field has genuinely affected that of the other. More recently, the law and literature movement has brought interpretive methods to bear on fundamental legal concepts and doctrines.⁹ In turn, literary critics have begun to write about the law and to draw on legal concepts with increasing frequency.¹⁰ Similar connections are being forged in critical legal studies,¹¹ critical race theory,¹² and law and feminism.¹³

Given the vitality and variety of interdisciplinary work found within the legal community, it is surprising that researchers in other "law and . . ." disciplines have not engaged in this sort of interactive dialogue but, instead, have continued to operate in a more traditional, unidirectional mode in which a master discourse scrutinizes a domain of objects. This form of analysis is particularly characteristic of much of the scholarship in law and medicine.¹⁴ Thus, the legal analyst typically approaches a particular medical topic using traditional legal theories and categories. The lack of dialogue between law and medicine may be due in part to the strength and insularity of the medical profession, particularly in the 1960s and 1970s, which led its members to feel no need to talk with others. The social and political power of the legal profession may also explain some of the hostility that physicians, who are accus-

1986).

9. See generally INTERPRETING LAW AND LITERATURE: A HERMENEUTIC READER (Sanford Levinson & Steven Mailloux eds., 1988).

10. Ellen W. Clayton & Jay Clayton, *Afterword: Voices and Violence—A Dialogue*, 43 VAND. L. REV. 1807, 1812 (1990).

11. See generally MARK KELMAN, A GUIDE TO CRITICAL LEGAL STUDIES (1987).

12. See generally DERRICK BELL, AND WE ARE NOT SAVED: THE ELUSIVE QUEST FOR RACIAL JUSTICE (1987); Richard Delgado, *Words that Wound: A Tort Action for Racial Insults, Epithets, and Name-Calling*, 17 HARV. C.R.-C.L. L. REV. 133 (1982); Patricia J. Williams, *Alchemical Notes: Reconstructing Ideals from Deconstructed Rights*, 22 HARV. C.R.-C.L. L. REV. 401 (1987).

13. There is a growing body of literature exploring feminist legal theory. See, e.g., Patricia A. Cain, *Feminist Jurisprudence: Grounding the Theorics*, 4 BERKELEY WOMEN'S L.J. 191 (1989-90); Christine A. Littleton, *Equality and Feminist Legal Theory*, 48 U. PITT. L. REV. 1043 (1987); Ann C. Scales, *The Emergence of Feminist Jurisprudence: An Essay*, 95 YALE L.J. 1373 (1986); Patricia A. Tidwell & Peter Linzer, *The Flesh-Colored Band Aid—Contract, Feminism, Dialogue, and Norms*, 28 HOUS. L. REV. 791 (1991); Robin West, *Feminism, Critical Social Theory and Law*, 1989 U. CHI. LEGAL F. 59.

14. See, e.g., Jon R. Waltz & Carol R. Thigpen, *Genetic Screening and Counseling: The Legal and Ethical Issues*, 68 NW. U. L. REV. 696 (1973). There have, however, been some notable exceptions to this trend. See, e.g., JAY KATZ, THE SILENT WORLD OF DOCTOR AND PATIENT (1984) (drawing on a wide array of material, ranging from philosophy and history to the insights of psychoanalysis, in his examination of informed consent).

tomed to a dominant position within their domain, feel when lawyers make incursions into their realm.

One result of the more traditional approach was that almost no attention was given to the pressures felt by the participants in the medical field, the practical constraints that they faced, or their perceptions of what was happening. Research and discourse in the medical field itself was often ignored, or at best, relegated to the footnotes. To the extent that law professors writing about law and medicine consider the experiences of those in the medical field, their attention generally extends only to the views expressed by its leaders, typically physicians. This focus is to be expected because physicians publish articles in highly prestigious and relatively accessible journals such as the *New England Journal of Medicine* and the *Journal of the American Medical Association*. Nurses and other ancillary health care providers publish their experiences, if at all, in less well-known journals. Patients' experiences almost never get into print.¹⁵ Correspondingly, law professors and practitioners publish in law reviews, a forum to which the objects of the discussion—nurses, doctors, psychologists, and certainly patients—generally do not have access in the ordinary course of their activities.

A typical example of an article employing the traditional approach is Jon R. Waltz and Carol R. Thigpen's *Genetic Screening and Counseling: The Legal and Ethical Issues*.¹⁶ The authors provide a masterful discussion of the constitutional, legislative, and common law constraints governing mandatory and voluntary genetic screening and counseling of adults.¹⁷ They discuss ways in which compulsory screening and limitations on marriage or reproduction might fail to pass constitutional scrutiny.¹⁸ In their discussion, the authors note, as a practical matter, that screening and counseling inevitably fail to prevent much genetic disease.¹⁹ They also demonstrate

15. A few patients and their families are beginning to tell their stories. See, e.g., NORMAN COUSINS, ANATOMY OF AN ILLNESS AS PERCEIVED BY THE PATIENT: REFLECTIONS ON HEALING AND REGENERATION (1979); MARTHA W. LEAR, HEARTSOUNDS (1980). Notably, even these persons are ones who, for other reasons, are relatively empowered in the society. As Sandra Harding has pointed out, "[n]o one expected the 'natives' to write books about the anthropologists or sociologists (let alone be expected to sit on their tenure and promotion committees)." SANDRA HARDING, WHOSE SCIENCE? WHOSE KNOWLEDGE? THINKING FROM WOMEN'S LIVES 132 (1991).

16. 68 NW. U. L. REV. 696 (1973).

17. See *id.*

18. See *id.* at 709-13.

19. See *id.* at 712-13.

the difficulties encountered in appointing an appropriate group of experts to establish criteria for these sorts of programs.²⁰ Although some of the legal doctrines applied in the article have undergone major change in the intervening years,²¹ the traditional legal framework applicable to issues of adult screening and counseling has not substantively changed.²² For example, people still routinely talk about the problems of confidentiality associated with the revelation of genetic information²³ or about whether a child born with a genetic disorder has suffered a legally cognizable injury because her parents were not given appropriate information.²⁴

One element lacking in the Waltz and Thigpen article, and many other similar articles, is consideration of the subjective experience of being or not being screened and counseled. It is one thing for Waltz and Thigpen to discuss how statutes preventing marriage between people at risk of having a child with sickle cell anemia might be based on suspect racial classifications.²⁵ It is entirely another to explore what it means to be told that you cannot marry the person you love. It is one thing to ask whether parents—who have a child with a genetic disorder because they were not warned—should have their damages offset by the joy of having a child, by their failure to mitigate their damages, by giving the child up for adoption, or by having a late abortion.²⁶ It is entirely another to explore what it means to the parents of a child who is severely handicapped to go into court and say, "We did not want this child;

20. See *id.* at 776-79.

21. Some courts, for example, now allow children with genetic disorders to assert so-called "wrongful life" claims, alleging that they were injured when their parents were denied the opportunity to prevent their birth, even though no courts permitted such claims 20 years ago. Compare *Gleitman v. Cosgrove*, 227 A.2d 689 (1967) (denying claims by both the parents and the child) with *Procanik v. Cillo*, 478 A.2d 755 (1984) (permitting the child to assert a limited claim).

22. The biggest change is the increasing attention being devoted to the impact of disability, culminating in the passage of the Americans with Disabilities Act of 1990, Pub. L. No. 101-336, 104 Stat. 327 (codified in scattered sections of 29 U.S.C.A., 47 U.S.C.A., and 42 U.S.C.A.).

23. Waltz & Thigpen, *supra* note 14, at 731-32, 746-49; see, e.g., Andrews & Jaeger, *supra* note 1; Andrea DeGorgey, Note, *The Advent of DNA Databanks: Implications for Information Privacy*, 16 AM. J.L. & MED. 381 (1991).

24. Waltz & Thigpen, *supra* note 14, at 759-67; see, e.g., Michael B. Kelly, *The Rightful Position in "Wrongful Life" Actions*, 42 HASTINGS L.J. 505 (1991); Melinda A. Roberts, *Distinguishing Wrongful from "Rightful" Life*, 6 J. CONTEMP. HEALTH L. & POL'Y 59 (1990).

25. See Waltz & Thigpen, *supra* note 14, at 713-15 (citing *Griswold v. Connecticut*, 381 U.S. 479 (1965), and *Loving v. Virginia*, 388 U.S. 1 (1967), to illustrate the Supreme Court's reluctance to uphold laws that interfere with marriage relationships, particularly when the laws disproportionately impact suspect classifications).

26. See Waltz & Thigpen, *supra* note 14, at 753-55.

her existence is nothing but a burden to us," praying that the child never learns that these words were uttered. Thus, although traditional legal analysis contributes much to how society thinks about the problems posed by genetic screening and counseling, the way in which it defines the issues is incomplete. In particular, legal discourse does not attend to the subjective experience of children and their parents, primarily because it has not developed research methods which give it access to this data.²⁷ As a result, the law gives insufficient weight to the personal, even intimate, implications of this information. What is needed is a new "law and genetics" discipline that attends specifically to the impact of this knowledge.

Fortunately, several interdisciplinary projects can provide models for the kind of work generally needed in law and medicine. The proponents of practice theory, for example, describe ways in which people use particular strategies and practices in their daily lives to evade the constraints of social institutions and formal rules.²⁸ Further anthropological inquiries can provide insights on the tactics patients use, for instance, to avoid obeying "doctors' orders."

Moreover, attending to the particular is already a central part of several discourses within the legal community. Some strands of law and feminism, as well as other forms of "outsider jurisprudence,"²⁹ base themselves on the premise that paying attention to individual, subjective experience is important.³⁰ One can achieve some understanding of subject-

27. Cf. Scales, *supra* note 13, at 1373 (noting the law's traditional dependence on abstract, objective, and universal solutions to social problems).

28. See, e.g., PIERRE BOURDIEU, *OUTLINE OF A THEORY OF PRACTICE* 16-22 (Richard Nice trans., 1977) (arguing for a theory of scientific practice that addresses the gap between sociological constructs and ethnological particularities); MICHEL DE CERTEAU, *THE PRACTICE OF EVERYDAY LIFE* 34-39 (Steven F. Rendall trans., 1984) (describing the unpredictable "trajectories" of individual behavior that cross the boundaries of the ordered social systems in which they operate).

29. Mari Matsuda uses this term to describe the body of literature that raises the voices of groups who have traditionally been excluded from jurisprudential discourse such as women, African Americans, Native Americans, and Hispanic Americans. Mari J. Matsuda, *Public Response to Racist Speech: Considering the Victim's Story*, 87 MICH. L. REV. 2320, 2323 n.15 (1989).

30. See, e.g., CAROL GILLIGAN, *IN A DIFFERENT VOICE: PSYCHOLOGICAL THEORY AND WOMEN'S DEVELOPMENT* 173-74 (1982) (noting that an understanding of the subjective experience of women will significantly expand the current perspective on human development); Christine A. Littleton, *Women's Experience and the Problem of Transition: Perspectives on Male Battering of Women*, 1989 U. CHI. LEGAL F. 23, 24-25 (defining feminism as a theory and practice based on the subjective experience of women); Matsuda, *supra* note 29, at 2323-24 (stating that the jurisprudence of people of color uses a "methodology grounded in the particulars of their social reality and experience," and frequently requires reference to previously ignored historical sources).

tive experiences in a number of ways, including practical reasoning,³¹ storytelling,³² and consciousness-raising.³³ Focusing on the particular acknowledges and takes into account inconsistencies, positionality, stereotypes, and individual moral and political choices.³⁴ For feminist legal theorists, attentiveness to personal experience also matters because the deeper appreciation of the context of individual actors suggests ways in which the law ought to work differently.³⁵ Indeed, these writers reject the validity of theory not situated in the particular. As one commentator recently wrote, "[w]e need fewer abstract theoretical typologies and more historically and empirically grounded analyses."³⁶

Law and medicine would also profit from close historical and sociological analyses of the ways that health care institutions came into being. Some studies have already demonstrat-

31. See Katherine T. Bartlett, *Feminist Legal Methods*, 103 HARV. L. REV. 829, 849-58 (1990) (defining and discussing the use of feminist practical reasoning as a method of incorporating individual experience into legal paradigms).

32. See Richard Delgado, *Storytelling for Oppositionists and Others: A Plea for Narrative*, 87 MICH. L. REV. 2411, 2414 (1989) (noting how stories build a common culture of shared understandings). See generally Symposium, *Legal Storytelling*, 87 MICH. L. REV. 2073 (1989).

33. See CATHARINE A. MACKINNON, TOWARD A FEMINIST THEORY OF THE STATE 84-87 (1989) (defining consciousness-raising as the process by which an oppressed group shatters the world's view of its existence and projects its own image, based on subjective experience, onto history); Scales, *supra* note 13, at 1402 (describing how consciousness-raising validates individual experience and is essentially a process of self-creation).

34. See Bartlett, *supra* note 31, at 849-62 (discussing how feminist practical reasoning embraces these ambiguities without attempting to resolve them).

35. For example, understanding the position of women has led to pressure to change the law relating to marital rape, the battered women's defense to murder, and the treatment of women in the workplace. See, e.g., CATHARINE A. MACKINNON, SEXUAL HARASSMENT OF WORKING WOMEN: A CASE OF SEX DISCRIMINATION 22-55 (1979) (discussing how women's subjective experiences of sexual harassment should inform the law); Rene I. Augustine, *Marriage: The Safe Haven for Rapists*, 29 J. FAM. L. 559, 562-64 (1990-91) (discussing reform in the area of the marital rape exemption); Susan Estrich, *Sex at Work*, 43 STAN. L. REV. 813, 861 (1991) (attributing advancements in the doctrines supporting sexual harassment actions to the fact that women are beginning to speak out about their individual experiences); Littleton, *supra* note 30, at 25-27 (describing how feminist jurisprudence refuses to accept the current outlines of established law and identifying battering as an area where the subjective experience of women is often distorted); Elizabeth M. Schneider, *The Dialectic of Rights and Politics: Perspectives from the Women's Movement*, 61 N.Y.U. L. REV. 589, 642-48 (1986) (identifying feminist thought and the revelation of women's subjective experiences as catalysts of reform in the area of sexual harassment and the treatment of battered women under the law); Note, *To Have and To Hold: The Marital Rape Exemption and the Fourteenth Amendment*, 99 HARV. L. REV. 1255, 1272-73 (1986) (connecting reform of the marital rape exemption with a strong focus on the individual experiences of women).

36. DEBORAH L. RHODE, JUSTICE AND GENDER: SEX DISCRIMINATION AND THE LAW 317 (1989).

ed that the health care delivery system and the medical profession did not always occupy their current powerful status but rather rose to their positions through a series of political and social actions.³⁷ The recognition that these institutions were not "natural" or inevitable makes it easier to think about change and about techniques that might be used to achieve reform.

This Article looks at the experiences of those who have participated in newborn screening, both by being screened and by establishing and running the screening programs. In particular, it relies heavily upon previous empirical work studying the responses of children and their families to screening. The empirical studies give only a partial picture because of the limitations of questionnaire designs and psychological testing. Furthermore, the investigators are all health care providers, academics, and psychologists who necessarily view the families through the lens of their own social and personal experiences.³⁸ In addition, much of the work was done in Europe, thus raising the issue of cross-cultural differences³⁹ as well as the confounding impact of different systems of health insurance and access to health care.⁴⁰ Nonetheless, this work does give some insight into how these programs actually feel to those they touch, enabling the voices of the subjects to be heard in

37. See, e.g., KATZ, *supra* note 14, at 30-47 (tracing physicians' historical quest for political power, freedom from legislative intervention, and dominion in the physician-patient relationship); PAUL STARR, *THE SOCIAL TRANSFORMATION OF AMERICAN MEDICINE* 17-30 (1982) (discussing the historical development of professional authority and economic control as a result of changes within the medical profession).

38. Recent feminist critiques, both inside and outside of science, have pointed out that no such thing as "objective" analysis exists. The fact that an investigator must choose which problems to study and which variables to consider demonstrates that the observations are made from a point-of-view and thus raises the possibility that things might look different if approached from a different perspective. While acknowledging that the nature of the human psyche requires that all factors cannot be taken into account, these critics demand that a more contextual approach be used, in which the situations of both the observer and the observed are recognized. See HARDING, *supra* note 15.

39. Just as feminism has come to acknowledge, however painfully, that it initially spoke with the voice of the white, upper-middle class, well-educated, heterosexual woman and that the voices of differently situated women were excluded, see, e.g., Kimberle Crenshaw, *Demarginalizing the Intersection of Race and Sex: A Black Feminist Critique of Antidiscrimination Doctrine, Feminist Theory and Antiracist Politics*, 1989 U. CHI. LEGAL F. 139, law and medicine needs to recognize that the experience of one patient may not be fully generalizable to that of others.

40. This actually cuts both ways. Sweden, a site for many of the studies, has universal health care so that the cost of treatment should not be an issue. In contrast, some say that prenatal diagnosis and abortion of fetuses with beta-thalassemia is common in Ferrara and Cyprus in part because the difficulty of obtaining and paying for adequate health care for affected children is practically insurmountable.

the formulation of legal rules. Moreover, the more formal nature of this work adds an element of rigor that strengthens and complements the contributions made by those involved in "empathy jurisprudence," a branch of legal inquiry which attempts to hear previously muted voices. After considering this disparate body of work to situate the participants in the screening process, this Article examines legal rules involving screening and presents suggestions for ways those rules should work.

III. WHAT IS NEWBORN SCREENING?

First, it is important to understand what newborn screening is and how screening programs are organized.⁴¹ Newborn screening involves the analysis of a child's blood—or, less commonly, urine or stool—to look for abnormal levels of enzymes, metabolites, or other chemicals.⁴² If an abnormal result occurs, the test is repeated or further testing is performed to reach a diagnosis.⁴³

There are two major reasons for newborn screening. The first is a practical one. Given the fragmented nature of American health care and the fact that virtually all children in this country are born in a hospital or some other health care facility, the newborn period is the easiest time to perform such testing. The second is that there are a number of diseases or inborn errors of metabolism that have severe consequences for the affected child unless treatment is initiated in the newborn period.⁴⁴ It was for this group of diseases that newborn

41. Screening is also used increasingly by employers, to keep high-risk individuals out of the workplace in order to avoid paying future health care costs, and by insurers, in order to exclude people who predictably will die early or will incur unusually high health care costs. ROTHSTEIN, *supra* note 1, at 6, 205-10; see Andrews & Jaeger, *supra* note 1, at 104 (stating that genetic screening can be used to deny work and insurance to employees or prospective employees); Gostin, *supra* note 1, at 134-35 (discussing the potential for genetic screening to lead to discrimination in employment and insurance). These practices raise issues that cannot be fully disclosed within the confines of this Article. It is worthwhile to point out, however, that screening by employers and insurers does not present a monolithic set of problems, in part because the consequences differ. It is one thing to be excluded from a particular job, especially if it is the only or highest-paying work in town, another to be denied health insurance, which has come in our society to be viewed as a way to spread risk in obtaining access to health care, a good that is viewed as fundamental, and yet another to be denied life insurance, which is basically a way of saving money.

42. See Louis J. Elsas, II, *Newborn Screening*, in RUDOLPH'S PEDIATRICS 281, 281 (Abraham M. Rudolph et al. eds., 19th ed. 1987).

43. See *id.* at 282.

44. See Elsas, *supra* note 42, at 281 (noting that one goal of newborn screening

screening was originally instituted.⁴⁵ Later, newborn screening was expanded to include additional disorders that were neither as harmful nor so amenable to treatment.⁴⁶

The first issue then that must be explored in evaluating newborn screening is the clinical implications for the child of an abnormal screening test. At the most basic level, the presence of any abnormal test result merely indicates that the child deviates in some way from the general population.⁴⁷ Whether the deviation is clinically significant is another matter. In some instances, an abnormal test result means that the child is or may become ill.⁴⁸ In other cases, the deviation is virtually meaningless because the child with such an "abnormality" will experience no noticeable illness at all.⁴⁹

It must also be acknowledged that abnormal test results often do more than create the opportunity to intervene to prevent clinical deterioration in the condition of the affected child. In particular, since many of the disorders detected are genetically inherited, diagnosing the disorder provides information about the genetic makeup of both the child and the parents.⁵⁰

is the prevention of mental retardation and other irreversible clinical manifestations through the discovery of metabolic disorders).

45. See Neil A. Holtzman et al., *Issues in Antenatal and Neonatal Screening and Surveillance for Hereditary and Congenital Disorders*, 2 ANN. REV. PUB. HEALTH 219, 219 (1981); Rowley, *supra* note 1, at 138.

46. See Elsas, *supra* note 42, at 281 (noting that selective screening for diseases that may not be preventable is utilized with the aim of providing amelioratory treatment and genetic counseling). Screening is becoming increasingly common. For example, young children routinely have their blood lead levels and hematocrits checked and are tested for tuberculosis. AMERICAN ACADEMY PEDIATRICS, GUIDELINES FOR HEALTH SUPERVISION II (2d ed. 1988).

47. The test result can also be simply incorrect. Refer to note 82 *infra* and accompanying text.

48. For example, a positive test for bacteria in the spinal fluid indicates that a child has meningitis. Jay Tureen, *Meningitis*, in RUDOLPH'S PEDIATRICS, *supra* note 42, at 559-60. A child showing unusually high blood pressure has a greater risk of developing heart disease. Norman M. Kaplan, *Systemic Hypertension: Mechanisms and Diagnosis*, in 1 HEART DISEASE: A TEXTBOOK OF CARDIOVASCULAR MEDICINE 819, 821-23 (Eugene Braunwald ed., 3d ed. 1988).

49. See FRIEDRICH VOGEL & ARNO G. MOTULSKY, HUMAN GENETICS: PROBLEMS AND APPROACHES 626 (2d ed. 1986) (stating that a positive screening test for phenylketonuria does not mean that the child will suffer from mental retardation if the child in fact has only hyperphenylalaninemia).

50. For example, each parent of a child with phenylketonuria (PKU) has the gene for this autosomal recessive trait. Therefore, the couple has a one in four chance of producing another child with PKU. VOGEL & MOTULSKY, *supra* note 49, at 617, 626-27. An autosomal trait arises from the expression of genetic information found on a chromosome other than sex chromosomes. TABER'S CYCLOPEDIA MEDICAL DICTIONARY A-146 (Clayton L. Thomas ed., 12th ed. 1973). An autosomal recessive trait will only express itself when the chromosomes inherited from the parents each contain the mutated gene for that trait. VOGEL & MOTULSKY, *supra* note 49, at 116. Therefore, other parents will be at risk for having a child with PKU, but will not

At present, however, the amount of genetic information provided by newborn screening has typically been relatively small. Two developments, one already in place and the other on the horizon, will change the amount of genetic risk information that can be generated by newborn screening. The first is the availability of tests that can distinguish intermediate abnormal blood levels. Currently, the best example of this type of test is hemoglobin electrophoresis, the test used to detect sickle cell anemia (SCA), a disease caused by the presence of two abnormal genes in red blood cells.⁵¹ Parents of a child with SCA have a one-in-four chance in each succeeding pregnancy of having another child with SCA. Electrophoresis, however, also detects a child who has only one copy of the abnormal gene, a condition known as sickle cell trait, which causes little, if any, morbidity. The birth of a child with this trait, which is of no particular significance to the child's medical needs, is potentially meaningful to the parents because it may indicate that they are at risk of having a child with SCA.⁵² Because many more children are born with sickle cell trait than with sickle cell anemia, the amount of genetic information that electrophoresis provides is much greater than that from tests which detect only children with two mutant genes. But even though tests like hemoglobin electrophoresis provide genetic information which draws finer distinctions, such tests are simply a refinement of more traditional "phenotype" tests which look for abnormal levels of proteins or other metabolites, the final gene products.

The second and more radical development is genotype testing which involves techniques, currently either contemplat-

know this until they first have an affected child.

Other patterns of inheritance are X-linked recessive, autosomal dominant, and multifactorial. In X-linked recessive disorders, expression of disorders occurs only when all X chromosomes have the mutant gene (examples include Duchenne muscular dystrophy and hemophilia). *Id.* at 119-20, 616. Therefore, the disorder is apparent if a boy has one mutant gene or if a girl has two mutant genes. For an autosomal dominant trait to be expressed, only one mutant gene is necessary (examples include Huntington's disease and myotonic dystrophy). *Id.* at 112-114, 616. Multifactorial disorders depend upon the interaction of multiple genetic, environmental, and behavioral factors. *Id.* at 186. Multifactorial seems to be characteristic of most of the "chronic" disorders in our society, such as heart disease. *See id.* at 223.

51. See Roland B. Scott & Joy H. Samuels-Reid, *Sickle Cell Disease*, in 13 CURRENT PEDIATRIC THERAPY 241, 241 (Sydney S. Gellis & Benjamin M. Kagan eds., 1990) (discussing the use of electrophoresis to detect sickle cell disease).

52. In most cases in which a child is born with sickle trait, one parent will have the trait and the other will not. These parents have no risk of having a child with SCA. In some cases, a child with sickle trait is born to parents who both have sickle trait. These parents have a 25% chance with each succeeding pregnancy of having a child with SCA.

ed or in progress, that look directly at the newborn's genes. While this genotype testing will not replace phenotype testing,⁵³ it will allow the detection of diseases or traits, such as Huntington's disease, that could manifest later in life but that have no detectable abnormalities in the newborn period.⁵⁴ Moreover, this sort of testing will necessarily provide information about the genetic makeup of the parents of any child tested.

Newborn screening is remarkable not only because of the information it reveals but also because of who is doing the testing. In most medical settings, screening becomes a part of standard medical practice as physicians decide that a particular test ought to be offered or performed.⁵⁵ Pediatricians, for example, as part of routine health maintenance, determine how well children can see and hear. By contrast with this physician-driven model, the state almost always performs newborn screening.⁵⁶

These state-run newborn screening programs differ from one another in the source of their authority. In some states, the legislature specifies the tests to be performed.⁵⁷ In others, the legislature delegates the authority to develop screening programs to other institutions, most frequently departments of

53. Genotype testing is much more costly than the screening that is currently performed. Many genetic diseases can be caused by any of a host of mutant genes or alleles. For example, there are at least ten different alleles that cause PKU. Genome testing for PKU would require ten or more different tests rather than the one, simple Guthrie inhibition assay. See Yoshiyuki Okano et al., *Molecular Basis of Phenotypic Heterogeneity in Phenylketonuria*, 324 NEW ENG. J. MED. 1232 (1991); Charles R. Scriver, *Phenylketonuria—Genotypes and Phenotypes*, 324 NEW ENG. J. MED. 1280 (1991).

54. VOGEL & MOTULSKY, *supra* note 49, at 616.

55. In some instances, official bodies like the American Academy of Pediatrics or the American College of Obstetrics and Gynecology promulgate guidelines. In other instances, individual practitioners may adopt certain tests in response to reports in literature or to lobbying by manufacturers. Once a large number of physicians adopt the test, its use becomes the standard of care, and failure to test may give rise to malpractice liability.

56. A growing number of private laboratories and institutions are developing newborn screening programs to test for diseases that are not currently being sought by the state. Interview with Benjamin Wilfond, Assistant Professor of Pediatrics, University of Arizona (June 1, 1991) (discussing a newborn screening program in Pittsburgh).

57. See, e.g., COLO. REV. STAT. ANN. § 25-4-1004(b) (West Supp. 1991) (requiring testing for PKU, hypothyroidism, abnormal hemoglobins, galactosemia, homocystinuria, maple syrup urine disease, cystic fibrosis, and biotinidase deficiency); GA. CODE ANN. § 31-12-6(a) (Michie 1991) (allowing testing for PKU, galactosemia, tyrosinemia, maple syrup urine disease, homocystinuria, hypothyroidism, and congenital adrenal hyperplasia); N.Y. PUB. HEALTH LAW § 2500-a(a) (McKinney Supp. 1992) (requiring testing for PKU, homozygous sickle cell disease, hypothyroidism, branched-chain ketonuria, galactosemia, and homocystinuria).

public health.⁵⁸ Even when the legislature takes a direct role, the statutes are usually quite simple in structure, occupying at most a few sections. Some states conduct screening programs even though they have no enabling legislation.⁵⁹

The states also vary in whether they allow parents to opt out of screening, and if so, what reasons suffice. In some states, parents can refuse testing only for religious reasons;⁶⁰ in others, any reason for objecting will do.⁶¹ Almost no state legislatures require parents to provide their informed consent to screening,⁶² despite the formal recognition that screening receives in other medical settings.

Despite these variations, once in place the programs have similar formats. Newborns have their blood drawn while in the hospital, usually by heel prick, and collected on cards with filter paper.⁶³ These cards are then sent to the state department of health where the department either performs the tests itself or subcontracts with private laboratories or, more commonly, with other states' laboratories.⁶⁴ Here the uniformity breaks down as states vary widely in their procedures for follow-up in the event of an abnormal test result.

Newborn screening can then be seen as a subset of the

58. Many states use committees to advise their health departments how to run state screening programs. See, e.g., FLA. STAT. ANN. § 383.14(z) (West Supp. 1992) (providing for promulgation of rules by the Department of Health and Rehabilitation Service in conjunction with the Genetics and Infant Screening Advisory Council); MD. HEALTH-GEN. CODE ANN. § 13-103 (1990) (establishing a State Commission on Hereditary and Congenital Disorders).

59. Delaware, North Carolina, Vermont, and the District of Columbia do not have enabling statutes but do have state-run screening programs. See OFFICE OF TECHNOLOGY ASSESSMENT, U.S. CONGRESS, HEALTHY CHILDREN: INVESTING IN THE FUTURE 93-94 (1988) [hereinafter HEALTHY CHILDREN].

60. E.g., TENN. CODE ANN. § 68-5-403 (1987); WIS. STAT. ANN. § 146.02(3) (West 1989); see also LORI B. ANDREWS, MEDICAL GENETICS: A LEGAL FRONTIER 238 n.168 (1987) (collecting such statutes).

61. See, e.g., FLA. STAT. ANN. § 383.14(4) (West Supp. 1992) (providing that a parent's or guardian's unqualified objection suffices to prevent any testing required by the statute); N.M. STAT. ANN. § 24-1-6(A) (Michie 1991) (not requiring parents or guardians to state any reason when they waive tests which the statute requires).

62. Wyoming's state statute is the only statute that mentions informed consent. See WYO. STAT. ANN. § 35-4-801(c) (Michie Supp. 1991) (stating that informed consent of the child's parents "shall be obtained" prior to testing and that the child is exempt from mandatory testing if his or her parent objects).

63. See Elsas, *supra* note 42, at 282. These pieces of filter paper contain information identifying the infant. *Id.* Blood is placed on the filter paper and allowed to dry. Small pieces of the paper with the dried blood are then punched out and used for testing. *Id.*

64. See William J. Callan & Paige L. Mitchell, *Newborn Screening Laboratory Concerns: 1986*, in ADVANCES IN NEONATAL SCREENING 565, 565 (Bradford L. Therrell, Jr. ed., 1987) (noting that most private or state laboratories which perform newborn screening are located in or associated with state health departments).

testing that goes on throughout medicine. Yet medical testing raises issues that are addressable in legal terms—questions, for example, of the implications of the test that goes awry, of confidentiality,⁶⁵ of who decides what to look for,⁶⁶ and of whether to test at all. Even if these dilemmas are rarely litigated in the context of newborn screening, they are important for their own sake as well as for the formation of rules that limit the ways that individuals and institutions act. There are three aspects of newborn screening—who is being tested, what information is and can be generated, and who is doing the testing—that distinguish it from other sorts of medical testing and make the elaboration of principles to control its use even more pressing. The next section explores these distinguishing characteristics in greater depth and points out some of the broader implications of newborn screening. Only after attaining a more complete appreciation of newborn screening can appropriate legal rules be devised.

IV. THE PLAYERS AND THE STAKES

A. *The Children*

1. *Treatment of newborns and limitations of screening.* Screening can confer a very substantial benefit on newborns who are appropriately identified by the process.⁶⁷ But

65. See Waltz & Thigpen, *supra* note 14, at 746-49 (discussing the types of confidentiality problems that could arise in the genetic screening context).

66. See *id.* at 701-08 (analyzing governmental involvement in sickle cell screening programs and whether such involvement is justified).

67. For example, a child with PKU or congenital hypothyroidism who begins treatment early can grow up with normal intelligence rather than severe mental retardation. See, e.g., HEALTHY CHILDREN, *supra* note 59, at 94-95 (presenting information about the effectiveness of newborn screening and treatment for PKU, congenital hypothyroidism, and other congenital disorders); Ron Aronson et al., *Growth in Children with Congenital Hypothyroidism Detected by Neonatal Screening*, 116 J. PEDIATRICS 33, 36 (1990) (reporting results of a study that confirmed that early detection and treatment of congenital hypothyroidism prevents retardation of growth); Anne E. Dzanne et al., *Speech and Language Skills in Children with Early Treatment Phenylketonuria*, 94 AM. J. MENTAL RETARDATION 625, 629-30 (1990) (reporting that children with early treated PKU did not exhibit speech or language disorders); Sonja Heyerdahl et al., *Intellectual Development in Children with Congenital Hypothyroidism in Relation to Recommended Thyroxine Treatment*, 118 J. PEDIATRICS 850, 854 (1991) (discussing the results of a study that demonstrated a positive correlation between early high levels of serum thyroxine and higher mental development scores in children with congenital hypothyroidism); New England Congenital Hypothyroidism Collaborative, *Elementary School Performance of Children with Congenital Hypothyroidism*, 116 J. PEDIATRICS 27, 30 (1990) (indicating that hypothyroid children who receive early treatment have no significant specific learning impedi-

for a variety of reasons, newborn screening may not always provide such clear benefits. To begin with, problems can accompany even the identification of "true positives"—those individuals who truly have abnormal results. In these cases, making a diagnosis does no more than provide data regarding the prevalence of the disorder within the population unless the result is provided to the parents and physicians of the affected child.⁶⁸ Following up screening results has been a problem since the advent of newborn screening. Despite the aggressive measures adopted by some states,⁶⁹ programs still report serious problems with getting children into treatment early enough to avert harm.⁷⁰

Moreover, the ability to make an early diagnosis does not necessarily mean that the disease entails significant morbidity or that fully effective therapy is available. The two diseases most commonly screened for in the United States—phenylketonuria (PKU) and congenital hypothyroidism—are, in many ways, paradigms of desirable targets of newborn screening. Both lead to severe mental retardation which is largely avoidable through early medical intervention. The fact that effective therapy exists, however, does not mean that it is actually accessible to the children who need it. For example, the special diet needed to avoid the adverse sequelae of PKU is costly, onerous for the family to administer, and is often not covered by private insurance or supplied by the state.⁷¹

ments unrelated to overall IQ). Studies also show that, even with treatment, some affected children do not develop normally. See Colleen B. Azen et al., *Intellectual Development in 12-year-old Children Treated for Phenylketonuria*, 145 AM. J. DISEASES CHILDREN 35, 35, 38 (1991) (indicating that, for children with PKU, arithmetic was an area of cognitive functioning for which maintaining dietary control had no apparent beneficial effect).

68. For example, the child with congenital hypothyroidism will suffer from the ill effects of the disease unless someone ultimately tells the parents to give the child thyroid hormone. See HEALTHY CHILDREN, *supra* note 59, at 94-95 (noting the cause of, recommended treatment of, and effects of treatment and nontreatment of congenital hypothyroidism).

69. In California, the state first notifies the child's private physician when testing reveals hemoglobin disease. Deborah Hurst, *Northern California's Experience*, 83 PEDIATRICS 868, 868 (1989). If the family does not respond, the state will contact the family directly, occasionally turning to the police and child protective services. *Id.*

70. See Scott T. Miller et al., *Newborn Screening for Sickle Cell Disease: When is an Infant 'Lost to Follow-up'?*, 144 AM. J. DISEASES CHILDREN 1343, 1344 (1990) (noting the failure of several state programs to provide for adequate follow-up after screening); see also Robert Listernick et al., *Delayed Diagnosis of Infants with Abnormal Neonatal Screens*, 267 JAMA 1095 (1992).

71. Cf. Charles R. Scriver et al., *The Hyperphenylalaninemias*, in THE METABOLIC BASIS OF INHERITED DISEASE 495, 517-520 (Charles R. Scriver et al. eds., 6th ed. 1989) (indicating that various factors, such as the restrictive nature of the dietary

Many programs screen for diseases that are even more problematic targets. Some programs screen for diseases such as maple syrup urine disease and galactosemia,⁷² for which therapy is, at best, only partially effective. These diseases, like PKU and congenital hypothyroidism, lead to severe mental retardation, but newborn screening typically detects them only after substantial permanent damage has occurred.⁷³ Thus, many affected children die early or suffer mental retardation despite vigorous treatment.⁷⁴ Several countries also screen newborn boys for Duchenne muscular dystrophy, a condition involving muscular degeneration.⁷⁵ The symptoms of this disorder usually appear in early childhood, and death tends to occur in adolescence or early adulthood. Only recently has there been any hope of effective therapy.⁷⁶ Whether children profit from receiving a diagnosis for which there is little or no effective treatment poses a serious question.⁷⁷ The best one could

treatment, the unpleasant properties of a semisynthetic diet, and the lack of knowledge regarding the diet, operate to discourage continued treatment).

72. See, e.g., COLO. REV. STAT. § 25-4-1004(b) (Supp. 1991).

73. See HEALTHY CHILDREN, *supra* note 59, at 98 (stating that, although the sensitivity of the test for maple syrup urine disease may generally be high, the disease is so rapidly fatal that the test may not be done in time to initiate effective treatment).

74. See Ayesha E. Gill & Patricia S. Amador, *A Retrospective Study of Galactosemia Cases Identified Through Newborn Screening in New York State, 1968-1985*, in ADVANCES IN NEONATAL SCREENING, *supra* note 64, at 251, 254 (indicating that 6 of the 57 children with galactosemia identified by the New York State screening program from 1968-1985 died); Seymour Packman et al., *Neurologic Sequelae in Galactosemia*, in ADVANCES IN NEONATAL SCREENING, *supra* note 64, at 261, 263 (reporting a study of siblings who were mentally retarded despite adequate dietary management since and even before birth); James J. Riviello, Jr. et al., *Cerebral Edema Causing Death in Children with Maple Syrup Urine Disease*, 119 J. PEDIATRICS 42, 44 (1991) (noting that four children died of cerebral edema despite early diagnosis and subsequent treatment of maple syrup urine disease); Geoffrey N. Thompson et al., *Acute Illness in Maple Syrup Urine Disease: Dynamics of Protein Metabolism and Implications for Management*, 119 J. PEDIATRICS 35, 35 (1991) (determining that acute illness episodes, which may lead to rapid neurological deterioration, pose a significant danger to longevity in children with maple syrup urine disease).

75. Kenneth F. Swaiman & Stephen A. Smith, *Progressive Muscular Dystrophies*, in PEDIATRIC NEUROLOGY: PRINCIPLES AND PRACTICE 1139, 1139 (Kenneth F. Swaiman ed., 1989).

76. There is some evidence that myoblast transfer therapy and steroids can help these patients. See G.M. Fenichel et al., *Long-term Benefit from Prednisone Therapy in Duchenne Muscular Dystrophy*, 41 NEUROLOGY 1874, 1874 (1991) (discussing a study that demonstrated positive results from prednisone therapy); Peter K. Law et al., *Dystrophin Production Induced by Myoblast Transfer Therapy in Duchenne Muscular Dystrophy*, 336 LANCET 114, 114-15 (1990) (suggesting that myoblast transfer therapy offers a safe and effective means of alleviating biochemical deficits inherent in the muscles of those with Duchenne muscular dystrophy).

77. Indeed, the proponents of these programs assert that their justification is "the detection of families at risk, which allows earlier genetic counselling," H. Plauchu et al., *Duchenne Muscular Dystrophy: Neonatal Screening and Prenatal Di-*

hope for is that vigilant parents and physicians could provide the affected children with any new therapies that become available. This potential benefit, however, is obtained at the cost of knowing that one's newborn has a serious disease for which there is no completely effective therapy at the time of diagnosis.

Moreover, some programs screen for metabolic abnormalities, such as histidinemia and dicarboxylic aminoaciduria, that cause little or no clinically significant disease.⁷⁸ Proponents of these programs have argued that the programs are justified because they help define the natural history of such benign variants.⁷⁹ However, even the most vigorous advocates of such surveillance admit that despite reassurances, some families remain fearful that their children will be harmed by the metabolic variants.⁸⁰

Even assuming that the identified disorder causes substantial morbidity and that effective treatment is available and accessible, accurately labelling a child as deviant may nonetheless be harmful in other ways. In American society, a substantial number of children are born to single women or into marriages that are under stress. A number of commentators have expressed concern that labelling a baby as "ill," particularly in the newborn period, may cause the dissolution of the family or cause the father to flee a relationship in which he otherwise would have remained.⁸¹ These authors are particularly fearful that the father's fleeing will occur when further testing reveals nonpaternity.

Another set of problems arises because newborn screening, like any medical test, is not completely accurate. Even under the most ideal testing conditions, some children who actually have disease will be missed, and some healthy children will inappropriately be labelled as "ill." From one perspective, "false negative" tests that fail to detect affected children should not

agnosis, 1 LANCET 669, 669 (1989), an approach that has nothing to do with the affected child himself.

78. See Elsas, *supra* note 42, at 281.

79. Serge B. Melançon, *Ethical Implications in Diagnosis and Treatment of Non-Disease (DIS) Phenotypes Issuing from Screening Programs*, in GENETIC SCREENING: FROM NEWBORNS TO DNA TYPING 33, 35-36 (Bartha M. Knoppers & Claude M. Laberge eds., 1990).

80. See *id.* at 36 (noting that some mothers indicated that they followed their child's development more closely because of the unknown nature of the metabolic disorder).

81. See, e.g., Peter T. Rowley & Donna J. Huntzinger, *Newborn Sickie Cell Screening: Benefits and Burdens Realized*, 137 AM. J. DISEASES CHILDREN 341, 344 (1983) (classifying destabilization of the parental relationship as the greatest potential burden of state mandated newborn sickie cell screening).

seem particularly troubling.⁸² After all, the argument goes, the disease surely would have gone undetected had there been no program at all, so children are not harmed when the program fails to work.

Things, however, are not that simple. To begin with, the existence of newborn screening programs can create a false sense of reassurance in physicians,⁸³ possibly causing them to fail to make a diagnosis as quickly as they would have were there no screening in place once symptoms begin to appear.

The most common reason that affected children are missed, however, is not because of the inherent inaccuracy of testing but because the tests were not properly administered, if at all.⁸⁴ Screening programs have encountered many problems, ranging from difficulties in getting adequate samples, to lab errors, to problems in recording and reporting results.⁸⁵ For a significant number of children, blood samples simply do not reach the state departments of health at all.⁸⁶ Although

82. There has long been concern that the increasing economic pressure in this country to discharge newborns shortly after birth will increase the likelihood that affected babies will be missed. See Holtzman et al., *supra* note 45, at 221 (reporting a high incidence of false negatives for infants screened before 24 hours of age). Although this has turned out to be less of a problem than was initially feared, efforts are continuing to find ways to avoid the problems caused by early discharge. See Lauren B. Doherty et al., *Detection of Phenylketonuria in the Very Early Newborn Blood Specimen*, 87 PEDIATRICS 240, 243 (1991) (suggesting a decrease in cutoff level from four mg/dl to two mg/dl, based on estimates that the higher cutoff level misses 30% of PKU infants while the lower detects more than 90% of these infants). But see George C. Cunningham et al., *Phenylalanine Level of Newborns in Their First Few Days of Life*, in ADVANCES IN NEONATAL SCREENING, *supra* note 64, at 181 (discouraging lower cutoff levels due to increased costs). Ironically, in some settings, early discharge has actually increased the number of false positives for congenital hypothyroidism. B.L. Foley et al., *Early Neonatal Discharge and its Effects on Thyroid Screening Results in Southern California*, in ADVANCES IN NEONATAL SCREENING, *supra* note 64, at 66.

83. Candy Holtzman et al., *Descriptive Epidemiology of Missed Cases of Phenylketonuria and Congenital Hypothyroidism*, in LEGAL LIABILITY AND QUALITY ASSURANCE IN NEWBORN SCREENING 17, 20 (Lori B. Andrews ed., 1985).

84. State newborn programs are not the only site for errors. Investigators in Illinois recently discussed 10 cases in which a newborn screening program correctly identified abnormal results, but the individual physicians did not appropriately follow up, thus leading to undue delay in definitive diagnosis and therapy. See Listernick et al., *supra* note 70, at 1096-97.

85. See Holtzman et al., *supra* note 83, at 18 (stating that in a survey of 76 missed cases, 16% occurred in the specimen collection, 50% in laboratory procedures, and 20% in the follow-up); Judith M. Tuerck et al., *Computerized Surveillance of Errors in Newborn Screening Practice*, 77 AM. J. PUB. HEALTH 1528, 1530 (1987) (reporting that 58.3% of samples taken were incorrectly submitted in Oregon). The frequencies of these problems vary from state to state. See HEALTHY CHILDREN, *supra* note 59, at 98-99; cf. J. Leger, *Screening for Congenital Hypothyroidism in France*, 149 EUR. J. PEDIATRICS 605, 606 (1990) (documenting that such problems are not unique to the United States).

86. See Holtzman et al., *supra* note 83, at 19 (reporting seven such cases in a

the move toward centralization of testing and emphasis on proficiency testing and quality assurance has improved procedures,⁸⁷ some states still do not keep statistics on lapses in screening.⁸⁸ Given all these problems with newborn screening programs, it is hardly surprising that litigation often results when a child's PKU or congenital hypothyroidism are not detected by screening tests.⁸⁹

Not only are some affected children missed, but some unaffected children are mislabelled as ill. Sometimes the screening test is diagnostic: the child with an abnormal result, in fact, has the disease being tested. In most instances, however, screening programs are set up as multistep processes in which, in order to capture all the true positives, the first step also yields abnormal results for some unaffected children who will later be distinguished by more sophisticated testing.⁹⁰ Hence, mislabelling is inherent in the early stages of the screening process. The number of unaffected children, the "false positives," who are identified as potentially ill in the initial screening depends on the nature of the illness and the test.⁹¹ The presence of false negatives is troubling because

survey involving 76 missed cases).

87. See HEALTHY CHILDREN, *supra* note 59, at 102-03.

88. See ILLINOIS DEPT OF PUB. HEALTH, NEWBORN SCREENING: AN OVERVIEW OF NEWBORN SCREENING PROGRAMS IN THE UNITED STATES AND CANADA 258 (1990) (listing nine states with no tracking programs for unsatisfactory specimen collection).

89. See, e.g., Marcel v. Louisiana State Dep't of Pub. Health, 492 So. 2d 103, 105 (La. Ct. App. 1986) (alleging negligence for failure to follow up a positive test for PKU and for failure to develop an effective program for identifying PKU); HEALTHY CHILDREN, *supra* note 59, at 102 (reporting as many as 25 lawsuits involving missed cases of PKU or congenital hypothyroidism); Callan & Mitchell, *supra* note 64, at 567 (reporting that individuals brought 25 claims regarding newborn screening and that settlements in some of these cases yielded between \$300,000 and \$1,500,000); Holtzman et al., *supra* note 83, at 20 (reporting a survey in which 22 of 76 missed cases resulted in claims ranging from \$1 million to \$20 million). Private physicians and hospitals have also been sued for failing to test for PKU. See, e.g., Foster v. Bass, 575 So. 2d 967, 968 (Miss. 1990); Horvath v. Baylor Univ. Medical Ctr., 704 S.W.2d 866, 867 (Tex. App.—Dallas 1985, no writ).

90. See HEALTHY CHILDREN, *supra* note 59, at 97 (indicating that physicians further evaluate infants who test positive in order to identify the specific disorder).

91. In the early days of screening for PKU about 1 in 10 children in New York City initially received abnormal results even though the true incidence of disease was 1 in 10,000 to 25,000. Michael B. Rothenberg & Edward M. Sills, *Iatrogenesis: The PKU Anxiety Syndrome*, 7 J. AM. ACAD. CHILD PSYCHIATRY 689, 690 (1968). The rate of false positives remains substantial. New Jersey, for example, reports that 0.8% of its newborn screening samples are suspect for PKU, making false positives 80 to 200 times more common than true positives. ILLINOIS DEPT OF PUB. HEALTH, *supra* note 88, at 117. See generally American Academy of Pediatrics, *Newborn Screening Fact Sheets*, 83 PEDIATRICS 449, 461 (1989) (reporting that the true incidence rate for PKU is 1 in 10,000 to 1 in 25,000). Most states do not provide these figures for individual diseases, but some states report that more than 6% of their samples are suspect for some disorder. ILLINOIS DEPT OF PUB. HEALTH, *supra* note

labelling any child as ill in the newborn period, even if only for a few weeks or months, can disrupt the developing parent-child relationship, sometimes with long-term adverse consequences for the child.⁹²

Inadequate medical knowledge also causes mislabelling. For example, when screening for PKU began, it was not known that some children with high levels of phenylalanine did not in fact have PKU, but rather had hyperphenylalaninemia, which does not cause significant mental retardation.⁹³ Until this fact was understood, children with this latter, benign condition were inappropriately thought to be ill and subjected to the restrictions and expense of treatment. Ironically, the treatment actually harmed some of these children, causing the very mental retardation that screening was supposed to avoid.⁹⁴ The increased understanding of human variation that has emerged from this experience is desirable in itself, but this example and the problems described earlier demonstrate that screening is not an entirely benign procedure for children. Those who engage in traditional legal analysis or who advocate widespread testing often seem to forget, or at least give inadequate weight to, these very real harms.

2. *Legal implications of screening for children.* The effects of newborn screening on children have a wide range of legal consequences as well. Some are relatively straightforward. For those affected children whose diagnoses were missed—the “false negatives,” the question is usually whether some institution involved in the screening process failed to exercise due care.⁹⁵ Traditional rules of negligence govern this

88, at 260.

92. Refer to notes 120-22 *infra* and accompanying text.

93. See NATIONAL ACADEMY OF SCIENCES, GENETIC SCREENING: PROGRAMS PRINCIPLES, AND RESEARCH 28 (1975) (stating that the original testing assumed that all cases of elevated phenylalanine level were PKU cases, when in fact two-thirds of these cases were hyperphenylalaninemia).

94. See HOLTZMAN, *supra* note 1, at 5 (stating that some infants which physicians falsely diagnosed with PKU consequently suffered irreparable damage); Rothenberg & Sills, *supra* note 91, at 690 (pointing out that physicians placed children who were thought to have PKU on diets and that these children suffered nutritional deficiencies resulting in brain injury and even death).

95. Robert Guthrie observed that most missed diagnoses occur when no record of the test exists or when a private hospital laboratory, which performed only a few tests, reported that the test result was negative. Robert Guthrie, *Lawsuits Involving Missed Cases of PKU: Lessons Learned*, in ADVANCES IN NEONATAL SCREENING, *supra* note 64, at 585.

Questions concerning due care in the context of screening would include whether the hospital unreasonably neglected to collect the sample or neglected to send it to the state, and whether the state lost or mishandled the sample or failed

issue but reflect the continuing erosion of charitable⁹⁵ and governmental immunity.⁹⁷ Even when an affected child who was missed can show negligence, he still must shoulder the burden of proving that he would have received adequate, effective therapy had the diagnosis been made in a timely fashion. For the "false positives," those healthy children who are inappropriately diagnosed as ill, the existence of a private legal remedy is more doubtful and raises such questions as whether a child can receive damages for interference with her relationship with her parents.⁸³

A larger problem is how the law can be used to limit the social consequences of labelling. For many years, this country has been engaged in a struggle involving how to deal with perceived or real differences between individuals—differences based upon race, gender, and disability.⁹⁹ Federal legislation, such as Title VII of the Civil Rights Act of 1964,¹⁰⁰ the Education for All Handicapped Children Act of 1975,¹⁰¹ and the Americans with Disabilities Act of 1990,¹⁰² embodies efforts to alleviate the problem of discrimination. State legislatures have enacted similar statutes.¹⁰³ Despite this legislation, the

to make adequate attempts to find the affected child. States vary with regard to the party who is responsible for receiving the report and who is responsible for finding affected children and getting them into care. In an effort to limit state liability, Michigan has directed its department of health to promulgate rules defining what constitutes a good faith effort to find children who have abnormal screening results. MICH. COMP. LAWS ANN. § 333.5431(2) (West Supp. 1992).

96. See W. PAGE KEETON ET AL., PROSSER AND KEETON ON THE LAW OF TORTS § 133, at 1070 (5th ed. 1984) (recognizing the rejection of complete immunity for charities).

97. See *id.* at 1055 (stating that governmental immunity has been abolished or at least restricted at most levels).

98. The child in this case might allege that bonding was less complete because the parents were grieving the loss of their "healthy" child. Such a loss of consortium is rarely compensable. See KEETON ET AL., *supra* note 96, § 125, at 935-936 (noting that courts continue to follow the tradition of denying damages for loss of society, guidance, and attention in children's claims of negligent interference with the parent-child relationship); see also *Borer v. American Airlines Inc.*, 563 P.2d 858, 860-61 (Cal. 1977) (refusing to extend the claim of loss of consortium to the parent-child relationship).

99. See generally CYNTHIA F. EPSTEIN, DECEPTIVE DISTINCTIONS: SEX, GENDER, AND THE SOCIAL ORDER (1988); MARTHA MINOW, MAKING ALL THE DIFFERENCE: INCLUSIONS, EXCLUSIONS, AND AMERICAN LAW (1990); THEORETICAL PERSPECTIVES ON SEXUAL DIFFERENCE (Deborah L. Rhode ed., 1990).

100. 42 U.S.C.A. §§ 2000e to 2000e-17 (West 1991).

101. Pub. L. No. 94-142, 89 Stat. 773 (codified at 20 U.S.C.); see also Education of the Handicapped Act Amendment of 1990, Pub. L. No. 101-476, 104 Stat. 1142 (changing the name of the Education of the Handicapped Act).

102. Pub. L. No. 101-336, 104 Stat. 327 (codified in scattered sections of 29 U.S.C.A., 47 U.S.C.A. and 42 U.S.C.A.).

103. See, e.g., ILL. ANN. STAT. ch. 23, paras. 3429-48 (Smith-Hurd Supp. 1990) (Disabled Persons Rehabilitation Act); TENN. CODE ANN. § 8-50-103 (Supp. 1990)

ongoing debate about such strategies as affirmative action and accommodation demonstrates that there is no consensus about what to do.

In addition, these laws are only partial responses to the problem of discrimination. As a result, some children identified as different by newborn screening will not be covered by these laws.¹⁰⁴ Some children, to be sure, will be protected because they will develop a dysfunction that allows them to qualify as disabled and will suffer at the hands of entities that are covered by the acts. Others, however, will not be officially disabled either because the manifestations of their diseases are effectively controlled by treatment or because their "disorders" have no clinical manifestations.¹⁰⁵ One could hope that medical norms of confidentiality would protect such children; if no one knows that they have a particular condition, they cannot be the victims of discrimination on the basis of being affected. Such information, however, is hard to keep completely private. One need only remember the way that schoolmates are aware of and tease peers who take medicine or eat a special diet. Even when a condition requires no intervention, mere entry of the diagnosis into medical records makes it available to a wide array of people and institutions. Other children will be symptomatic but will be discriminated against by institutions or individuals not governed by these laws. These children who fall between the legislative cracks may nonetheless suffer real injury by virtue of being identified as different.

While history reveals that the enactment of laws is not a complete remedy for the ills of labelling and discrimination, experience with discrimination on the basis of race, gender, and disability suggests some of the dilemmas that may be posed by differences based on genetic makeup.¹⁰⁶ Discussions

(governing employment of the handicapped).

104. See 42 U.S.C.A. § 12102(2) (1991) (defining who qualifies as disabled for purposes of federal law).

105. The Americans with Disabilities Act may cover some of these children because it defines disability as "(A) a physical or mental impairment that substantially limits one or more of the major life activities . . . (B) a record of such impairment, or (C) being regarded as having such an impairment." *Id.*

106. There is some overlap between genetic and other sorts of differences. It may be more acceptable in some parts of our society to say that a person with sickle cell anemia is different than to say that an African American is different even though both references are to the same individual. But this example also suggests that many genetic traits are found more frequently in one population than another, so that focusing on genetic characteristics may serve as a proxy for racial or ethnic discrimination. Discussions about genetic discrimination already occur in the setting of screening for employment and insurance. See generally OFFICE OF TECHNOLOGY ASSESSMENT, U.S. CONGRESS, THE ROLE OF GENETIC TESTING IN THE PREVENTION OF

about genetic discrimination already occur in the setting of screening adults for employment and insurance.¹⁰⁷ Some have considered, for example, whether it is more appropriate to exclude a worker from a job whose genetic makeup makes her hypersusceptible to job-related injury or to change the workplace to allow her to work in safety.¹⁰⁸ Consideration of similar issues is also important in the context of newborn screening. It is necessary to decide whether the labelling of children as genetically ill, either accurately or inaccurately, will adversely affect those children by subjecting them to differential treatment in school or in sports, or the parents of those children by making it more difficult to change jobs or obtain insurance because of their child's expensive treatment. It is also possible that these hurdles facing such parents will, in turn, impair their ability to care for their children. The challenge then is to decide which differences ought not to make a difference—which should not be the basis for distinguishing one person from another—and to extend to children the protection of the law, which often is already at least partially available to adults. The first step in this inquiry is to recognize the potential power of present and future newborn screening techniques to demonstrate ways in which children vary from one another as well as the fact that the results obtained are not always accurate.¹⁰⁹

B. *The Parents*

1. *How parents respond to screening.* The impact of newborn screening upon parents depends upon numerous variables, including the accuracy of the test, the nature of the disease being screened for, the availability of effective therapy,

OCCUPATIONAL DISEASE (1983); Gostin, *supra* note 1.

107. See OFFICE OF TECHNOLOGY ASSESSMENT, *supra* note 106, at 123-25 (1983) (asserting that screening for certain genetic traits may have a disparate impact on persons of a particular race, sex, or ethnic background and that this disparate impact may require an employer to justify using such a genetic test); ROTHSTEIN, *supra* note 1, at 177-79 (discussing the potential for employers to abuse genetic screening of employees by discovering an individual's predisposition to both specific occupational and nonoccupational diseases); Gostin, *supra* note 1, at 110-19 (noting that employers may use genetic screening results to the disadvantage of job applicants and current employees).

108. See *International Union v. Johnson Controls Inc.*, 111 S. Ct. 1196, 1199-1200 (1991) (finding that an employer's exclusion of potentially fertile women from working in an environment that contained lead based on fear of injury to fetuses would violate the Civil Rights Act of 1964).

109. See Gostin, *supra* note 1, at 113-15 (criticizing individuals who believe that genetic tests are infallible).

and the heritability of the disease. It is one thing to make the diagnosis of congenital hypothyroidism in the newborn period for which there is easy-to-administer, effective treatment and for which there are no implications for future procreation. It is entirely another to diagnose Duchenne muscular dystrophy where the parents can use the information only to prepare themselves for the impending deterioration in the condition of their son and to consider the fact that any future sons may also be affected.

Recent studies reveal what some parents say about newborn screening in general and how they react to finding out that their children are affected.¹¹⁰ In a recent survey of postpartum women, almost all said that they wanted to know if their newborns were going to have handicapping conditions.¹¹¹ They also wanted their newborn sons tested for Duchenne muscular dystrophy even though they knew that the only use for such information was in planning future pregnancies.¹¹² Although the investigators in that study asserted that they spent sufficient time to ensure that the women understood what was at stake,¹¹³ one can wonder whether new mothers of healthy babies truly comprehend what it would mean to learn that their new infants in fact had a genetically determined fatal disease.

More information can be gleaned from asking mothers of children who are actually affected by diseases detectable in the neonatal period what they think about newborn screening, because they have first-hand knowledge of the effects of having a child with a chronic illness. One study reported that the over-

110. One might argue that because most children "pass" the newborn screening tests, their parents would benefit from the knowledge that their children do not have PKU or congenital hypothyroidism. Certainly one of the central arguments in support of prenatal diagnosis is that most people get "good news" and therefore feel better about continuing their pregnancies. Mary G. Ampola, *Prenatal Diagnosis, in THE CUSTOM-MADE CHILD?: WOMEN-CENTERED PERSPECTIVES* 75, 80 (Helen B. Holmes et al. eds., 1981). Whatever the validity of this argument, it has little applicability in the context of newborn screening because parents rarely know that physicians have tested their children unless they receive "bad news."

111. R.A. Smith et al., *Attitudes of Mothers to Neonatal Screening for Duchenne Muscular Dystrophy*, 300 *BRIT. MED. J.* 1112, 1112 (1990).

112. *Id.*; see also Rachel B. Unger & Edwin W. Naylor, *Parental Attitudes Towards Neonatal Screening for Cystic Fibrosis*, in *ADVANCES IN NEONATAL SCREENING*, *supra* note 64, at 383 (noting that 98% of postpartum women surveyed favored screening for cystic fibrosis, even though 75% of the women thought it would be difficult to raise a child with the disease, 37% expressed desire for early treatment, 21% stated that it was better to know about the baby's health, and 20% indicated that "hospitals might as well" test for cystic fibrosis because they already had blood samples).

113. Smith et al., *supra* note 111, at 1112.

whelming majority of such women favored early detection.¹¹⁴ The women, however, offered an interesting array of reasons. Mothers with children diagnosed on clinical grounds (often after an extended period of time between the onset of symptoms and diagnosis) favored newborn screening simply to avoid the anxiety of the delay in diagnosis.¹¹⁵ Others favored early detection because they believed that early intensive medical intervention would lead to a better outcome for their children, even if the children had diseases for which this belief was not necessarily true.¹¹⁶ Still other families favored early detection in order to avoid having more affected children. This justification was given more frequently among mothers of boys with Duchenne muscular dystrophy¹¹⁷ than among mothers of children with less onerous diseases,¹¹⁸ a finding that conforms with the long-held wisdom that reproductive attitudes depend primarily on the prospective parents' sense of the burden of the disease.¹¹⁹

Issues become more complex when one looks at how families actually respond to receiving bad news from newborn screening. The care of a chronically ill child, a "true positive," can be very costly to the family in terms of both economic

114. See L.N. Al-Jader et al., *Attitudes of Parents of Cystic Fibrosis Children Towards Neonatal Screening and Antenatal Diagnosis*, 38 *CLINICAL GENETICS* 460, 462-63 (1990) (finding that 83% of parents surveyed whose children were screened early and 91% of parents surveyed whose children were diagnosed later supported neonatal screening); see also Melinda A. Firth & Elizabeth J. Wilkinson, *Screening the Newborn for Duchenne Muscular Dystrophy: Parents' Views*, 286 *BRIT. MED. J.* 1933, 1933 (1983) (listing the emotional aspect of raising a handicapped child as a primary reason why parents support neonatal screening).

115. Al-Jader et al., *supra* note 114, at 464; Ronald G. Worton, *Does Research Success in Duchenne-Becker Muscular Dystrophy Now Warrant Neonatal Mass Screening? The Perspective of a Molecular Biologist*, in *GENETIC SCREENING: FROM NEWBORNS TO DNA TYPING*, *supra* note 79, at 197, 199-200 (determining that parents of afflicted children favor neonatal screening because it alleviates the anxiety associated with delayed diagnosis).

116. See Al-Jader et al., *supra* note 114, at 463.

117. See Firth & Wilkinson, *supra* note 114, at 1933 (finding that 75% of parents of boys with muscular dystrophy favored neonatal screening because such screening could prevent later births); Smith et al., *supra* note 111, at 1112 (finding that approximately three-fourths of the mothers studied wanted early screening to be performed in order to avoid conceiving any more children); Worton, *supra* note 115, at 199 (noting that one of the primary reasons for the popularity of early screening is that it procures information with which to make family planning decisions).

118. For example, only 2 out of 25 families whose children had cystic fibrosis thought that early diagnosis "could be helpful when making decisions with regard to future children." Al-Jader et al., *supra* note 114, at 462.

119. See Claire O. Leonard et al., *Genetic Counseling: A Consumer View*, 287 *NEW ENG. J. MED.* 433, 437 (1972). The term "burden" includes the potential for the child's early death, as well as the physical, emotional, and financial toll that the disease takes on the parents. *Id.* at 433-34.

expense and the burden and disruption of providing care.¹²⁰ Having a child with a genetic or congenital disorder, no matter when the diagnosis is made, creates emotional stress for parents because their sense of psychological well-being is affected and they cannot blame an external cause to alleviate their guilt.¹²¹ Making such a diagnosis shortly after birth may also have its own particular effects on the emerging parent-child relationship.¹²²

120. See Seymour Kessler, *The Psychological Foundations of Genetic Counseling*, in *GENETIC COUNSELING: PSYCHOLOGICAL DIMENSIONS* 32 (Seymour Kessler ed., 1979); Leonard et al., *supra* note 119, at 437; see also Worton, *supra* note 115, at 199 (suggesting that one argument in favor of neonatal screening is that such screening provides a family with time to prepare for the difficulties of caring for the disabled child).

121. Kessler, *supra* note 120, at 24. Kessler points out that the inability to displace guilt is particularly severe when the disease is not inherited as an autosomal recessive, but rather is the result of one parent's "bad" gene. *Id.*

122. See Al-Jader et al., *supra* note 114, at 464 (voicing concerns about the effect that a diagnosis of cystic fibrosis has on the burgeoning parent-child relationship); Worton, *supra* note 115, at 199 (observing that individuals who oppose neonatal screening fear that the early diagnosis may cause a parent to either reject the child or become overprotective of the child).

Regarding the impact of discovering PKU during the newborn period, one writer concluded:

The early diagnosis takes on an illusive, somewhat nebulous quality, as the parents watch the treated newborn PKU child grow and thrive without apparent pathology. The parents operate under a constant threat that if they fail in maintaining the diet, their child will become brain damaged. They tend to respond with excessive monitoring and rigid management of the diet.

Sylvia Schild, *Psychological Issues in Genetic Counseling of Phenylketonuria*, in *GENETIC COUNSELING: PSYCHOLOGICAL DIMENSIONS*, *supra* note 120, at 135, 145.

In Sweden, researchers conducted a study that recorded the responses of parents whose children were diagnosed with alpha₁-antitrypsin deficiency (ATD) shortly after birth. ATD can cause liver disease in the young child and chronic lung disease in the adult, the latter of which can be seriously aggravated by cigarette smoking. JAMES S. THOMPSON & MARGARET W. THOMPSON, *GENETICS IN MEDICINE* 180 (4th ed. 1986). Screening for ATD was discontinued after 1974 due to concerns that the screening was adversely interfering with the parent-child relationship. T. Thelin et al., *Identifying Children at High Somatic Risk: Parents' Long-Term Emotional Adjustment to Their Children's Alpha 1 Antitrypsin Deficiency*, 72 *ACTA PSYCHIATRICA SCANDINAVICA* 323, 323 (1985). Investigators found that even after several years, and despite significant interaction with the health care system, many of the parents did not understand what the disease implied or why their child had been tested. T. Sveger & T. Thelin, *Four-Year-Old Children with Alpha 1-Antitrypsin Deficiency: Clinical Follow-up and Parental Attitudes Towards Neonatal Screening*, 70 *ACTA PAEDIATRICA SCANDINAVICA* 171, 175 (1981); see Thelin et al., *supra*, at 326-29 (noting that parents experienced feelings of worry, anxiety and fear five to seven years after diagnosis and that about one-half of the mothers and one-third of the fathers had poor long-term adjustment). While the interviews and questionnaires administered to the parents did not reveal disturbances in the parent-child relationship, actual observation of the children diagnosed with ATD as neonates demonstrated that they had more problems interacting with their mothers than did children without the disease. See T.F. McNeil et al., *Identifying Children at High Somatic Risk: Long-Term Effects*

No matter what the early detection of disease does to the evolving relationship between the parents and the affected child, some writers advocate newborn screening on the ground that it gives parents the opportunity to make financial arrangements for the future.¹²³ Perhaps the unspoken thought present here is that some of the cost to the child in impairment of emotional support or nurturance from the parents may be offset by his or her economic security in the future. No systematic attempt has been made to determine whether parents actually want or use this information for financial planning purposes. Much anecdotal evidence exists, however, which indicates that aging parents worry a great deal about what will happen after their deaths to their retarded or otherwise handicapped children.¹²⁴ Even if parents want to provide economic security for their child, receiving this sort of information may actually limit rather than expand parents' options. Many

on *Mother-Child Interaction*, 74 ACTA PSYCHIATRICA SCANDINAVICA 555, 562 (1986); T.F. McNeil et al., *Identifying Children at High Somatic Risk: Possible Long-Term Effects on the Parents' Attitudes and Feelings Associated with the Child*, 74 ACTA PSYCHIATRICA SCANDINAVICA 341, 345 (1986).

Other studies have reported similar findings of parental guilt and anxiety following detection of disease by newborn screening. One recent study found that 6 out of 10 families of children with PKU showed signs of depression and anxiety and worried that their children would not have normal intellectual development. P. Vetrone et al., *Psychological Effects on Parents of Children with Early Detected Phenylketonuria*, 12 J. INHERITED METABOLIC DISEASE 345, 345-46 (1989). Interestingly, even though both parents had to contribute mutant genes for the child to be affected, these investigators found that the mothers were the individuals who felt guilty about their children's disease. *Id.* at 346. Perhaps more troubling is another study demonstrating that roughly half of 21 families whose children had been identified in the newborn period as having non-pathologic conditions—entities that do not in fact cause dysfunction—said that they had initially been quite worried and two continued to follow their child's development more closely. Melançon, *supra* note 79, at 36; see also Holtzman et al., *supra* note 45, at 227 (stating that such parents feel "excessive anxiety, depression, anger, or guilt").

On the other hand, another group of investigators who compared the responses of mothers whose children had been diagnosed with cystic fibrosis as newborns with the responses of mothers whose children had been diagnosed with the disease later in life concluded that presymptomatic diagnosis may actually benefit the parent-child relationship. See Carol Boland & Norman H. Thompson, *Effects of Newborn Screening of Cystic Fibrosis on Reported Maternal Behavior*, 65 ARCHIVES DISEASES CHILDHOOD 1240, 1244 (1990) (reporting the results of a study conducted in New South Wales). The investigators found that delays in diagnosis lead to "increased cynicism towards medical professionals," *id.* at 1243-44, and that screening particularly benefitted mothers who were already concerned about their children's health by the time of the newborn's diagnosis, *id.*

123. See, e.g., Jeffrey R. Botkin, *Ethical Issues in Human Genetic Technology*, 17 PEDIATRICIAN 100 (1990).

124. See, e.g., BARBARA K. ROTHMAN, *THE TENTATIVE PREGNANCY* 60 (1986) (quoting "Valerie", and her description of her mother-in-law, who intends to care for a child with Down's syndrome until she or her child dies).

health insurance policies do not cover preexisting conditions.¹²⁵ Altering our current employer-based system of health insurance¹²⁶ could address these problems, at least in part. This alteration, however, seems unlikely any time in the near future. Thus, given the present circumstances, one cannot assume that more information will enable the parents to engage in more effective financial planning.

2. *The special implications for procreation of detecting parents' heritable conditions.* What most clearly distinguishes the position of the parents from that of the child is the fact that most of the disorders currently being sought are genetically inherited. As a result, the existence of disease in one child means that the parents have a definable risk¹²⁷ of having another similarly affected child.¹²⁸ Unlike prenatal diagnosis, where the prospective parents usually understand that they are being tested and may even seek out procreative risk information,¹²⁹ parents who receive the unsolicited news from

125. Thus, if a mother whose newborn child had tyrosinemia, which might require a liver transplant in the future, were to try to change jobs, she might find that her new employer's insurer would refuse to pay for the child's care.

126. Various alterations have been suggested. See, e.g., Robert H. Brook, *Health, Health Insurance, and the Uninsured*, 265 JAMA 2998, 3000-02 (1991) (recommending a federal health care plan); Carl J. Schramm, *Health Care Financing for All Americans*, 265 JAMA 3296, 3297 (1991) (proposing to change health care financing by implementing insurance reform for small employers).

127. Finding genetic illness in one child is a sufficient reason to test older children to see if they are affected but, as of yet, undiagnosed. See Rowley & Huntzinger, *supra* note 81, at 344 (noting that subsequent screening of siblings is a benefit of initial screening). Failure to discover affected siblings in related contexts has led to litigation in the past. See, e.g., *Turpin v. Sortini*, 643 P.2d 954, 966 (Cal. 1982) (regarding a failure to diagnose hereditary deafness in an older sister); *Schroeder v. Perkel*, 432 A.2d 834, 839-40 (N.J. 1981) (regarding a failure to diagnose cystic fibrosis in an older child).

128. The diagnosis of a genetically inherited disease has implications for the reproductive risk faced by the affected child as well, assuming that the child will live to adulthood and be fertile. See VOGEL & MOTULSKY, *supra* note 49, at 616. Even assuming that the child might have children in the future, the risk faced by the child is usually different from that faced by his or her parents. *Id.* For instance, if a child has an autosomally recessive condition, like PKU, he or she will risk having a similarly affected child only if his or her partner also carries the gene, the chance of which varies depending on the frequency of the gene in the population at large. See *id.* at 265-66. If a boy has an X-linked recessive condition, such as hemophilia, none of his children will be afflicted, although some of the sons born to his daughters might. See *id.* at 362-63 (discussing obligatory and probable carriers of hemophilia). Only in the case in which a child has an autosomal dominant condition, such as achondroplasia or Huntington's disease, is the chance that he or she will have affected children the same or greater than that faced by his or her parents. See *id.* at 419.

129. The extent to which parents want to receive genetic risk information is the subject of great controversy. There is a growing body of literature documenting the

newborn screening that their apparently healthy baby is in fact ill may perceive the added information that they also face a risk of having more sick children as a one-two punch. The question then becomes how parents will respond to being told about their increased chance of having an affected child in future pregnancies.

It may be inappropriate to assess parents' responses solely by asking whether they changed their reproductive plans based on test information. Despite the fact that the concept of "genetic risk" connotes a value judgment that the birth of another affected child is an undesirable event to be avoided, some people do not view having a child with a given genetic condition as particularly onerous.¹³⁰ Others do not view some or all of the methods available to prevent the birth of a child with a genetic disorder as viable options, no matter how burdensome the child's disorder may be.¹³¹

social construction of genetic risk and the notion that women are led to believe that the birth of a child with a genetic disorder is an ill to be avoided even at great cost. ROTHMAN, *supra* note 124, at 243 (perhaps the preeminent empirical study on this topic); Lippman, *supra* note 1, at 27 (citing the body of feminist literature in this area). Moreover, many women do not know what is at stake when they undergo prenatal diagnosis until they reach the stage of amniocentesis or chorionic villus biopsy or even until they get a "bad" test result. Rayna Rapp, *Communicating About the New Reproductive Technologies: Cultural, Interpersonal, and Linguistic Determinants of Understanding*, in *WOMEN AND NEW REPRODUCTIVE TECHNOLOGIES: MEDICAL, PSYCHOSOCIAL, LEGAL, AND ETHICAL DILEMMAS*, *supra* note 5, at 135. This situation has become particularly common because maternal serum alpha fetoprotein (MSAFP) screening has become such a routine part of obstetric care that physicians are performing the test without asking the prospective mother's consent.

130. For example, the fact that doctors perform amniocentesis most frequently in this country to afford women an opportunity to abort fetuses that have Down's syndrome, a condition leading to mental retardation among other things, demonstrates that many upper-middle class whites view the birth of such a child as a result that they should avoid. See Ampola, *supra* note 110, at 96 (noting that the most important reason for amniocentesis is to determine whether older women are carrying fetuses with Down's syndrome). Other cultures may view the burden of retardation as less onerous. One recent study cited the statement of a Haitian man in New York who said that there was no reason to diagnose Down's syndrome prenatally. He reasoned that people in the United States view all the children from his ethnic group as slow but that the children performed well in the local Haitian private school. Rapp, *supra* note 129, at 135. Indeed, there is no word for Down's syndrome in the Haitian language even though the incidence of this syndrome around the world varies only with the age at which women have children. This investigator also noted that people in other cultures view conditions leading to physical defects as more handicapping than mental retardation.

131. For many, the birth of an affected child may be seen as divinely ordained and a burden that should willingly be borne. Thus, abortion or a decision not to have more children may be viewed as morally unacceptable. Others may not see artificial insemination by a donor, a technique that can avoid the risk faced by a man and woman who both carry a particular autosomal recessive trait, as a viable option. Regina A. Kenen, *A Look at Prenatal Diagnosis Within the Context of Changing Parental and Reproductive Norms*, in *THE CUSTOM-MADE CHILD?: WOMEN-CEN-*

Nonetheless, despite the limitations inherent in assessing the response to genetic risk by looking at its impact on procreation, this is the outcome measure most frequently used. In examining women at risk for having children with sickle cell disease, one investigator who interviewed thirty women found that the majority of them would want prenatal diagnosis even though only one quarter would abort an affected fetus.¹³² Another group of researchers who looked not at what women said but what they did found that of twenty-two pregnant women who were at risk for having a child with sickle cell anemia, fourteen had amniocentesis, and of the four fetuses found to be affected, three were aborted.¹³³ Although these results suggest that parents value this sort of information, some selection bias appears in these studies in that these women came in for counseling. The verbal and nonverbal information that these women received about sickle cell disease may also have affected their decisions.

The potential problems in generalizing from studies that look at what individuals do about reproduction after counseling are highlighted more clearly when one looks at the acceptance

TERED PERSPECTIVES, *supra* note 110, at 67, 70.

132. See Peter T. Rowley, *Parental Receptivity to Neonatal Sickle Cell Trait Identification*, 83 PEDIATRICS 891, 892 (1989).

133. See Ranjeet Grover et al., *Newborn Screening for Hemoglobinopathies: The Benefit Beyond the Target*, 76 AM. J. PUB. HEALTH 1236, 1236-37 (1986). Similarly high rates of changed reproductive plans have been found in other countries. See *General Discussion*, in GENETIC SCREENING: FROM NEWBORNS TO DNA TYPING, *supra* note 79, at 304-05 (noting that prenatal diagnosis and abortion of fetuses affected by beta-thalassemia is commonly conducted in Cyprus and Ferrara, in part because having an affected child is enormously expensive and appropriate medical management is not widely available). An overwhelming majority of couples whose boys are diagnosed in the newborn period as having Duchenne muscular dystrophy accept reproductive counseling. *Session I: Classical Screening: An Update; Neonatal Genetic Screening; Highlights of Contributed Papers*, in GENETIC SCREENING: FROM NEWBORNS TO DNA TYPING, *supra* note 79, at 115-16. A recent study in the Netherlands found that "77% of the families [of children with cystic fibrosis] decided against further children after genetic counseling, resulting in a 50.8% reduction of subsequent childbirth as compared to the general population." Jeannette E. Dankert-Roelse et al., *Effect of Screening for Cystic Fibrosis on the Influence of Genetic Counseling*, 32 CLINICAL GENETICS 217, 273-74 (1987); see also Gerry Evers-Kiebooms, *Decision Making in Huntington's Disease and Cystic Fibrosis*, in GENETIC RISK, RISK PERCEPTION, AND DECISION MAKING 115 (Gerry Evers-Kiebooms et al. eds., 1987); H. Plauchu et al., *Systematic Neonatal Screening for Duchenne Muscular Dystrophy*, in ADVANCES IN NEONATAL SCREENING, *supra* note 64, at 371 (finding that three-fourths of mothers who were found not to be carriers of Duchenne muscular dystrophy nonetheless remained concerned about the health of future children and chose not to procreate again).

By contrast, none of the families changed their reproductive plans when their children had been identified as having "non-pathological conditions" and were undergoing surveillance following newborn screening. Melançon, *supra* note 79, at 33.

of information about genetic risk itself. A commentator from Baltimore, where newborn screening is completely voluntary and highly accepted, stated that "genetic counseling for reproductive guidance continue[s] to be, for many reasons, not readily accepted by target populations."¹³⁴ Many studies report that families simply do not show up for appointments.¹³⁵ Other investigators asked families their reasons for declining counseling. The reasons given by some of these families suggest that they were inadequately informed about the screening process or that they generally viewed the health care system as punitive.¹³⁶ Other families whose children had sickle trait simply did not understand why they were being given information about their healthy children.¹³⁷ By contrast, some families who may have had a fuller grasp of what was at stake justified their refusal by saying either that they believed that they already had adequate information about the genetic disease or that they wanted to go to other sources for follow-up.¹³⁸

Regardless of whether parents actually desire or act upon the genetic risk information unearthed by newborn screening,¹³⁹ a significant percentage are not offered this informa-

134. Philip L. Townes, *Newborn Screening: A Potpourri of Policies*, 76 AM. J. PUB. HEALTH 1191, 1191 (1986).

135. See, e.g., Lindsey K. Grossman et al., *Neonatal Screening and Genetic Counseling for Sickle Cell Trait*, 139 AM. J. DISEASES CHILDREN 241, 242 (1985) (stating that 26% of trait families contacted did not show up for scheduled counseling appointments); Rapp, *supra* note 129, at 135 (asserting that many women cancel appointments for prenatal diagnosis). There is increasing recognition that "dropping out" is a way that patients express dissatisfaction with the medical care that they are receiving. See Gerald B. Hickson et al., *First Step in Obtaining Health Care: Selecting a Physician*, 81 PEDIATRICS 333, 335 (1988) (finding that 74 out of 84 mothers who changed physicians did so because of dissatisfaction with medical care provided by the doctor or the doctor's staff). People who feel disempowered in the health care system may be inclined to use this tactic because it allows them to do as they wish while avoiding the need to confront the offerer directly. See generally DE CERTEAU, *supra* note 28, at 29-42 (discussing how weak parties in power relationships use certain tactics to avoid conforming to society's rules).

136. Vivien Diaz-Barrios, *New York's Experience*, 83 PEDIATRICS 872, 873-74 (1989). Some investigators have pointed out that families are reluctant to come in for further testing and counseling because the difference between sickle trait, AS, and AIDS confused them or because of prior experiences with neonatal toxicology screens, which have been used to remove babies from mothers at birth. *Id.*

137. See Darleen Powars, *Diagnosis at Birth Improves Survival of Children with Sickle Cell Anemia*, 83 PEDIATRICS 830, 833 (Supp. 1989).

138. Grossman et al., *supra* note 135, at 243. It is possible that these people did not actually want the information, but simply knew to give an excuse that was more acceptable to the institutions that were providing counseling.

139. The consensus of opinion is that these parents ought to be offered genetic counseling notwithstanding some agreement that generating such information is not appropriately the primary goal of screening.

tion at all. For example, at least one group of researchers reported that physicians performing state-mandated screening did not offer genetic counseling to all parents of children with sickle cell anemia, despite the one-in-four chance of recurrence.¹⁴⁰ Even more telling is the wide variation among states in the extent to which they provide genetic counseling to the parents of children who are found to have sickle cell trait.¹⁴¹ Most frequently, the lack of follow-up is blamed on the lack of resources to pursue and talk with families who were hard to find.¹⁴² Regardless of the reason, the fact that so many parents go unwarned demonstrates the lack of consensus about or commitment to the importance of providing genetic information to parents.

3. *The special problems of false positives.* Making a diagnosis of genetic disease in the newborn period may not be an unmitigated good. The parents' relationship with the child may be altered in subtle and not-so-subtle ways. Furthermore, parents may or may not want to know that they are at risk for having similarly affected children in the future. But as complex and potentially harmful as these effects may be, one might argue that they are worth it, especially if there is effective, accessible therapy for the child's condition or if the parents value the information in future childbearing.

No such compensatory benefits exist when the initial results are falsely positive. Moreover, with the advent of newborn screening, concern developed that false positive results

140. See Rowley & Huntzinger, *supra* note 81, at 343 (citing various reasons for failure to counsel parents).

141. See, e.g., Renee V. Gardner & Alan Keitt, *The University of Florida Sickle Cell Screening Program for Neonates: Design and Results*, 80 J. NAT'L MED. ASS'N 273, 277 (1988) (asserting that in early state screening programs parents were not always informed that their children had the sickle cell trait); Grover et al., *supra* note 133, at 1236 (providing results of a New York study that found that only one-third of families of children with sickle cell trait were counseled); Hurst, *supra* note 69, at 870 (providing results of a California study that found that approximately 70% of families of children with sickle cell trait were ultimately counseled).

142. Several states, however, have made efforts to overcome this obstacle. Georgia dealt with the problem by training public health nurses to provide counseling. Herman Harris, *Follow-up of Children with Trait in a Rural Setting*, 83 PEDIATRICS 876, 877 (Supp. 1989). Some states tried to obtain results before the hospital discharged the child so that the mother could more easily be found. Jeffrey S. Lobel et al., *Value of Screening Umbilical Cord Blood for Hemoglobinopathy*, 83 PEDIATRICS 823, 825 (Supp. 1989). One writer suggested that the immediate postpartum period is an especially good time to provide genetic counseling because "[t]he new mother would be available, concerned, and have time to comprehend the information." Kathleen K. Ralston et al., *Screening for Major Hemoglobinopathies in Newborn Blacks*, 79 J. KY. MED. ASS'N 649, 651 (1981).

can adversely affect the developing parent-child relationship.¹⁴³ In a long-term Swedish study of the effect of false positive diagnoses of congenital hypothyroidism, investigators found that approximately three-fourths of the parents initially had strong emotional reactions to the news and after six to twelve months almost twenty percent had residual concerns about their child's health.¹⁴⁴ When the researchers interviewed a subset of these families again four years later, most of those who had initially been worried were still inappropriately concerned, and one third of those who had seemed to be coping well earlier were having problems.¹⁴⁵ Moreover, psychological testing revealed signs of disturbance in fully half of the children.¹⁴⁶ While these investigators admitted that this degree of dysfunction may not have been wholly iatrogenic but rather may have been due in part to underlying psychopathology in the family, which perhaps was unmasked by the screening process,¹⁴⁷ the results confirm that the inaccurate labeling of newborn children as ill may not be benign.

4. *Legal implications of newborn screening for parents.* 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

143. See George J. Annas, *Mandatory PKU Screening: The Other Side of the Looking Glass*, 72 AM. J. PUB. HEALTH 1401, 1401-03 (1982) (noting that heightened parental anxiety may arise from the increase in false positives that would result from routine screening); Rothenberg & Sills, *supra* note 91, at 691-92 (reporting that several families still believed that their child was, or would be, mentally retarded, despite receiving repeated negative results upon retesting and advocating the creation of liaison services to provide support for such families).

144. Göran Bodegård et al., *Psychological Reactions in 102 Families with a Newborn Who Has a Falsely Positive Screening Test for Congenital Hypothyroidism*, 304 ACTA PAEDIATRICA SCANDINAVICA 1, 20 (Supp. 1983); see also James R. Sorenson et al., *Parental Response to Repeat Testing of Infants with "False-Positive" Results in a Newborn Screening Program*, 73 PEDIATRICS 183, 185-86 (1984) (citing different ways in which parents were told about the need for retesting and pointing out that some parents had concerns about their children's health even after their children received a clean bill of health).

145. Karen Fyrö & Göran Bodegård, *Four-Year Follow-up of Psychological Reactions to False Positive Screening Tests for Congenital Hypothyroidism*, 76 ACTA PAEDIATRICA SCANDINAVICA 107, 111 (1987).

146. *Id.*; see also Karen Fyrö & Göran Bodegård, *Difficulties in Psychological Adjustment to a New Neonatal Screening Programme*, 77 ACTA PAEDIATRICA SCANDINAVICA 226, 229-31 (1988) (finding a similar rate of adverse effects on the mother-child relationship, but a lower rate of disturbance in children and ascribing this difference to the act of parents directing their anger toward health care providers).

147. Fyrö & Bodegård, *supra* note 146, at 229-31; Fyrö & Bodegård, *supra* note 145, at 112-13.

the effects of such screening appear to the outside observer to be beneficial or harmful, these consequences have legal implications because they represent intrusions into matters that society has generally concluded the family, and not the state, is to decide.¹⁴⁸ Newborn screening can alter what parents know and do about their children's health care. While most families may well value this knowledge, some will not, especially when they understand the broader implications of being informed.

The realm of family privacy or governance, however, extends not only to parents' decisions about how to raise the children they already have but also to the relationships between the parents themselves and especially to their decisions about whether to have more children. Parents often alter their childbearing plans when they discover that they are at risk of having a child with a serious genetic disorder. Similar changes occur when parents have a child who is very impaired, even when the risk that future children would be similarly affected is not so clear.¹⁴⁹ The problem of state involvement is clearest when children are incorrectly diagnosed as having a genetic or other serious disorder. In some instances, the parents may decide unnecessarily to undergo prenatal diagnosis in future pregnancies, which may result in miscarriage. They may also choose not to have more children. No matter what weight one gives to the interest in procreation,¹⁵⁰ it is of sufficient importance that negligent or intentional interference with its exercise should give rise to liability in tort.¹⁵¹

148. One might also argue that the parent-child relationship suffers interruption when the medical community incorrectly diagnoses the child as having disease, thus causing harm to both the child and the parent. Even if negligence caused this injury, the courts would be unlikely to recognize a parent's claim for tortious loss of consortium or interference with the relationship given the limited protection of such relational interests. *But cf. Selders v. Armentrout*, 207 N.W.2d 686, 688-89 (Neb. 1973) (recognizing parents' claim for loss of child's consortium in a wrongful death case).

149. I have often seen families who have children with multiple medical problems devote all of their attention to caring for those children and who choose not to have other children.

150. John Robertson, for example, has argued that the right to procreate is a fundamental interest protected by the Constitution. John A. Robertson, *Procreative Liberty and the Control of Conception, Pregnancy, and Childbirth*, 69 VA. L. REV. 405, 414-20 (1983). Others believe that the Constitution does not go that far. *See, e.g., Ellen W. Clayton, Women and Advances in Medical Technologies: The Legal Issues, in WOMEN AND NEW REPRODUCTIVE TECHNOLOGIES: MEDICAL, PSYCHOSOCIAL, LEGAL, AND ETHICAL DILEMMAS, supra note 5, at 90-91.*

151. That the interest in procreation is protectable in tort is illustrated by the number of cases that women have brought alleging that they were made infertile by abortion-related infections or, more commonly, by intrauterine devices. *See, e.g., Rose*

Parents' privacy in matters of procreation is also affected when their child is correctly diagnosed as having a genetic disease. News that they might have future affected children is unexpected and certainly is not information that parents actively seek. They may even have known that the diagnosed disorder "ran in the family" but chose to have children as a leap of faith. It is difficult to imagine, however, that such parents can be awarded damages for being given news about the particular risks they face in childbearing.

Here as well, the state's role in newborn screening poses particular problems, for there are limits on the amount of information that the state can require individuals to receive on matters so fundamental as those concerning whether to have children. In the related context of abortion, the Supreme Court has repeatedly affirmed that while the state has a legitimate interest in ensuring that pregnant women know about the consequences of their decisions, this interest "will not justify abortion regulations designed to influence the woman's informed choice between abortion or childbirth."¹⁵² Indeed, the only reason that the state can require that women be told anything at all about the procedure is the state's interest in "protecting the health of the pregnant woman."¹⁵³ If the state cannot go out of its way to urge a woman to carry a fetus to term despite its asserted fundamental interest in life,¹⁵⁴ then

v. Fife, 255 Cal. Rptr. 440, 442-44 (Ct. App. 1989) (alleging sterility and other health problems related to an intrauterine device); *Cole v. Delaware League for Planned Parenthood, Inc.*, 530 A.2d 1119, 1120-21 (Del. 1987) (claiming that an abortion caused plaintiff's sterility or incapacity to bear children); *Courtney v. Searle Pharmaceuticals, Inc.*, 567 N.E.2d 370, 370-71 (Ill. App. Ct. 1990) (alleging that an intrauterine device damaged plaintiff's reproductive organs and severely reduced her fertility).

152. *City of Akron v. Akron Ctr. for Reprod. Health, Inc.*, 462 U.S. 416, 444 (1983) (footnote omitted); see *Thornburgh v. American College of Obstetricians & Gynecologists*, 476 U.S. 747, 759-765 (1986) (finding that the state's informed consent requirements for women seeking abortions amounted to an attempt to intimidate women into continuing their pregnancies and holding that such requirements were impermissible). The Court recently distinguished this line of cases on the ground that the statutes struck down in those cases applied to all physicians and all patients. See *Rust v. Sullivan*, 111 S. Ct. 1759, 1777 (1991). In contrast, the "gag" rule before the *Rust* Court dealt only with the recipients of Title X funds. *Id.* at 1777-78. The other difference, of course, is that the first set of cases dealt with efforts to tell women too much, whereas *Rust* deals with prohibitions on telling women anything at all.

153. *City of Akron*, 462 U.S. at 443.

154. The Supreme Court has held that the state's interest in life can override an individual's freedom of choice in two types of cases. The first type of case involves abortion funding. See, e.g., *Harris v. McRae*, 448 U.S. 297, 312-18 (1980); *Poelker v. Doe*, 432 U.S. 519, 519-522 (1977); *Maher v. Roe*, 432 U.S. 464, 474 (1977). The second involves the rights of incompetent patients to refuse life-sustaining treatment.

it cannot go out of its way to dissuade couples from procreating by providing them with genetic risk information they do not seek. As hard as it is to understand why the state can justifiably require pregnant women to go through an informed consent procedure before they can get an abortion in order to protect their health,¹⁵⁵ it is even harder to believe that the state can insist that prospective parents hear about their genetic risk "for their own good" so they can avoid the burden of having a child with defects. There would be no small irony in a rule of law that would hold, on the one hand, that the state cannot mandate that pregnant women hear arguably accurate information¹⁵⁶ to persuade them to carry their pregnancies to term but on the otherhand, can require people to receive disclosures designed to encourage them not to have more children or, even more paradoxically,¹⁵⁷ to seek out prenatal diagnosis and selective abortion. This is not to say that people should be denied access to information about reproduction and its risks. The law does and should ensure that this sort of information is made available to those who want it. Rather, it is to say that individuals, and not the government, should decide what

See, e.g., Cruzan ex rel. Cruzan v. Director, Mo. Dep't Health, 110 S. Ct. 2841, 2852-56 (1990).

155. To begin with, the premise upon which the requirement of informed consent is usually based is respect for patients' autonomy, not a perception that patients will be healthier if they participate in decision making. Moreover, there is reason to doubt that the states are actually seeking primarily to protect women's health when erecting barriers to abortion. In *Thornburgh v. American College of Obstetrics and Gynecologists*, 476 U.S. 747, 764 (1986), the Supreme Court demonstrated that in its elaborate disclosure requirements the Pennsylvania legislature primarily sought to discourage abortion by passing by pointing out that "the Commonwealth does not, and surely would not, compel similar disclosure of every possible peril of necessary surgery or of simple vaccination . . ." If promoting the woman's health is neither the actual nor a legitimate reason for requiring women to receive information, then the state could not enforce any sort of disclosure in the abortion setting. The state, through common law and increasingly through statutes, does give patients a limited right to give informed consent prior to undergoing medical procedures. What is important here, however, is that when physicians fail to inform, it is the injured patient, and not the state, who must decide whether to sue. Physicians are rarely, if ever, punished by the state for failing to obtain informed consent.

156. *Cf. Thornburgh*, 476 U.S. at 761 (citing a Pennsylvania statute that required such disclosure). No one really disputes, for example, that women who have unwanted pregnancies can choose to carry the fetus to term then give the child up for adoption and that there are agencies that will facilitate such transactions. Some legislative requirements have been struck down in part because they require physicians to disclose matters that are speculative at best. *See, e.g., City of Akron*, 462 U.S. at 444 & n.34 (rejecting the requirement that physicians disclose "anatomical and physiological characteristics of the particular unborn child").

157. The paradox arises because the federal government has recently taken the stance that it need not tell poor women who are pregnant anything about abortion. *See Rust v. Sullivan*, 111 S. Ct. 1759, 1777-78 (1991) (upholding this stance).

factors they will consider when deciding whether to have children.¹⁵⁸

C. *The State*

Although most people ordinarily think of health care decisions as being made privately by individual physicians (increasingly in conjunction with their patients),¹⁵⁹ the state has always engaged in activities intended to improve the health of its citizens. While many state actions seek to promote health by creating a safer or less toxic environment¹⁶⁰ or by expanding access to traditional medical care,¹⁶¹ the state has also, for many years, directly intervened in the lives of its citizens¹⁶² in the name of public health.¹⁶³

158. Finding out that one's child has a genetic disease may carry implications that extend outside the family as well. Employers, particularly small ones, may be reluctant to hire a person whose child requires expensive, episodic, or burdensome care that requires a parent to take time off from work. In addition, for some disorders, such as neurofibromatosis, the presence of disease in a child usually means that a parent is affected. The parent may then have to confront many of the problems of labelling and discrimination that affect children with the disorder.

159. For general background in the theory and development of informed consent, see PAUL S. APPELBAUM ET AL., *INFORMED CONSENT: LEGAL THEORY AND CLINICAL PRACTICE* (1987); RUTH R. FADEN & TOM L. BEAUCHAMP, *A HISTORY AND THEORY OF INFORMED CONSENT* (1986); KATZ, *supra* note 14.

160. The examples of such actions are myriad and often have had profound effects. Many commentators cite the development of public sewer systems as one of the most effective actions ever taken in the name of public health. *E.g.*, John M. Last, *Scope and Methods of Prevention*, in *PUBLIC HEALTH AND PREVENTIVE MEDICINE* 3, 5 (John M. Last ed., 12th ed. 1986). More recently, we have created extensive bureaucracies at both the state and federal levels devoted to the promotion of environmental and occupational health.

161. Prior to World War II, most people paid for medical care out of their pockets so that there was obviously a multi-tiered system. GEORGE J. ANNAS ET AL., *AMERICAN HEALTH LAW* 17-25 (1990). The rich received care from private practitioners, the middle class did without care to varying degrees, and the very poor went to the charity hospitals for care. *Id.* at 23-25. This system has changed in the last 40 years due to the emergence of the federal and state governments as major payers for health care and the increasing importance of employer-based health insurance. *Id.* at 17-22. Preferential treatment by the government has helped to enhance the growth of employer-based health insurance. *Id.* at 20-22.

162. Sometimes the line between direct and indirect intervention becomes murky, as is evidenced by the controversy regarding fluoridation of water. Although the state's purpose in fluoridating water is to prevent dental caries, some people object to the alteration of water that they drink. *See, e.g.*, *Dowell v. City of Tulsa*, 273 P.2d 859, 864 (Okla. 1954), *cert. denied*, 348 U.S. 912 (1955).

163. The term "public health" includes a number of possible definitions, each of which may have different implications. At one level, it can simply mean the health of the population as a whole, to be assessed almost as a part of the resources of the community. How many able-bodied people are there in the population? At another level, the term seems to focus more on threats posed to the health of individuals within the community, which then raises issues of appropriate response: What is the incidence of measles in the population? How can we increase the vaccination rate,

The state has been the primary provider of newborn screening since shortly after such tests were developed. In some ways, having the state in this role should confer advantages. At the most mundane level, the existence of a state-run program usually means that the testing is paid for,¹⁶⁴ thus avoiding the inequities inherent in the piecemeal health insurance that exists in this country.¹⁶⁵ The involvement of the state should also mean that all children are tested, especially in states where screening is mandatory. In reality, the states vary widely in the percentage of children who are tested. Finally, given the fact that families move and change health care providers frequently, the state has more tools at its disposal with which to find children who are diagnosed with serious conditions at birth and to ensure that they receive continuity of care. Here as well, the success of states in the context of finding and tracking children varies widely.¹⁶⁶

1. *Limits upon state action in the name of health.* Even if these practical problems were resolved, questions would exist concerning how far the state can go in the pursuit of the health of its citizens. The earliest debates in this country regarding these limits occurred in the context of mass vaccination, culminating in the Supreme Court's decision in *Jacobson v. Massachusetts*.¹⁶⁷ In *Jacobson* the Court held that the state could require citizens to be vaccinated for

especially in high-risk populations?

164. See, e.g., KAN. STAT. ANN. § 65-180(b) (1990) (explicitly stating that there is no fee for newborn screening). Some states, however, permit the costs to be passed to the families of the children being tested. See, e.g., ILL. ANN. STAT. ch. 111-1/2, para. 4904 § 2(e) (Smith-Hurd 1988); KY. REV. STAT. ANN. § 214.155(1) (Michie/Bobbs-Merrill 1991). Wisconsin imposes a surcharge on all families to pay for the treatment of children with PKU. WIS. STAT. ANN. § 146.02(2) (West Supp. 1991).

165. Ten to twelve million children have no health insurance at all, and many more are underinsured. Birt Harvey, *A Proposal to Provide Health Insurance to All Children and All Pregnant Women*, 323 NEW ENG. J. MED. 1216, 1216 (1990); Charles N. Oberg, *Medically Uninsured Children in the United States: A Challenge to Public Policy*, 85 PEDIATRICS 824, 824 (1990). Moreover, insurers in the private market are free within very broad limits to define the scope of their coverage; therefore, an insurer might choose to refuse to pay for newborn screening, although this seems unlikely given its cost effectiveness.

166. See, e.g., Ranjeet Grover, *Newborn Screening in New York City*, 83 PEDIATRICS 819, 821 (1989) (demonstrating that 51 of 708 children identified for follow-up testing in New York City were unlocatable for more than six months); Miller et al., *supra* note 70, at 1344 (finding that 36% of children with SCA are not found in time to treat the disease); see also Listernick et al., *supra* note 70 (suggesting that state programs consider contacting parents directly regarding abnormal screening test results). See generally Rowley & Huntzinger, *supra* note 81, at 341 (discussing the results of follow-up testing of children afflicted with sickle cell anemia).

167. 197 U.S. 11 (1905).

smallpox against their will,¹⁶⁸ reasoning that "a community has the right to protect itself against an epidemic of disease which threatens the safety of its members"¹⁶⁹ so long as the means adopted by the state were reasonably related to public health.¹⁷⁰ This issue then lay quiescent for almost three-quarters of a century,¹⁷¹ only to reemerge in questions concerning the propriety of the involuntary treatment of the mentally ill¹⁷² and the appropriate response to the advent of AIDS.¹⁷³

Two major lessons can be learned from this questioning. The first is that the state has two sources of power with which to protect the public health, each applying in different circumstances and having different limits. The more commonly invoked and broader power is the police power—the state's authority to prevent one person from harming another.¹⁷⁴ This power justifies many actions that the state takes to prevent the spread of infectious disease,¹⁷⁵ or efforts to confine indi-

168. *Id.* at 38.

169. *Id.* at 27.

170. *See id.* at 26.

171. During this period, the occasional cases that did occur usually involved prostitution and/or tuberculosis. *See, e.g., Reynolds v. McNichols*, 488 F.2d 1378, 1383 (10th Cir. 1973) (upholding a city ordinance that required physical examinations of prostitutes in an effort to help combat venereal disease).

172. This issue has led to much litigation and literature. *See, e.g., Washington v. Harper*, 494 U.S. 210, 218 (1990) (allowing medical treatment of a mentally ill prisoner against his will); *Mills v. Rogers*, 457 U.S. 291, 306 (1982) (discussing whether involuntarily committed mental patients must submit to drug therapy and remanding the case for further discussion); *Rivers v. Katz*, 495 N.E.2d 337, 345 (N.Y. 1986); Ellen W. Clayton, *From Rogers to Rivers: The Rights of the Mentally Ill to Refuse Medication*, 13 AM. J.L. & MED. 7 (1987) (arguing against forced medical treatment of the mentally ill).

173. *See* RONALD BAYER, PRIVATE ACTS, SOCIAL CONSEQUENCES: AIDS AND THE POLITICS OF PUBLIC HEALTH 137-146 (1989) (discussing opposition to compulsory screening of groups with a high risk of contracting AIDS); Lawrence O. Gostin et al., *The Case Against Compulsory Casefinding in Controlling AIDS—Testing, Screening and Reporting*, 12 AM. J.L. & MED. 7, 19-21 (1987) (discussing the effects of compulsory screening of selected groups for the HIV virus); *see also* Larry Gostin, *Traditional Public Health Strategies*, in AIDS AND THE LAW: A GUIDE FOR THE PUBLIC 47 (Harlon L. Dalton et al. eds., 1987) (discussing the impact of the AIDS epidemic).

174. Statutes that criminalize so-called "victimless" crimes, such as pornography or prostitution, are often justified as appropriate exercises of the police power even though they are designed to protect the participants themselves. Many feminists argue that these practices are not victimless at all, but rather harm many people, especially women. *E.g.,* CATHERINE A. MACKINNON, FEMINISM UNMODIFIED: DISCOURSES ON LIFE AND LAW 148 (1987). The critique levelled more commonly against such statutes is that they intrude too much on individuals' rights of privacy. PETER W. LAW ET AL., CRIMINAL LAW: CASES AND MATERIALS 1076 (2d ed. 1986).

175. These actions include requirements for vaccinations, quarantines and the reporting of infectious diseases. *See Jacobson v. Massachusetts*, 197 U.S. 11, 39

viduals who are mentally ill in order to prevent them from injuring others.¹⁷⁶ Although the police power has historically been invoked only to protect others from physical harm,¹⁷⁷ pressure is increasing to force individuals to "live healthier" to decrease the costs they might otherwise impose on the health care system.¹⁷⁸ The second and narrower power is that of the state as *parens patriae*, the authority to intervene to prevent a person at risk from the self-infliction of serious harm.¹⁷⁹

The second lesson is that the state's decisions to provide treatment for certain diseases result, at least in part, from politics rather than from an objective analysis of those medical problems that cause the greatest avoidable morbidity. The response to the advent of AIDS provides a good example.¹⁸⁰

(1905) (upholding a state statute that required smallpox vaccination); *Compagnie Francaise De Navigation a Vapeur v. State Bd. of Health*, 186 U.S. 380, 396-97 (1902) (upholding the mandatory quarantine of immigrants); see, e.g., CAL. HEALTH & SAFETY CODE § 3125 (West 1990) (requiring medical personnel to report a communicable disease case to state health officers); WIS. STAT. ANN. § 143.04 (West 1989) (requiring notification of health officers of all communicable diseases); see also CAL. HEALTH & SAFETY CODE § 3380 (West 1990) (providing the legislative intent behind the California immunization statute).

176. See Clayton, *supra* note 172, at 29.

177. *Id.*

178. SYLVIA N. TESH, HIDDEN ARGUMENTS: POLITICAL IDEOLOGY AND DISEASE PREVENTION POLICY 58-82 (1988). But see GENETIC SCREENING: FROM NEWBORNS TO DNA TYPING, *supra* note 79, at 326. Laberge has proposed that societies that have universal health insurance

do not need to have informed consent for their citizens to participate in preventive programs, because when they are born into it they use their accessibility to medicare as a right and the society has the structures and the representation at all levels to make sure that the good of the society is taken care of within that accessibility.

Id.

179. See Clayton, *supra* note 172, at 29 (discussing the power of *parens patriae* and how it infringes on personal autonomy). For example, the state can treat the mentally ill against their will if medication will prevent them from causing themselves serious harm. C.M. CULVER & B. GERT, PHILOSOPHY AND MEDICINE: CONCEPTUAL AND ETHICAL ISSUES IN MEDICINE AND PSYCHIATRY 148-57 (1982). Similarly, as effective therapy for HIV and its sequelae becomes available, support continues to grow for the identification of infected individuals. See Ronald Bayer, *Public Health Policy and the AIDS Epidemic—An End to HIV Exceptionalism?*, 324 NEW ENG. J. MED. 1500, 1501 (1991) (describing the recent growth in support of mandatory testing for HIV).

180. Various commentators have elaborated on the politics that we are involved in defining a governmental response to AIDS. See, e.g., RONALD BAYER, *supra* note 173, at 232-44; RANDY SHILTS, AND THE BAND PLAYED ON: POLITICS, PEOPLE, AND THE AIDS EPIDEMIC 466-76, 528-38 (1978) (defining a governmental response to AIDS).

Political targeting of health care and research money is, in fact, quite common. For example, it has recently been revealed that researchers have systematically excluded women as research subjects and have studied medical problems that primarily affect women much less frequently than those that primarily affect men. See Bernadine Healy, *Women's Health, Public Welfare*, 266 JAMA 566, 566 (1991) (advocating

Initially, states ignored the disease because it primarily afflicted gay men, a disfavored group. That state of affairs changed, however, as gay men mobilized their political power to obtain larger amounts of money for the areas of medical care and research. More recently, AIDS has spread most rapidly among intravenous drug abusers, especially among lower class and minority groups, affecting their children and sexual partners as well. Many believe that because these groups are disempowered in the political process they will not be as effective in mobilizing funding for AIDS research and treatment.¹⁸¹

2. *Questioning the state's role in newborn screening.*

How do these lessons apply to newborn screening programs? To begin with, if the affected child is the target, the state cannot justify screening as an exercise of the police power. Because genetic disorders are not "catching," the child does not pose a health risk to others. One might argue that the parents could "harm" future children by passing on the genetic disorder and that the state can appropriately intervene to prevent this injury. The problem with this argument is that the only way to protect the child from getting the genetic disorder is to prevent the child from being born. Even if one concedes that some

cating the NIH's stance that medical research on women's health and medical concerns must play a pivotal role in the elimination of disparities between genders). As a result, women's health problems may be less well-understood because findings from studies of men are routinely extrapolated to women without considering whether these problems affect women in the same manner as men. See JoAnn E. Manson et al., *A Prospective Study of Aspirin Use and Primary Prevention of Cardiovascular Disease in Women*, 266 JAMA 521 (1991) (suggesting that data from earlier studies regarding the efficacy of aspirin may not be generalizable from men to women). Similarly, regarding conditions that both men and women suffer from, evidence from recent studies suggests that women are routinely offered less medical intervention, even when they suffer greater morbidity from the condition. E.g., John Z. Ayanian & Arnold M. Epstein, *Differences in the Use of Procedures Between Women and Men Hospitalized for Coronary Heart Disease*, 325 NEW ENG. J. MED. 221 (1991) (pointing out that women undergo fewer necessary medical procedures than men and suggesting factors that may lead to this difference); Council on Ethical and Judicial Affairs, American Medical Ass'n, *Gender Disparities in Clinical Decision Making*, 266 JAMA 559 (1991) (discussing evidence that physicians treat women who require medical treatment less than men for kidney, lung and cardiac disease); Steingart et al., *Sex Differences in the Management of Coronary Artery Disease*, 325 NEW ENG. J. MED. 226 (1991) (observing that studies demonstrate that doctors are less likely to pursue aggressive treatment for women with coronary artery disease than for men, despite the fact that coronary artery disease is the leading cause of death among women). See generally Lawrence K. Altman, *Men, Women and Heart Disease: More Than a Question of Sexism*, N.Y. TIMES, Aug. 6, 1991, at B5 (arguing that factors other than cultural bias may be responsible for the gender disparities in medical treatment).

181. See David Concar, *Protesters Ask for More*, 345 NATURE 376, 376 (1990) (claiming that minority groups do not receive enough medical services).

conditions may make a child's life not worth living,¹⁸² the disorders for which newborn screening is currently performed do not qualify. Nor is it likely that the diseases sought in newborn screening will ever be the basis for wrongful life claims because newborn screening is most appropriate when effective treatment is available.

The state, then, is far more likely to invoke its role as *parens patriae* as the source of its authority to conduct newborn screening. At first, the analogy between the state as parent and parents as parents seems compelling, but further analysis reveals two problems with viewing the state as "parent." First, these children have "real" parents, whether by biological or other social connections, who have far-reaching authority to make important decisions regarding their children. The state is not completely free to override the parents' choices.

Second, concern for children does not seem to be the state's primary motivation for participation in newborn screening.¹⁸³ The fact that the state bases its decisions about which diseases to seek on cost-benefit analyses¹⁸⁴ makes clear that avoiding burdens on the public fisc is a major reason for screening.¹⁸⁵ Further, the cost benefit analyses that have

182. This concession is the essence of a wrongful life claim, which has received only grudging recognition by the courts. Compare *Turpin v. Sortini*, 643 P.2d 954, 966 (Cal. 1982) (allowing a child to recover special damages for medical expenses) and *Harbeson v. Parke-Davis, Inc.*, 656 P.2d 483, 488 (Wash. 1983) (allowing a claim for wrongful birth) with *Becker v. Schwartz*, 386 N.E.2d 807, 813 (N.Y. 1978) (recognizing a claim only for medical expenses) and *Elliott v. Brown*, 361 So. 2d 546, 548 (Ala. 1978) (denying that a claim for wrongful life exists). For articles forcefully advocating recognition of wrongful life claims, see Alexander M. Capron, *Tort Liability and Genetic Counseling*, 79 COLUM. L. REV. 618, 682-84 (1979); John A. Robertson, *Procreative Liberty and the Control of Conception, Pregnancy, and Childbirth*, 69 VA. L. REV. 405, 463 (1983); Margery W. Shaw, *Conditional Prospective Rights of the Fetus*, 5 J. LEGAL MED. 63, 109-11 (1984). *Contra Note, Father and Mother Know Best: Defining the Liability of Physicians for Inadequate Genetic Counseling*, 87 YALE L.J. 1488, 1500-02 (1987).

183. One of the primary justifications offered for compulsory screening is the desire to help children who cannot help themselves. See George C. Cunningham, *Balancing the Individual's Rights to Privacy Against the Need for Information to Protect and Advance Public Health*, in *GENETIC SCREENING: FROM NEWBORNS TO DNA TYPING*, *supra* note 79, at 210; Faden, *supra* note 5, at 45.

184. A cost-benefit analysis compares the costs of detection and treatment with the costs associated with late diagnosis. See *HEALTHY CHILDREN*, *supra* note 59, at 105-06. Researchers calculate the costs of conditions that lead to mental retardation in light of the costs of long-term care or decreased earning potential. See *id.* at 106.

If non-economic effects are not taken into account, these sorts of analyses can lead to troubling conclusions. Recently, a group of investigators performed a cost-effectiveness analysis of newborn sickle cell screening directed only at blacks. They acknowledged that stigmatization could accompany such an approach, but did not attempt to weigh this effect in their work. Joel Tzevat et al., *Neonatal Screening For Sickle Cell Disease: A Cost-Effectiveness Analysis*, 118 J. PEDIATRICS 546, 553 (1991).

185. George Cunningham, the director of these programs in California, concluded

been done are fundamentally flawed because they are based on the invalid premise that affected children receive care.¹⁶³ This assumption is invalid because many states neither provide treatment nor require insurers to pay for it¹⁶⁷ and many families have trouble meeting the demands of dietary and other therapeutic regimens necessary to provide care for affect-

that because the state pays for long-term care, "it therefore has a compelling interest in promotion of such prevention programs as will reduce that expense." Cunningham, *supra* note 183, at 210. In a recent study, the Office of Technology Assessment calculated that the cost of early detection and treatment of children with PKU and congenital hypothyroidism was less than the cost of long-term care of affected children who were not treated. HEALTHY CHILDREN, *supra* note 59, at 106.

Some criticize newborn screening because the costs are borne by all, while the benefits are reaped by a few. Peter Mamunes, *Neonatal Screening Tests*, 27 PEDIATRIC CLINICS N. AM. 733, 735 (1980). Such complaints miss the point that government engages in many such activities and that actions that benefit the few also benefit the many. Society benefits from having healthy children.

186. That is, the analysis usually assumes that when screening detects a disorder, the disorder will be treated and associated costs in the future will be avoided. See HEALTHY CHILDREN, *supra* note 59, at 105-06 (balancing the costs of detection against averted treatment costs).

187. The most complete description of who pays for treatment is found in ILLINOIS DEPT. OF PUB. HEALTH, *supra* note 88. Several states provide medical and dietary treatment for some individuals through statutory provisions regarding expenditure of state funds. See, e.g., ALASKA STAT. § 18.15.200(d) (1991) (providing treatment for PKU); CAL. HEALTH & SAFETY CODE § 341 (West 1990) (providing access to social services); D.C. CODE ANN. § 6-318 (1989) (providing care for the indigent); FLA. STAT. ANN. § 383.14(2)(e) (West 1990) (providing treatment "where practicable . . . [if] not otherwise available"); LA. REV. STAT. ANN. § 40:1299.1.A.(4) (West Supp. 1992) (providing medical care, dietary, and other related needs where necessary or desirable); MINN. STAT. ANN. § 144.128(1) (West 1990) (providing treatment if an individual is uninsured and unable to afford the treatment). Some states provide treatment only if sufficient funds are available. See, e.g., TEX. HEALTH & SAFETY CODE ANN. § 33.032(a) (Vernon 1992); WASH. REV. CODE ANN. § 70.83.040 (West 1992).

Some states do not even go that far. One legislature makes clear that treatment is the responsibility of the family, see NEB. REV. STAT. § 71-519 (1990), and another provides that the state can require families to pay up to two percent of their gross income for special diets, VA. CODE ANN. § 32.1-67 (Michie Supp. 1991). One might argue that the state still provides a benefit by performing newborn screening because treatment for most children will be covered by their parents' insurance. Few states, however, require insurance policies to pay the cost of treatment, and in some of these states, the requirement covers only PKU. See MASS. GEN. LAWS ANN. chs. 175, § 47C; 176A, § 8B; 176B, § 4C (West Supp. 1992) (PKU, tyrosinemia, homocystinuria, maple syrup urine disease, propionic acidemia, methylmalonic acidemia); MINN. STAT. ANN. §§ 62A.26(2), 62E.06(1)(f), 256B.0625(13)(a) (West 1989 & Supp. 1990 & Supp. 1992) (PKU and other metabolic diseases); MONT. CODE ANN. §§ 33-22-131, 33-31-102 (1990) (PKU); TEX. INS. CODE ANN. art. 3.79 (Vernon 1990) (PKU); WASH. REV. CODE ANN. § 48.20.520 (West Supp. 1992) (PKU). Of course, these requirements do not apply to all insurance within those states because ERISA will govern a large percentage of the insurance. See Mary Anne Bobinski, *Unhealthy Federalism: Barriers to Increasing Health Care Access for the Uninsured*, 24 U.C. DAVIS L. REV. 255, 347-48 (1990) (claiming that ERISA will preempt many state attempts to legislate insurance).

ed children.¹⁸⁸

To be fair, the state must engage in a balancing process in deciding how to spend its money because money spent for one program is then not available for others. Even so, it is one thing to decide whether a particular expenditure is an effective way to help people and another to establish a program in order to avoid future burdens.¹⁸⁹ One simply cannot assume that the state will have the child's interest primarily at heart.

3. *How newborn screening became a function of the state.* The political process that led to the adoption of newborn screening laws reveals another reason to scrutinize the state's motives. As Katherine Acuff and Ruth Faden recently pointed out, there is real reason to question why the issue of newborn screening ever entered into the public health and legislative/regulatory arenas at all.¹⁹⁰ The process by which PKU screening came to be required by law is illustrative.

Some suggest that states enacted PKU screening laws to overcome the reluctance of individual physicians to test newborns.¹⁹¹ Although many practitioners were already incorpo-

188. The fact that the state usually fails to provide treatment has led some observers to point out that "[l]aws that compel screening but do not provide funds for counseling and treatment . . . suggest that the state, arbitrarily, is not willing to pay the full price to gain the benefit to society." Holtzman et al., *supra* note 45, at 240.

189. The desire to avoid burdens on the state led to the enactment of eugenic sterilization laws in the earlier part of this century. See generally PHILIP R. REILLY, *THE SURGICAL SOLUTION: A HISTORY OF INVOLUNTARY STERILIZATION IN THE UNITED STATES* (1991). In the words of Justice Oliver Wendell Holmes:

It would be strange if it [the State] could not call upon those who already sap the strength of the State for these lesser sacrifices . . . in order to prevent our being swamped with incompetence. It is better for all the world, if instead of waiting to execute degenerate offspring for crime, or to let them starve for their imbecility, society can prevent those who are manifestly unfit from continuing their kind.

Buck v. Bell, 274 U.S. 200, 207 (1927).

A few courts have recently upheld the validity of involuntary sterilization laws, citing concerns about burdens on the state in their opinions. See, e.g., *In re Sterilization of Moore*, 221 S.E.2d 307 (N.C. 1976). The growing official consensus is that it is inappropriate for the state to pursue eugenic goals. See, e.g., NATIONAL ACADEMY OF SCIENCES, *supra* note 93, at 228; PRESIDENT'S COMM'N FOR THE STUDY OF ETHICAL PROBLEMS IN MEDICINE AND BIOMEDICAL AND BEHAVIORAL RESEARCH, SCREENING AND COUNSELING FOR GENETIC CONDITIONS 54 (1983). Note, however, that *Buck v. Bell* was cited with approval in *Roe v. Wade*, 410 U.S. 113 (1973) for the proposition that the Constitution does not provide individuals with an "unlimited right to do with one's body as one pleases . . ." *Id.* at 154.

190. See Katherine L. Acuff & Ruth R. Faden, *A History of Prenatal and Newborn Screening Programs: Lessons for the Future*, in AIDS, WOMEN, AND THE NEXT GENERATION: TOWARDS A MORALLY ACCEPTABLE PUBLIC POLICY FOR HIV TESTING OF PREGNANT WOMEN AND NEWBORNS 59, 60 (Ruth R. Faden et al. eds., 1991).

191. See, e.g., *Blood Spots in the Year 2000: Directions for Policy*, in GENETIC

rating these tests into their routine neonatal care, institutions such as the American Academy of Pediatrics initially opposed legislatively mandated screening.¹⁹² Yet the perception of medical foot-dragging regarding newborn screening does not suffice to explain the state's virtually complete occupation of this field. After all, legislators usually do not intervene merely because they believe that changes in medical practice are coming too slowly.

To say that states enacted newborn screening laws because of lobbying by individual practitioners and political interest groups is closer to the truth.¹⁹³ For example, early PKU laws were put into place largely in response to the pressure exerted by Dr. Robert Guthrie, the developer of the test for PKU,¹⁹⁴ and the National Association for Retarded Children (NARC).¹⁹⁵ Although the legislative process typically

SCREENING: FROM NEWBORNS TO DNA TYPING, *supra* note 79, at 339, 354.

192. This opposition was due to concerns that practitioners had little experience with screening for PKU and, therefore, were not aware of the problems which might result from screening. This concern was eventually justified. See PHILIP REILLY, GENETICS, LAW, AND SOCIAL POLICY 48-49 (1977) (observing that the American Academy of Pediatrics made a formal "statement on Compulsory Testing of Newborn Infants for Hereditary Metabolic Disorders" criticizing PKU screening laws, but advocating future screening efforts based on further scientific research).

193. The visibility of recent efforts by AIDS activists to hasten research and release of new treatments represents a recent example of political pressure on medicine. See J. Daniel Kiser, *Legal Issues Raised by Expedited Approval of, and Expanded Access to, Experimental AIDS Treatments*, 45 FOOD DRUG COSM. L.J. 363, 363-64 (1990) (arguing that the response of Congress and the Food and Drug Administration to political pressure to speed the approval of new drugs for the treatment of AIDS is a dramatic exception to the more usual hands-off approach of the government); Elizabeth Schaefer, *AIDS Politics Change Rules*, 349 NATURE 187, 187 (1991) (suggesting that promising new AIDS drugs such as dideoxyinosine and dideoxycytidine may win quick approval from the Food and Drug Administration due to political pressure, despite the potential for serious side effects). See generally Symposium, *Panel Discussion on the Expedited Drug Approval Procedures*, 45 FOOD DRUG COSM. L.J. 327 (1990) (including papers that address the traditional approach to drug regulation and approval, how recent changes in those procedures affect the work of clinical researchers and their sponsors in AIDS research, and the various legal issues raised by such changes).

194. Over the years Robert Guthrie has continued to be a vocal proponent of newborn screening. See Robert Guthrie, *Techniques and Efficacy of Screening: Newborn Screening*, 83 PEDIATRICS 836, 837 (Supp. 1989) (outlining the historical development of the PKU test and advocating the application of newborn screening techniques for sickle cell anemia and cystic fibrosis).

195. See NATIONAL ACADEMY OF SCIENCES, *supra* note 93, at 45-47; REILLY, *supra* note 192, at 45-46 (arguing that the efforts of the NARC and Dr. Guthrie were instrumental in the passage of New York's PKU screening law in 1964); see also Judith Swazey, *Phenylketonuria: A Case Study in Biomedical Legislation*, 48 J. URB. L. 883 (1971) (discrediting other possible explanations for the development of legislatively mandated PKU screening for newborns). More recently, Barry Wolf has championed the consideration of newborn screening programs around the world for biotinidase deficiency. See Barry Wolf & Gregory S. Heard, *Screening for Biotinidase*

moves in response to the voices of individual and institutional advocates,¹⁹⁶ this response still does not resolve the question of whether the state may justifiably involve itself in newborn screening.

One might argue that, given the complex social, economic, and emotional consequences of newborn screening, the state might make better decisions concerning screening—through extended political and regulatory consideration—than would the medical profession. After all, physicians engage in practices of questionable merit which are incorporated into routine care on a relatively haphazard basis; they may also have conflicts of interest with their patients in a fee-for-service system. Yet there is reason to worry about how well the state can do in this area. First, the process of adopting screening legislation has often been quite politicized. In addition, Neil Holtzman and others point out that public participation on this topic tends to overstate the benefits and to underestimate the problems associated with screening.¹⁹⁷

Moreover, while the states' approaches to screening vary widely, most of the approaches taken present some serious problems. In some states, the legislature defines which diseases are to be sought.¹⁹⁸ In New York, for example, the legislature directs the state department of health to test for PKU, sickle cell anemia, congenital hypothyroidism, branched chain

Deficiency in Newborns: Worldwide Experience, 85 PEDIATRICS 512, 512 (1990) (arguing that each state, region, and nation should individually determine if biotinidase deficiency screening should be incorporated into its screening program based on the incidence of the disorder, the availability of resources, and the priorities of the law in that area). In other cases, specific ethnic or racial groups supported screening for disorders that were particularly prevalent within their populations. For example, prominent members of the black community, including, interestingly enough, the Black Panthers, supported legislation to require screening for sickle cell disease and trait. TROY DUSTER, *BACKDOOR TO EUGENICS* 47-50 (1990). It has also been suggested that white legislators acquiesced because these programs seemed like a visible but inexpensive ways to help blacks, a goal that seemed desirable in the aftermath of the Great Society. REILLY, *supra* note 192, at 65 (1977). Congress also passed a series of ethnically-based programs until the late 1970s, when it finally adopted a broader approach to genetic diseases. *Id.* at 78-82.

196. See generally Cass R. Sunstein, *Interest Groups in American Public Law*, 38 STAN. L. REV. 48 (1985) (discussing the role of private interest groups in the formulation of the republican political agenda since the time of the American Revolution).

197. Holtzman et al., *supra* note 45, at 238.

198. See, e.g., COLO. REV. STAT. ANN. § 25-4-1004(1)(b) (West Supp. 1991) (mandating that all infants be tested for PKU, hypothyroidism, abnormal hemoglobins, galactosemic, homocystinuria, maple syrup urine disease, cystic fibrosis, and biotinidase deficiency); GA. CODE ANN. § 31-12-6 (Michie 1991) (requiring the department of health to establish a system for the prevention of phenylketonuria, galactosemia, tyrosinemia, homocystinuria, maple syrup urine disease, hypothyroidism, congenital adrenal hyperplasia, and other inherited metabolic disorders).

ketonuria (maple syrup urine disease), galactosemia, and homocystinuria.¹⁹⁹ While one may applaud this "laundry-list" as permitting more accountability, such an approach presents some difficulties. If, for example, the state were to mandate testing for a disorder such as histidinemia that was later determined to be a benign condition, it is hard to imagine who would push for amendment of the statute to stop testing for the condition. Certainly, the families of the few children with the particular inborn error of metabolism are unlikely to have the political clout to do so. Furthermore, the companies that make the test and the laboratories that perform it might lobby against change.²⁰⁰

Other state legislatures delegate authority to agencies to establish programs and to decide what to test for.²⁰¹ One might expect this approach to lead to better choices because it not only permits greater flexibility but also ensures that individuals who have greater expertise than legislators will make the decisions. The requirement in many states of public hearings prior to administrative action makes it even more likely that there is some public input into the process. Yet administrative agencies have less direct accountability to the public than do legislators. The possibility that regulators will be subject to less restraint is of some importance because they may not be even-handed in their actions, if for no other reason than their need to respond to the pressures of the bottom line and the implications of cost-benefit analyses. Moreover, evi-

199. N.Y. PUB. HEALTH LAW § 2500-a (McKinney 1985 & Supp. 1992).

200. The problem of how to respond to inappropriately required screening was recently addressed in Colorado. The Colorado legislature directed that newborns be tested for cystic fibrosis and other diseases. COLO. REV. STAT. § 25-4-1004(1)(b) (West Supp. 1991). Recent evidence suggests that early intervention may not alter the course of cystic fibrosis, thus raising questions about whether this disorder should be sought in the newborn period. Refer to note 234 *infra*. If so, families need not lobby the legislature to repeal the statutory provision; last year the legislature empowered the state department of health to stop testing even for named disorders if it finds that early detection will not confer a benefit on affected children. Act of May 6, 1991, § 17(1)(b), 1991 Colo. Sess. Laws 142.

201. See, e.g., ARIZ. REV. STAT. ANN. § 36-694(B) (1986) (authorizing a metabolic screening committee to promulgate rules and regulations for the testing of metabolic disorders); CAL. HEALTH & SAFETY CODE § 309(a) (West Supp. 1992) (requiring the state department to establish a genetic disease unit to coordinate all California genetic disease programs); D.C. CODE ANN. § 6-316(4) to (6) (1989) (requiring that the Committee on Metabolic Disorders reevaluate on a continuing basis the need for various newborn screening tests and advise the mayor which screening tests the District should add or delete); FLA. STAT. ANN. § 383.14(1) (West Supp. 1992) (requiring the Department of Health and Rehabilitative Services to promulgate rules for genetic screening tests after consultation within the Genetics and Infant Screening Advisory Council).

dence suggests that eugenic or other concerns that are publicly unacceptable motivate some administrators consciously or subconsciously.²⁰² Consequently, there is reason to question whether the state will necessarily make better decisions about screening than the medical profession.

Thus, the state's role in newborn screening is complex and problematic. One can ask whether the states exceed their constitutional authority in establishing such programs. Certainly, the powers that generally justify state intervention into matters of health do not fit comfortably here, and the state's interest, no matter how well conceived, is hardly compelling. Even assuming that the states are acting within the limits of their power, it is not obvious that these programs should be in the public domain at all, particularly since similar screening efforts are undertaken as a matter of course in the context of routine medical care. No reasons suggest that the state is a particularly dispassionate or wise decision-maker in this area, for the state is subject to cost constraints that can oppose the interests of the children being screened and their families. In addition, history reveals that political advocacy by individual practitioners and special interest groups greatly influenced the development of newborn screening programs. Finally, although one can argue that the involvement of the state can lead to more uniform access, this potential has only been partially met.

V. COMPLETING THE FRAME—NEWBORN SCREENING WITHIN THE MEDICAL MODEL

Drawing material from a range of discourses has provided a more complete picture of the impact of newborn screening. Not surprisingly, the results depict a system that neither finds all affected children nor directs them efficiently into treatment which will ensure them a normal life. They also show that the screening process does not leave all unaffected children unharmed. Although no screening system is perfect, all such programs must factor in the consequences of mistaken diagnoses. At the same time, people who engage in newborn screening must decide what frequency of false positives and false negatives are acceptable. Clearly the rate of inaccurate diagnoses

202. See generally DUSTER, *supra* note 195, at 58-59 (discussing the role of state bureaucracy in the formulation and implementation of genetic disorder politics and arguing that rather than operating as a neutral organ, health organizers have "favorite" disorders and ailments).

could be reduced in some programs.

Research also demonstrates that the screening process has implications extending beyond the identification of disease. On a personal level, screening affects the children's emotional development and interactions with their parents and the parents' decisions about further childbearing. Additionally, screening results can have far reaching legal and economic consequences for how children and their families fit into society as a whole. Children identified, accurately or not, as "different" may face discrimination for which they have little remedy. Their parents may find themselves locked into their present jobs or unable to obtain health insurance for their families. To complicate the picture even further, the reasons for the state's prominent involvement in this process are complex and not obviously justifiable. Also, how fully the state directs its involvement toward promoting the interests of children is debatable. The broad impact of newborn screening, then, contributes to the potential for conflict between the interests of children, their parents, and the state.

Looking at this more complete consideration of newborn screening makes it surprising that little formal regulation of this type of testing has been enacted. The final section of this article looks more closely at the legislative and regulatory response to these programs and suggests ways in which the laws and rules ought to be amended. First, however, weighing two more factors helps to complete the picture: (1) the implications of locating newborn screening within the medical model²⁰³ and (2) the ways that the predictive potential of the new genetics should lead to reconsidering the appropriateness of thinking about screening in this way.

Despite their shortcomings, current programs address newborn problems that are susceptible, albeit to varying degrees, to amelioration by obviously medical interventions. Such therapies include thyroid hormone replacement for congenital hypothyroidism,²⁰⁴ penicillin for sickle cell disease,²⁰⁵ and radi-

203. A recent international consensus conference stated as its first conclusion that "[n]ewborn genetic screening is a medical act in the context of preventive medicine." Claude M. Laberge & Bartha M. Knoppers, *Genetic Screening: From Newborns to DNA Typing*, in GENETIC SCREENING: FROM NEWBORNS TO DNA TYPING, *supra* note 79, at 379, 382.

204. Jean H. Dussault, *15 Years of Screening for Congenital Hypothyroidism: The Remaining Controversies*, in GENETIC SCREENING: FROM NEWBORNS TO DNA TYPING, *supra* note 79, at 19, 23.

205. It is now known that the commencement of penicillin prophylaxis in infancy can be lifesaving for children with sickle cell anemia. See Marilyn H. Gaston et al., *Prophylaxis with Oral Penicillin in Children with Sickle Cell Anemia*, 314 NEW ENG.

cally altered diets for PKU.²⁰⁶ Thinking about these diseases within a medical model seems appropriate because these diseases are viewed as medical problems, clearly within the purview of the health care system. Yet this type of thinking has far reaching political and economic implications.²⁰⁷ It places responsibility for the care of these children clearly within the family with some important restrictions. Parents are the ones who must ensure that the child is treated, but physicians tell parents what to do, and the state enforces the doctors' orders through the law of child abuse and neglect.²⁰⁸ In addition, the parents are usually responsible for much or all of the cost of care.²⁰⁹ Thus, the family has burden of providing for an affected child with only some of the control.

The potential power of the new genetic diagnostics and prognostics makes thinking about newborn screening in solely medical terms problematic in at least two ways. First, many diseases that cause significant morbidity in society are multifactorial in origin. These diseases are the result of interactions between an individual's genetic makeup and factors in his lifestyle and environment.²¹⁰ Certain types of disease, such as heart disease and special types of cancer, run in families—the products of shared genes, shared environment, or both.²¹¹

Given the enormous amount of interest and money being devoted to genetics at present, both the definition of the contribution that genes make to these diseases and the ability to distinguish which individuals have the predisposing genes will increase.²¹² Yet political views about the shape of the world

J. MED. 1593, 1598 (1986) (concluding that administration of prophylactic therapy with oral penicillin within four months of age may decrease the mortality associated with pneumococcal septicemia for children with sickle cell anemia).

206. Melançon, *supra* note 79, at 117, 119.

207. The work of Sylvia N. Tesh has strongly influenced my thinking on this topic. See SYLVIA N. TESH, *supra* note 178.

208. See CHRONIC CHILDHOOD DISORDERS 270-72 (Gwilym Hosking & Ruth Powell eds., 1985) (including failure to provide medical treatment in the definition of punishable child neglect).

209. Even if the state pays for treatment, the parents must alter their lives to ensure that the care is provided. In other settings, one parent may need to quit work to provide care or the parents may need to accept the intrusion of having health care providers, such as nurses, in their home.

210. Fletcher & Wertz, *supra* note 5, at 757. A classic example of such a disease is alpha₁-antitrypsin deficiency in which the appearance of lung dysfunction is aggravated by cigarette smoking and environmental toxins. See ROBIN MCKIE, THE GENETIC JIGSAW: THE STORY OF THE NEW GENETICS 97 (1988) (noting that the lungs of people with AAT deficiency are less resistant to damage from cigarette smoking).

211. MCKIE, *supra* note 210, at 93-94.

212. Fletcher & Wertz, *supra* note 5, at 758.

may underlie the decision to look for genetic rather than other causes of diseases and characteristics.²¹³ In addition, political consequences will differ depending upon which notion of causation for the disease is sought.²¹⁴ If the increase in lung disease and cancer is thought to be the result of the growing burden of environmental toxins, then society may question how it can force government and industry to clean up the air and water.²¹⁵ If heart disease is seen to be the result of a high fat diet and inadequate exercise, it seems acceptable to ask the individual to shoulder much of the burden of helping himself. Even under such a model of causation, however, there is still room to think about how society can create incentives to encourage the desired behavior and about how institutions, such as the media, lead to such bad habits.²¹⁶ If the focus is on genetic factors, however, the temptation is to put the responsibility entirely on the individual. She cannot change her genes, but she can do whatever it takes to minimize the occurrence of disease in herself and her children.²¹⁷ Thus, the genetic/medical model is the most isolating, and it is the model to which we increasingly turn when thinking about multifactorial disease.²¹⁸

213. See MCKIE, *supra* note 210, at 7 (referring to past efforts by some individuals to use alleged genetic differences between groups or races to obtain political gain). Troy Duster recently pointed out, for example, that while there have been repeated efforts to attribute the poor performance of many black children on standardized tests to genetic inferiority, the superior performance of Jewish children on such examinations is routinely ascribed to cultural and environmental influences. DUSTER, *supra* note 195, at 9-10. Duster also pointed out that the poor performance of Jews on such tests in the early part of this century was ascribed to genetic inferiority and was the basis for limiting their immigration into this country. *Id.* at 9. The political reasons to look for one cause for intelligence in one setting and another cause in a different setting are obvious. It suits many in the dominant culture to assert that African Americans are inferior "by nature," but it would threaten many to assert that Jews are inherently superior.

The crux of this argument is that the manner in which one frames a question affects the answer that will be obtained. If one is looking only for genetic contributions to intelligence, only the genetic contributions will be found (assuming that they play a role at all), despite the fact that other factors may play a role. It is an entirely different issue to choose not to examine certain information because the consequences of the resulting knowledge may be too great. Can one choose, for example, not to elucidate the genetic contributions to intelligence on the ground that information about those factors would undermine other important social norms?

214. DUSTER, *supra* note 195, at 18.

215. MCKIE, *supra* note 210, at 92-93.

216. TESH, *supra* note 178, at 161-62.

217. See Fletcher & Wertz, *supra* note 5, at 758 (discussing a "moral obligation" to use genetic knowledge to benefit future generations).

218. As a striking example of this in the context of newborn screening, there has recently been interest in testing neonates for hyperlipidemias, see Frank Franklin, *Neonatal Screening for Familial Hypercholesterolemia: Implications for the Pediatrics*

The enormous prognostic potential of new genetic technologies raises other questions about newborn screening. At present, even though the point of newborn screening is to find children while they are asymptomatic, something must be measurably different in the affected children if they are to be found.²¹⁹ Yet many people who will have diseases with some genetic contribution later in life have no abnormalities detectable by ordinary means in the newborn period. The ability to look directly at the genome, however, will make it possible to know who has these "bad" genes from infancy.²²⁰ The question is what to do with this power to know what is coming.

One concern is that people are not able to deal emotionally with knowing the manner of their own or their children's death.²²¹ In addition, the structure of the insurance system in this country certainly provides a strong practical incentive for deciding not to obtain the information that one has a genetic predisposition to a burdensome disease.²²² Yet, surveys suggest that some mothers want to know, for whatever reason, if their newborns are going to suffer from disabling conditions.

But whether individuals want or should be allowed to know about their own and their children's genetic predispositions, other groups—insurers and employers among them—have strong economic reasons for wanting this information.²²³ Many people do not realize that the genetic data is

cian, in *ADVANCES IN NEONATAL SCREENING*, *supra* note 64, at 329, even though there is no consensus that cholesterol levels in childhood, to say nothing of infancy, are predictive of cholesterol levels later in life or if dietary or medical intervention is appropriate. Neil A. Holtzman, *The Great God Cholesterol*, 87 *PEDIATRICS* 943, 943 (1991).

219. HOLTZMAN, *supra* note 1, at 55. For example, a child with congenital hypothyroidism has a high level of thyroid stimulating hormone and a low thyroxine in the blood, Dussault, *supra* note 204, at 23, a child with PKU has elevated levels of phenylalanine, *CHRONIC CHILDHOOD DISORDERS*, *supra* note 208, at 172-73, and boys with Duchenne muscular dystrophy have high levels of a muscle enzyme, *id.* at 57.

220. See Fletcher & Wertz, *supra* note 5, at 748.

221. See Marlene Huggins et al., *Ethical and Legal Dilemmas Arising During Predictive Testing for Adult-Onset Disease: The Experience of Huntington Disease*, 47 *AM. J. HUM. GENETICS* 4, 5 (1990) (discussing the responsibility of genetic counselors to avoid harming persons who are not psychologically or emotionally equipped to deal with predictive-testing results). Researchers who study Huntington's disease, for example, have joined together and promulgated guidelines under which they refuse to look for the mutant gene in children and even in adults who do not meet their rigorous psychological criteria. *Id.* at 11. Others have criticized this practice as inappropriately paternalistic. Mary Z. Pelias, *Duty to Disclose in Medical Genetics: A Legal Perspective*, 39 *AM. J. MED. GENETICS* 347, 349 (1991). In any event, it is foreseeable that these researchers will be subjected to a wrongful birth claim by a woman who is at risk for Huntington's disease but who has been refused testing. *Id.* at 348.

222. See HOLTZMAN, *supra* note 1, at 197.

223. See *id.* at 193-205 (discussing the use of genetic information by insurers and

contained in the blood samples obtained by the state at birth.²²⁴ It becomes imperative, then, to ensure the confidentiality of this information.²²⁵ A harder question is what the state will do with these results. After all, DNA testing promises to be the ultimate technique for identification.²²⁶ Can blood samples then be saved to be used later for forensic and other related purposes?²²⁷ However one answers these questions, the information potentially obtainable by newborn screening can clearly be put to uses that far exceed any purposes that can comfortably be cabined within the medical model.²²⁸

Consideration of the old and the new genetics raises fundamental concerns about how to think about the source of disease, how society and individuals ought to respond to illness and dysfunction, how to decide which problems deserve study, and the unspoken and perhaps unconscious assumptions that are applied in formulating and answering questions. These issues are knotty and not susceptible to simple answers, especially if one considers not only systemic concerns but also the local impact of genetic information on individuals in particular

employers).

224. See PRESIDENT'S COMM'N FOR THE STUDY OF ETHICAL PROBLEMS IN MEDICINE AND BIOMEDICAL AND BEHAVIORAL RESEARCH, *supra* note 189, at 2 (1983) (noting that genetic testing often requires only a simple blood test and laboratory analysis).

225. *Id.* at 6. Several commentators have discussed the problems associated with this "DNA banking." *E.g.*, Lori B. Andrews, *DNA Testing, Banking, and Individual Rights*, in GENETIC SCREENING: FROM NEWBORNS TO DNA TYPING, *supra* note 79, at 217, 223; Laberge & Knoppers, *supra* note 203, at 389.

226. See Paul C. Giannelli, *Criminal Discovery, Scientific Evidence, and DNA*, 44 VAND. L. REV. 791, 796 (1991).

227. See Laberge & Knoppers, *supra* note 203, at 389 (discussing the implications of "banking" newborn blood samples). Some have suggested that the state could keep such samples only at the cost of assuming greater responsibility for the children tested. For discussions of the potential duty of geneticists to recontact patients in order to inform them about newly discovered genetic data, see generally Andrews, *supra* note 225, at 223-26; Pelias, *supra* note 221. One might argue that when the state begins to screen for a new disorder, it must apply the test not only to blood samples of all newborns, but also to all blood samples that it has in storage. *Id.* at 352. The possibility of so-called "look back" liability has been an issue of increasing concern in genetic counseling literature. See, *e.g.*, Andrews, *supra* note 225, at 223 (discussing the physician's duty to recontact the patient); Pelias, *supra* note 221, at 352 (discussing potential liability for failure to disclose newly discovered, material genetic information). Although this theory seems particularly burdensome because it implies that a one-time encounter can lead to a duty of care that extends into perpetuity, certainly no reason exists to think that its application should not extend to all areas of medicine, whether provided by individual practitioners or the state, particularly because the cases on which this theory relies involve routine medical practice. See Andrews, *supra* note 225, at 223-224.

228. See Andrews, *supra* note 225, at 219-226 (noting that banked DNA can be used for multiple purposes, including research and insurance investigations).

contexts. That genetics poses such intractable problems suggests that even for something as "easy" as newborn screening, society ought to "proceed with caution."²²⁹

VI. WHAT THEN IS SOCIETY TO DO?

Over the years, several prominent groups of commentators have said that state-run newborn screening programs are justified only if they are voluntary and directed at diseases which cause serious harm that can be avoided only if treatment is begun in the newborn period.²³⁰ Increasingly, these limitations are coming under attack. A growing number of authorities assert that these programs should be mandatory and that parents should have no right to refuse screening.²³¹ Moreover, history demonstrates a pressure to screen for disorders that do not meet the strict criteria initially set forth, to look for diseases that are not that serious or for which there is no or only partially effective therapy, or to test infants primarily to provide genetic information to parents so that they can "choose" not to have more affected children. The questions then become how screening affects children and their families and how the complex role of the state affects what society should do in the future about these controversies.

A. *The Objects and Objectives of Screening*

Newborn screening affects numerous people and institutions and can bring the participants into conflict with one another.²³² As a result, it is necessary to decide who is the primary focus of these programs. The interests of children should be of central importance because screening principally affects them.²³³

Several consequences follow from focusing on the way screening affects children. First, testing ought to be limited to those disorders that must be treated in the newborn period if serious sequelae are to be avoided. The consequences of screen-

229. HOLTZMAN, *supra* note 1, at 5.

230. See, e.g., NATIONAL ACADEMY OF SCIENCES, *supra* note 93, at 1-5; PRESIDENT'S COMM'N FOR THE STUDY OF ETHICAL PROBLEMS IN MEDICINE AND BIOMEDICAL AND BEHAVIORAL RESEARCH, *supra* note 189, at 5-8.

231. Faden, *supra* note 5, at 45; Fletcher & Wertz, *supra* note 5, at 39.

232. See Pelias, *supra* note 221, at 349 (discussing the conflicts between the interests of parents and those of the unborn children who are tested).

233. Although the impact on parents and other family members must also be taken into account, placing the greatest weight on their interests raises other troubling questions.

ing on children are too serious and far reaching to risk when there is little chance that they will benefit from early detection. Second, screening programs must continually be reevaluated to see if early diagnosis actually helps children.²³⁴ As part of the effort to determine whether newborn screening helps children, it is also necessary to ask how the state's actions affect the families in which the children live. Upsetting the family dynamic without conferring some other benefit may do a child more harm than good. The fact that state involvement is justified only if benefit to the child will ensue raises again the question of whether the state must provide treatment once a diagnosis is made.²³⁵ Surely, identifying a child's illness does him or her no good unless treatment is actually given.²³⁶

Other justifications for screening are less compelling. The potential consequences of labelling are too great to justify iden-

234. For example, Wisconsin began a study several years ago to determine whether early identification of children with cystic fibrosis leads to better outcomes. The data from this study suggests that early intervention does not materially alter the course of the disease. Interview with Benjamin Wilfond, Assistant Professor of Pediatrics, University of Arizona (June 1, 1991); see also P.H. Weller & J.V. West, *Neonatal Screening—Should We Or Shouldn't We?*, 84 J. ROYAL SOC. MED. 78 (Sept. 18, 1991) (stating that "objective significant clinical benefit resulting from early diagnosis is still lacking . . ."). The course of CF in infancy was recently described in Steven H. Abman et al., *Early Bacteriologic, Immunologic, and Clinical Courses of Young Infants with Cystic Fibrosis Identified by Neonatal Screening*, 119 J. PEDIATRICS 211, 212 (1991). These investigators, who work in Colorado, the only state that currently screens for CF on a routine basis, were unable to determine whether early detection actually helped the children because they had no controls. See *id.* at 216 (noting that the relationship between early detection and long-term outcome is not clear). If anything, their findings tend to suggest that early intervention does not help. As a result, some of the early enthusiasm for detection in newborns has waned. Weller & West, *supra*, at 8 (expressing reservations about national screening). But see Ian C.T. Lyon & Dianne R. Webster, Letter to the Editor, *Newborn Screening for Cystic Fibrosis*, 87 PEDIATRICS 954, 955 (1991) (urging continued evaluation of newborn screening programs).

235. See, e.g., PRESIDENT'S COMM'N FOR THE STUDY OF ETHICAL PROBLEMS IN MEDICINE AND BIOMEDICAL AND BEHAVIORAL RESEARCH, *supra* note 189, at 8 (recommending that individuals have access to prescreening and follow-up prior to their introduction to a genetic screening program); see also Fletcher & Wertz, *supra* note 5, at 757 (arguing that increased knowledge about genetics should encourage government to develop a public health insurance plan).

236. The problems do not end even if the economic resources are available to pay for treatment. Patricia Baird recently suggested in a related context that unless compliance with the recommended treatment is high, which is a problem even in the most simple treatment regimens and clearly is difficult to achieve for onerous, long-term therapy, state money might better be spent "on a broad social campaign to decrease the level of a known environmental disease determinant for all people." Patricia A. Baird, *Opportunity and Danger: Medical, Ethical and Social Implications of Early DNA Screening for Identification of Genetic Risk of Common Adult Onset Disorders*, in GENETIC SCREENING: FROM NEWBORNS TO DNA TYPING, *supra* note 79, at 279, 283-84.

tifying children with "benign" variants in the newborn period so that states can observe the clinical course of these differences. Even if families might want to know whether their newborns will suffer from some disorder which is only partially treatable or which may not cause any substantial morbidity at all, it is unclear that the children would actually benefit from the state's efforts to provide their parents with this knowledge.²³⁷ Moreover, while parents clearly should receive the information about genetic risk revealed by newborn screening,²³⁸ testing newborns in order to acquire such information about the parents is both inefficient and unjustified. It is one thing for the state to provide carrier testing or prenatal diagnosis because individuals can decide for themselves whether to be tested.²³⁹ It is entirely another for the state to test newborns to generate information about the parents because neither the infants nor their parents have any practical ability to

237. In some instances, parents insist that their children undergo testing for conditions for which there is little or no treatment. Because it is apparent that children may suffer from such testing, physicians often have difficulty deciding how to respond to these demands. It is not always clear whether a child would be harmed more by the parents' unhappiness and repeated trips to the doctor or by simply performing the test and making a diagnosis. There are also limits on the degree to which the physician can override the parents' wishes to pursue the physician's notion of the child's good. There may be times when the provider should acquiesce. On a practical level, the physician who refuses to perform the desired intervention also faces the prospect of dealing with the disappointed parents. The state, by contrast, will receive such demands much less frequently, and its ability to meet these requests is limited by the need to invoke the legislative and regulatory processes and to weigh explicitly the impact of acquiescence upon limited resources.

238. Indeed, it is possible that state agencies that failed to provide such information would later be held liable if a couple had another affected child. There are numerous cases sustaining such "wrongful birth" claims against health care providers. *See, e.g.,* *Blake v. Cruz*, 698 P.2d 315, 321 (Idaho 1984); *Schroeder v. Perkel*, 432 A.2d 834, 842 (N.J. 1981). While state agencies traditionally have been immune from similar tort claims on the basis of governmental immunity, that citadel has been under vigorous assault, and state health departments have already been sued when their lapses in newborn screening have led to injury in an affected child. *E.g., Marcel v. Louisiana State Dep't of Pub. Health*, 492 So. 2d 103, 107 (La. Ct. App. 1986) (holding the state liable for its failure to test for phenylketonuria).

239. It is interesting, particularly in contrast with the prevalence of newborn screening, that the state provides far less testing that is directed solely at defining genetic risk. Ellen W. Clayton, *Reproductive Genetic Testing: Regulatory and Liability Issues*, in *FETAL DIAGNOSIS AND THERAPY* (forthcoming 1992). California, for example, provides maternal serum alpha fetoprotein screening and other forms of prenatal diagnosis to pregnant women. CAL. HEALTH & SAFETY CODE § 156 (West Supp. 1992). New York City provides prenatal diagnosis to women on Medicaid. Rapp, *supra* note 129, at 138. Few states explicitly provide carrier screening. It is remarkable that the state provides any of this testing at all, given the opposition to abortion that has emanated from the White House in the last decade. *See* 42 C.F.R. § 51a.7 (1990) (regulating use of Department of Health and Human Services funds for abortions and related medical services in federally assisted programs of the Public Health Service).

decline testing. Constitutional limitations may also impede the state's power to force people to receive such information against their will.

B. Voluntariness and the Rights to Know and to Refuse

When lawyers consider medical decision-making, most think of informed consent. This doctrine, at least in its aspirational terms, holds that patients have the right to choose among alternative medical treatments or to choose no treatment at all, based upon information about the risks and benefits of various courses of action. In reality, the law's commitment to this principle is lukewarm at best.²⁴⁰ More importantly, this doctrine takes as its premise the notion that people ought to be able to use their own values in making decisions that affect their lives. Thus, informed consent cannot apply when others decide—whether the decision-maker is a spouse, a child of an adult in a persistent vegetative state, or a parent who is deciding for a child.²⁴¹

But before considering whether parents can or should be able to refuse, it is necessary to determine whether parents actually know about screening. On a practical level, they must know that screening is occurring if they are to exercise any meaningful choice. There are many reasons why states should inform parents about testing before the fact, even if they have no choice in the matter. To begin with, parents have a right to know what is being done to their children out of respect for their special status as the presumptive decision-makers for their offspring.²⁴² In addition, the information that newborn screening generates may have important implications for the parents themselves in terms of their burdens of caring for the affected child and for their future childbearing. Parents may also cope better with bad results if they know about the testing beforehand,²⁴³ and at least one commentator has suggest-

240. Clayton, *supra* note 150, at 94.

241. Two alternative standards have emerged in matters of life and death; however, the boundaries between the standards are not precisely defined. When a now incompetent patient formerly expressed wishes about his or her care, the decision-maker is said to be exercising "substituted judgment." When the patient had never been competent or had never expressed any opinions, as is inevitably the case with infants, the decision-maker can only act in the patient's "best interests," however defined. PRESIDENT'S COMM'N FOR THE STUDY OF ETHICAL PROBLEMS IN MEDICINE AND BIOMEDICAL AND BEHAVIORAL RESEARCH, *supra* note 189, at 101.

242. One study demonstrated that 80% of women want to know that doctors are performing the test. Ruth R. Faden et al., *A Survey to Evaluate Parental Consent As Public Policy for Neonatal Screening*, 72 AM. J. PUB. HEALTH 1347, 1350 (1982).

243. See Gardner & Keitt, *supra* note 141, at 277 (finding that parental notifi-

ed that parents should be told because they will police the system by looking for the bandaid on the baby's heel to verify that the testing was done.²⁴⁴

Yet states rarely provide complete information to parents. In many states, parents are told nothing at all.²⁴⁵ In others, parents receive a pamphlet about screening in the peripartum period, a time when parents may not fully absorb and comprehend the information if they even read the pamphlet.²⁴⁶ Even in Maryland, which has consistently demonstrated great solicitude toward voluntary screening by requiring disclosure to parents of the purpose of testing and the consequences of genetic disorders and that they then agree to screening,²⁴⁷ nurses who obtain the consent usually spend only a few minutes with the mothers.²⁴⁸ Although it is encouraging that even these brief encounters sharply increase the mothers' immediate knowledge,²⁴⁹ a few minutes may not be sufficient to

cation increased parental interest and information dissemination).

244. See also Lori B. Andrews, *New Legal Approaches to Newborn Screening*, in LEGAL LIABILITY AND QUALITY ASSURANCE IN NEWBORN SCREENING, *supra* note 83, at 4.

245. Most statutes mention nothing regarding informing parents about screening, even when they give parents an opportunity to opt out of the screening. See, e.g., OR. REV. STAT. ANN. § 433.285(3) (1992) (allowing parents to opt out for religious reasons); PA. STAT. ANN. tit. 11, § 875-301(14) (Supp. 1992) (requiring a procedure for a child to exit from early intervention services).

246. As evidence of this, I often tell the following story. My eldest child was born in Wisconsin. At that time, new mothers were given pamphlets about newborn screening which stated in bold print that Wisconsin was engaged in a research project for which researchers tested infants for cystic fibrosis and provided parents with a phone number that they could call to obtain their children's results. In fact, I had earlier been involved in the discussions that led to the inclusion of this information in the pamphlet. Yet a year after his birth, when I became concerned that my child might actually have CF (which fortunately he does not have), it did not even cross my mind that he had already been screened for that disease. Instead, I scheduled him for a sweat test the next day. This experience suggests to me that if I cannot remember what my child was screened for after reading a pamphlet that I had helped design, most other people will not.

247. The District of Columbia requires the most expansive disclosure to parents, stipulating that risks must be disclosed in addition to the purpose and consequences. D.C. CODE ANN. § 6-314(3)(c) (1989).

248. Most nurses did not spend more than ten minutes with the mothers. Faden et al., *supra* note 242, at 1350.

249. One study demonstrated that women interviewed one hour after they had been counseled were more informed about the disorders for which physicians test, the causes and effects, the nature and effectiveness of therapy, and the mechanics and interpretations of the results of the screening than women who had not been counseled. Holtzman et al., *Effect of Informed Parental Consent on Mothers' Knowledge of Newborn Screening*, 72 PEDIATRICS 807, 809-10 (1983). This study was carefully constructed to assess the degree of comprehension, but it is important to recognize that these investigators did not measure long-term retention of information or look at the women's understanding of the psychosocial consequences of screening.

convey the potential implications of screening.

Even if states informed parents about newborn screening, the question of whether participation should be voluntary remains. Although most states give at least some parents the opportunity to opt out of screening,²⁵⁰ a few states have no provisions for refusal,²⁵¹ and two provide criminal penalties for parents who object to screening for nonreligious reasons.²⁵² As a practical matter, this issue of voluntary participation is almost academic because the few studies which actually address the issue demonstrate that parental refusal in voluntary settings is quite rare.²⁵³ Moreover, refusal usually occurs as a result of a parent's misunderstanding of the test's function,²⁵⁴ suggesting that better communication would reduce refusal even further.

Why then permit choice and incur the costs of providing it when everyone will agree to testing anyway?²⁵⁵ Choice is essential because testing has far-reaching implications.²⁵⁶

250. Some states permit parents to opt out of screening for religious or other reasons of conscience. See, e.g., TENN. CODE ANN. § 68-6-403 (1987); WIS. STAT. ANN. § 146.02(3) (West 1989); see also ANDREWS, *supra* note 60, at 238 n.167 (1987) (collecting state statutes that allow parents to opt out for religious reasons). Others permit parents to refuse screening for any reason at all. See, e.g., FLA. STAT. ANN. § 383.14(3) (West Supp. 1992); N.M. STAT. ANN. § 24-1-6(A) (Michie 1991). Even though administrators in California claim that state law requires physicians to obtain parental consent before screening a child, they circumvent that requirement by having the physicians include testing in their postpartum orders. See Deborah Hurst, *Northern California's Experience*, 83 PEDIATRICS 868, 869-870 (Supp. 1989) (claiming that the California statute does not clearly indicate whether consent is required).

251. See GA. CODE ANN. § 31-12-6 (Michie 1991); MICH. COMP. LAWS ANN. § 333.5431 (West Supp. 1992).

252. See MO. ANN. STAT. § 191.331(5) (Vernon Supp. 1992); S.C. CODE ANN. § 44-37-30(B) (Law. Co-op. Supp. 1991).

253. Faden et al., *supra* note 242, at 1347.

254. *Id.* at 1350.

255. More infants are tested in states that have implemented voluntary screening programs. Lori B. Andrews, *Overview of Legal Issues*, 83 PEDIATRICS 886, 887 (1989). In recent years, advocates of voluntary screening have routinely used these findings to bolster their argument, asserting that more testing is performed if parents are permitted to choose, so let them choose. *Id.*; Capron, *supra* note 2, at 687; Louis J. Elsas, II, *A Clinical Approach to Legal and Ethical Problems in Human Genetics*, 39 EMORY L.J. 811, 829 (1990). Not only does this argument seem somewhat cynical, but it also strains credulity to think that the voluntary nature of the test made the difference, because even the so-called voluntary programs are not truly voluntary. Instead, it seems far more likely that the states that are sufficiently interested in providing for voluntary screening are also the states that care enough to ensure that the programs actually work.

256. In the one study that actually asked parents what they thought of mandatory screening, Faden and her collaborators found that of the women who "said they preferred to have the screening test without their consent, . . . [a]t least 80 per cent . . . said that consent was not necessary because the test was simple and not dangerous." Faden et al., *supra* note 242, at 1350. This proffered rationale suggests

Testing can alter the developing parent-child relationship both when clinically significant disease is discovered and when false positive results are obtained. The impact of testing will only grow as the number of diseases screened for increases, and this increase is likely despite the desirability of screening only when clearly defined criteria are met. One can even envision a situation in which so many disorders are sought that every child would have one or more abnormal results, most of which would be falsely positive.²⁵⁷ Just because parents accept screening now does not mean that they would accept it if the rate of false positives were greater. Moreover, parents need to be told why they might choose *not* to know about their child's illness or about their own genetic risk in light of the current structure of society and of the health insurance system. Knowledge is not necessarily positive or autonomy-creating if society penalizes a person for her knowledge.

The argument that programs should be mandatory because they protect innocent children who are unable to help themselves²⁵⁸ fails because the risk that any particular child is a true positive is actually quite low.²⁵⁹ The consequences of mislabelling children who are falsely positive may actually exceed the benefits to the truly affected children of early de-

that these women did not fully appreciate what was at stake.

257. See Annas, *supra* note 143, at 1402-03 (concluding that the more disorders tested for, the more false positives each infant is likely to receive).

258. See PRESIDENT'S COMM'N FOR THE STUDY OF ETHICAL PROBLEMS IN MEDICINE AND BIOMEDICAL AND BEHAVIORAL RESEARCH, *supra* note 189, at 51; Ruth R. Faden et al., *Parental Rights, Child Welfare, and Public Health: The Case of PKU Screening*, 72 AM. J. PUB. HEALTH 1396, 1396-97 (1982); Fletcher & Wertz, *supra* note 5, at 790. One commentator argues that "it is clear that failure to have a newborn tested constitutes unreasonable conduct or, perhaps reasonable but impermissible conduct, given the parental responsibility for care. This determination represents a societal decision as expressed by the state in legislation and regulation after due process hearings." Cunningham, *supra* note 82, at 210.

259. Just because parents should be permitted to refuse screening does not necessarily mean that they should be permitted to refuse treatment if their child is found to have clinically significant disease. Many states, however, have passed statutes that allow parents to refuse at least some medical treatment. See, e.g., GA. CODE ANN. § 15-11-2(8) (Michie 1990) (stating that a child is not deprived if treated "in accordance with the tenets and practices of a recognized church or religious denomination by a duly accredited practitioner thereof"); WASH. REV. CODE ANN. § 26.44.020(3) (West Supp. 1992) (limiting the religious exemption to individuals who practice Christian Science). These provisions have increasingly come under attack, particularly when the child could suffer serious harm that medical intervention could avert. See American Academy of Pediatrics, *Religious Exemptions from Child Abuse Statutes*, 81 PEDIATRICS 169, 169 (1988) (asserting that the constitutional rights of freedom of religion do not justify harming another person in the practice of one's religion). The fact that distinguishes refusal of treatment from refusal of screening is that the identifiable risk to the particular child at issue is much greater in the former case than in the latter.

tection and treatment, particularly if the disease sought is one for which there is questionable or little gain from early intervention.²⁶⁰ It may be that society is willing to impose these costs on children who are false positives in order to secure the benefits to those who are true positives, but it should be acknowledged that this is the trade-off to be made.²⁶¹

There may be other benefits from routinely asking parents about newborn screening. Continual discussion of these programs would keep them in the public eye and hence more likely to undergo periodic reassessment. Such discussion could work to the benefit of children both individually and collectively. Moreover, the need to address the implications of the heritable nature of many of these disorders may increase the pressure on society to consider how it should respond to difference among its citizens, no matter what the sources of the variation might be.

How then should the state approach newborn screening?²⁶² The first step is to establish mechanisms to ensure that children are screened for disorders that would cause substantial morbidity unless effective therapy is begun before the diseases become apparent. One approach would be to establish a commission to consider the risks and benefits of screening for particular conditions. This entity could be empowered either to decide what tests should be performed or to advise regulators and legislators. The membership of such a body should include not only physicians, experts and family members of affected children but also individuals who will inquire into the broader impact of medical intervention. Such sceptics, as they may be viewed, can be found both within and without the medical profession. The real challenge from the legislative perspective, however, is to describe these individuals in order to provide for their representation. Another approach that may be less difficult to implement would be to require periodic evaluation of newborn screening programs according to specified criteria.

The states should also address more clearly the role of

260. See Annas, *supra* note 143, at 1402.

261. See *id.* at 1403.

262. Although one could argue that states should dismantle their programs because they had no business getting involved in the first place, the day for that has long since passed. Besides, one would still be left with the issue of the regulation of newborn screening in the private sector. Although exploring the implications of private newborn screening is beyond the scope of this article, such a system would raise concerns that individual practitioners might be even less likely than the state to question the medical model or to resist the advertising appeals of the tests' manufacturers.

parents in newborn screening. At a minimum, parents must be told that their infants are being tested. Anything less fails to acknowledge their interest in their children. Parents should also be informed about the implications of screening and given the option to reject testing if they wish.²⁶³ The potential adverse consequences of screening are too great and the benefits too small in any particular case to justify mandatory testing.

263. Creating exemptions only for religious objections will not suffice. There are many rational reasons why parents may refuse testing, and the establishment clause suggests that religious excuses should not be privileged over others.