Citizens' Council on Health Care

CCHC Report
April 2009

NEWBORN GENETIC SCREENING
The New Eugenics?

The Case for Informed Consent Requirements for Genetic Testing, Baby DNA Storage and Genetic Research

By Twila Brase, R.N., P.H.N.

Introduction

Newborn screening "represents the largest single application of genetic testing in medicine."[1] It is also "the first and largest example of systematic populationwide genetic testing."[2] Although most States provide parents with the right to opt out of the testing program, primarily for religious reasons, only Wyoming, Maryland and Washington, D.C. require parent consent.[3]

Increasingly, the specter of eugenics has emerged over State government newborn genetic screening programs. For example, The Changing Moral Focus of Newborn Screening, the December 2008 report issued by The President's Council on Bioethics, states:

> "Advocates of a broadened notion of 'benefit' often extol the utility of newborn screening for helping parents make future reproductive decisions…But this notion of 'benefit to the family' is not unproblematic…Suppose that expanded screening of an infant reveals not a fatal and incurable disease but instead a host of genetic variants, each of which merely confers elevated risk for some condition or other. Who is to say at what point an uncovered defect becomes serious enough to warrant preventing the birth of other children who might carry it? **At what point have we crossed the line from legitimate family planning to capricious and morally dubious eugenics?**"[4] *[emphasis added]*

Few people discuss eugenics today. Many don't even know what the term means. Those that do probably think it could never happen again. However, former practitioners of eugenics never lost their zeal, instead seeking ways to recast eugenics in a positive light. American Eugenics Society president Frederick Osborn wrote in 1946, "Population, **genetics,** psychology, are the three sciences to which the eugenist must look for the factual material on which to build **an acceptable philosophy of eugenics** and to develop and defend practical eugenics proposals.[5]

In short, the eugenic programs of the 20th century may now have transformed themselves into 21st century State and Federal 'public health genetics' programs. The compendium of published quotes at the end of this report provides a comprehensive array of evidence that proponents of newborn genetic screening are moving *toward* eugenics—not away from it.

This evidence underscores today's pressing need for fully informed written parent consent requirements for State newborn genetic screening programs, including government storage of—and genetic research using—newborn genetic test results and the DNA specimens collected at birth from the heel of every newborn baby.

Reproductive Suitability Scrutinized Today

Throughout history, proponents of eugenics have focused on the reproduction of children, either through encouraging the "healthy" to reproduce or discouraging the "unhealthy" from procreation.

This focus has been evidenced in history by 29 State sterilization laws, the American Eugenics Society *(1922 – present),* and the horrific Nazi campaign aimed at ridding Germany of the "unfit"—the Jews, the physically deformed, the mentally retarded, the "feebleminded," the inferior, the epileptic, the deaf, the blind, "those suffering from hereditary conditions,"[6] the deviant "asocial" and the politically dissident. That the focus on reproduction still exists today is more than troubling.

Courtesy of Eugenics Archive*, Dolan DNA Learning Center, Cold Spring Harbor Laboratory*

Table 4. Respondents' Perceived Education vs Advice Goals for Counseling Parents*

Goal of Counseling	Rating by Respondents: Important	Neutral	Unimportant
Education			
Understanding of the inheritance pattern	25 (100)†	0	0
Provide information about risk that can be shared with relatives	25 (100)†	0	0
Understand the difference between the affected homozygote children and any heterozygote carriers	7 (30)	1 (4)	15 (65)
Advice			
Identify children who might be, for genetic reasons, unsuitable choices for future reproduction	19 (76)†	4 (16)	2 (8)
Whether parents would plan future pregnancies	13 (57)	2 (9)	8 (35)
Suggest options for prenatal diagnoses (amniocentesis or other prenatal testing) during future pregnancies	6 (24)	15 (60)	4 (16)

*Data are reported as number (percentage).
†Using χ^2 test, compared with even split, $P<.05$.

The authors of a 2001 study "were struck" by the large number of State government officials who agreed with a specific statement regarding assessment of a child's suitability for future reproduction *(see full quote, p. 17).*[7] As the table on the left shows, "19 (54%) of 35 of *[sic]* respondents" who routinely provide counseling—mostly newborn genetic screening follow-up staff at State health departments across the country— thought it important when giving advice to parents to "identify children who might be, for genetic reasons, unsuitable choices for future reproduction."

Graphic found online at http://archpedi.ama-assn.org/cgi/reprint/155/2/120.pdf

CCHC, 1954 University Ave W. Ste. 8, St. Paul, MN 55104 p 651-646-8935 f 651-646-0100 www.cchconline.org

Eugenics Defined

This frank admission by State public health officials aligns with the goal of many who still support eugenics—the reduction or elimination of individuals with disabilities or disease:

Nazi poster: "This hereditarily ill person will cost our national community 60,000 Reichmarks over the course of his lifetime. Citizen, this is your money." Found at: http://www.ushmm.org/propaganda/archive/poster-neues-volk/

"In 1883, Sir Francis Galton coined the term 'Eugenics.' Eugenics refers to the doctrine which holds that the human race can be 'improved' by selective control of breeding to eradicate less 'desirable' traits in society. The supporters of eugenics argue that social problems are caused by inherited genetic traits in people which can be bred out to resolve the problem for future generations. The logical conclusion of this theory is deeply racist and reactionary based on dubious research and prejudice. This led to the introduction of sterilization laws in 27 States in the USA in 1931, and the sterilization of 350,000 people due to unwanted traits during the rise of the National Socialist Party in Germany in 1933."[8]

Sterilization Laws Remain

Compulsory sterilization of the "unfit" was the primary American method of eugenics in the twentieth century. In the first seven decades of the 1900s, 29 states passed sterilization laws and "an estimated 70,000 were eugenically sterilized."[9] For example, on June 17, 1924 the Virginia eugenic sterilization law took effect.

On May 2, 1927 the U.S. Supreme Court wrote in *Buck v. Bell*, a case pertaining to Virginia, "heredity plays an important part in the transmission of insanity, imbecility." Justice Oliver Wendell Holmes Jr., writing for the majority, added, "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. The principle that sustains compulsory vaccination is broad enough to cover cutting the Fallopian tubes."[10]

On October 19, 1927, 21-year old Carrie Buck was sterilized in Virginia against her wishes. She eventually wed William Eagle. They remained married for 25 years, until he died. In May of 2002, Governor Mark R. Warner of Virginia formally apologized to all living and dead victims

of forced sterilization, including Carrie Buck who died in 1983. In 1988, 14 states still had laws permitting involuntary sterilization.[11]

Public Health Eugenics?

Newborn screening began in 1963 with PKU testing—and unintended but devastating effects on some children.[12] This public health genetics program was later promoted as a simple prick of a baby's heel to obtain a few drops of blood to screen not only for PKU (phenylketonuria – 1 out of every 19,000 babies) but also for a few rare disorders that could benefit from early intervention. Such disorders include sickle cell disease (1 of every 1,800 babies) and argininemia (1 of every 300,000 babies).[13]

Found *at The Noble Lie* blog

Today's newborn genetic screening advocates envision a much more comprehensive program in the future. The Heartland Regional Genetics and Newborn Screening Collaborative looks forward to every infant being screened for at least 200 different conditions.[14] Others predict the full genomic sequencing of each child at birth. Søren Holm writes in the book, A Companion to Genethics:

> Newborn screening, which is usually mandated by governments to identify and treat diseases of infancy, has been limited, for ethical reasons, to disorders where early diagnosis and treatment would benefit the newborn, but with multiplex tests the focus of testing may be expanding to include some nontreatable disorders. Kitcher (1996) foresees the day when parents will receive **an entire 'genetic report card"** at the child's birth predicting lifetime health."[15] *[emphasis added]*

Such predictive capability in the hands of government officials and others is not without significant eugenic risk. Despite scientific evidence that a single gene or a group of less than desirable genes does not condemn a person to actually getting the predicted diagnosis,[16] those who know a person's hereditary risks may treat him or her as a threat to the health of others:

> "On a societal level, the goal of reducing the harmful effects of genetic disease through screening and prevention strategies may promote false analogies with the control of infectious disease and its vectors, implicitly identifying carriers of specific genetic mutations as a threat to the public health."[17]

Others, including Federal agencies, argue that the financial cost to society of debilitating genetic conditions is a matter of great concern. In 1998, the U.S. Office of Technology Assessment, in discussing the "Social and Ethical Considerations" raised by the Human Genome Project, wrote, "Human mating that proceeds without the use of genetic data about the risks of transmitting diseases will produce greater mortality and medical costs than if carriers of potentially deleterious genes are alerted to their status and encouraged to mate with no carriers or to use artificial insemination or other reproductive strategies." [18]

CCHC, 1954 University Ave W. Ste. 8, St. Paul, MN 55104 p 651-646-8935 f 651-646-0100 www.cchconline.org

Government detailing of a citizen's genome is a controversial idea, but it is not a new idea. In 1912, the president of the American Breeders Association—renamed the American Genetic Association in 1914—said, "Who, except the prudish, would object if public agencies gave to every person a lineage number and genetic percentage ratings, that the eugenic value of every family and of every person might be available to all who have need of the truth as to the probable efficiency of the offspring."[19]

Who except the prudish would object if public agencies gave every person a lineage number and genetic percentage ratings?

Perhaps a lineage number would not be sufficient to obtain the desired eugenic results. Forty years ago, Linus Pauling, a Nobel-prize winner said the answer to stopping the spread of hereditary disorders would essentially require a tattooed 'Scarlet Letter':

> "I have suggested that there should be ***tattooed on the forehead*** of every young person a symbol showing possession of the sickle-cell gene or whatever other similar gene, such as the gene for phenylketonuria, that has been found to possess…If this were done, two young people carrying the same seriously defective gene…would recognize this situation at first sight, and would refrain from falling in love with one another."[20] *[emphasis added]*
>
> "It is my opinion that legislation along this line, compulsory testing for defective genes before marriage, and some form of semi-public display of this possession, should be adopted."[21]

Is it thus noteworthy that the government-funded Sickle Cell Trust in Jamaica is now providing fifth and sixth grade students with the results of their sickle cell tests on a laminated card with the hope that they will "select partners with normal genes and avoid having a child with sickle-cell disease."[22] The Sickle Cell Trust has also recently set up newborn genetic screening sites to "determine whether the intervention of free screening and counseling will reduce the frequency of births with the disease."[23] On a side note, Jamaica's oldest citizen with sickle cell disease, Isadore Simms-Franklyn, turned 85 years old in 2003.[24]

More Parents Opt Out to Protect Baby

Although most States allow parents to refuse genetic testing—many only for religious reasons—most parents and many hospital staff are unaware of the government's involvement or the opt-out option.[25] Parents and staff likely do not even know the testing is genetic testing.

Furthermore, the parent's right to opt out is typically only the right to refuse the testing in its entirety, not the right to choose the conditions for which their child is tested. All States screen for 21 or more conditions.[26] California screens for 76 conditions with the disclaimer that they may not actually identify an affected child: "Due to biological variability of newborns and differences in detection rates for the various disorders in the newborn period, the Newborn Screening

CCHC, 1954 University Ave W. Ste. 8, St. Paul, MN 55104 p 651-646-8935 f 651-646-0100 www.cchconline.org

Program will not identify all newborns with these conditions." [27]

Currently, State health departments determine the list of tested conditions—some with advice from a state advisory committee. The passage of the federal *Newborn Screening Saves Lives Act of 2007*, enacted on April 24, 2008,[28] will provide Federal funding for the establishment of a uniform set of conditions for which all children would be tested. Today, most States have a set of mandatory tests. A few States have additional supplemental or optional tests for which parent consent is sought. Thus, testing is usually testing for all conditions—or no testing at all.

This presents a dilemma to parents who have become aware of the government's deep involvement in newborn genetic screening. To avoid giving the State health department their child's blood or genetic test results, some parents opt out of the testing altogether, even if they would like their child tested.

This "rock and a hard place" decision forces parents to choose between the risk of not finding out early that their child has a rare newborn condition and the risk of government genetic profiling, which increasingly includes government ownership of their child's DNA *(see next page)*.

For these reasons and perhaps for other reasons as well, some parents with the right to opt out of testing are opting out in greater numbers *(see following chart)*. As the specter of eugenics rises publicly over the program, the refusal rate is expected to increase:

Table 1. Minnesota Newborn Genetic Screening Refusal Rate Rises*

Year	Number of Children Whose Parents Refused Newborn Screening *(per MN Dept of Health, 2/20/09)*
2003	**2**
2004	**11**
2005	**12**
2006	**56**
2007	**72**
2008	**89**

**In 2003, Minnesota parents obtained the legal right to opt out of testing.*

Genetic Registries Emerge

Newborn genetic screening is done at State health department laboratories. Hospitals send newborn blood on a special card to the health department. The test results are then sent to the infant's physician. Some States—perhaps all States—register newborn test results in a state database. The Minnesota Department of Health database holds the newborn genetic test results of all children born since July 1, 1986—more than 1.5 million children. Although the database is

CCHC, 1954 University Ave W. Ste. 8, St. Paul, MN 55104 p 651-646-8935 f 651-646-0100 www.cchconline.org

referred to as the newborn screening database, this database is essentially a State genetic registry filled with hereditary data. There can be no doubt that newborn genetic screening is focused on hereditary-based disorders. The titles of State newborn genetic screening laws tell the story:

- *Screening for metabolic disorders, other hereditary and congenital disorders, and environmental risk factors* (FLORIDA)
- *Hereditary and Congenital Disorders Programs* (MARYLAND)
- *Tests of Infants for Heritable and Congenital Disorders* (MINNESOTA)
- *Phenylketonuria, Other Heritable Diseases, Hypothyroidism, and Certain Other Disorders* (TEXAS)
- *Phenylketonuria and other preventable heritable disorders* (WASHINGTON)

Hitler used family histories, vast hereditary data banks and government patient registries to locate people with disorders.

State government registration of genetic information on children—and their family bloodline—is of particular concern given the history of how such registries have been used in the past for eugenic purposes. Hitler's regime had hundreds of "hereditary and racial care clinics" that examined family histories and "created vast hereditary data banks for the regimes' future use."[29] **Many state health departments already have cancer registries, birth defect registries, stroke registries and myriad other government patient databases**. Most are electronic, linkable and searchable. As we are reminded by the American Council of Human Genetics: "The Nazi sterilization program owed part of its success to the efficiency with which the government maintained patient registries, which made it comparatively easy to locate persons with various disorders."[30]

Baby DNA — Government Property?

Public health agencies not only collect genetic testing data, they collect DNA—the baby's blood. Hospitals are required to send more blood to the agency than is needed for the testing. This *over-collection* provides health officials with a rich supply of citizen DNA that some states are already using for research without consent.[31] The Hastings Center explains the connection:

> "Because only a fraction of each blood sample taken for newborn screening is used in the screening, the remainder is a valuable potential resource for research and program evaluation." [32]

More than 13.5 million newborn genetic screening cards in storage

Twenty states store newborn blood samples from one to 23 years.[33] With 4 million babies born each year and at least ten states retaining newborn blood indefinitely,[34] the repository of infant DNA is large and growing. The baby's DNA is considered state government property. According to the book, The Stored Tissue Issue, there are currently "more than 13.5 million newborn screening cards in storage and new cards being stored at a rate of 10,000 - 500,000 cards a year, depending on state populations."[35] Most parents have no idea this is happening.

CCHC, 1954 University Ave W. Ste. 8, St. Paul, MN 55104 p 651-646-8935 f 651-646-0100 www.cchconline.org

However, a recent University of Michigan study found that parents are opposed to government storage of newborn blood spots (NBS) and the use of baby DNA for research without parent consent: **"A majority of parents are willing to have their children's NBS samples used for research—if their permission is obtained."** The study concluded, "Using NBS samples for research without obtaining permission [is] not palatable to parents."[36] The data on the following two tables clearly shows parents' sharp disagreement with research on newborn blood without their consent:

Table 2. Use of Baby Blood for Research *With* Parent Permission

Very Willing	39%
Somewhat Willing	37%
Somewhat Unwilling	14%
Very Unwilling	10%

Table 3. Use of Baby Blood for Research *Without* Parent Permission

Very Willing	11%
Somewhat Willing	17%
Somewhat Unwilling	16%
Very Unwilling	**56%**

Furthermore, of those parents *willing* to permit research, 92% of the survey respondents were willing to have their baby's blood specimen stored and 8% were not. Of those *not* willing to permit research, 33% were willing to have their baby's blood specimen stored and 67% were not willing to have their baby's blood stored.[37] This may explain why more Minnesota parents are asking that their baby's DNA and data be destroyed as awareness about State storage grows:

Table 4. Minnesota Destruction Requests Rising*

Year	Number of Parent Requests for DNA and Test Results Destruction *(per MN Dept. of Health, 2/20/09)*
2003	**1**
2004	**6**
2005	**7**
2006	**24**
2007	**40**
2008	**157**

**In 2003, parents obtained the legal right to opt out of testing.*

CCHC, 1954 University Ave W. Ste. 8, St. Paul, MN 55104 p 651-646-8935 f 651-646-0100 www.cchconline.org

Research Trumps Rights?

Despite parent opposition, government health officials and others say infant DNA is critical to genetic research and essential to the development of new newborn genetic screening tests.[38] State officials also claim a repository of baby DNA is necessary for the improvement of public health.[39] Those who oppose the retention and use of newborn DNA without parent consent are said to be engaging in "social terrorism."[40]

In March 2009, lawsuits against State health departments were filed in Texas and Minnesota

These kinds of statements disregard the DNA property rights and human civil rights of citizens. Genetic research and development of newborn genetic screening tests is genetic research on children and their family bloodlines. Although some state officials prefer to call test development "public health studies" or "newborn screening studies," *test development is genetic research*. One newborn test development project in Texas is said to cost more than $1,000,000 just to finish the project.[41] Clearly, this is research. All citizens, including newborns, have the right not to become involuntary subjects of genetic research.

Researchers at the California Department of Health Services disagree. Questioning the need for informed parent consent, they conclude that retained newborn DNA can be used without parent consent for the development of additional genetic tests on newborns:

> All screening tests use the same newborn bloodspot and no additional blood is required. The panel of disorders available for screening will continue to expand as new technologies emerge and as new disorders are determined to be appropriate for large-scale public health screening programs…
>
> It is concluded that the legitimate ***needs of society*** and the interests of newborns should not be sacrificed to respond to the autonomy interests of the few parents who did not wish their infant to participate in the study, and that in the future, parental consent should be waived for projects evaluating new screening technologies."[42] *[emphasis added]*

This disturbing conclusion—from the State that conducted the most eugenic sterilizations[43]—negates the rights of parents to protect their children and others from genetic analysis and future discrimination. Such test development research will likely provide public health officials with an ever-increasing ability to claim that they have identified at birth each citizen's genetic weaknesses and potential susceptibility to disease and disability over his or her entire lifetime.

The controversy over genetic ownership rights and government use of citizen DNA collected at birth has recently intensified. After several years of legislative battles in Minnesota, litigation has now moved to center stage. On March 11, 2009, nine families sued the Minnesota Department of Health and the State of Minnesota.[44] One day later a lawsuit was filed in Texas.[45]

CCHC, 1954 University Ave W. Ste. 8, St. Paul, MN 55104 p 651-646-8935 f 651-646-0100 www.cchconline.org

Every Child a Profiled Child?

Together, the retention of newborn citizen DNA and the creation of government genetic registries provide State health officials with the opportunity to build genetic profiles on citizens. As more newborn genetic tests are created, or complete genomic sequencing is secured, each child—or fully grown adult whose DNA is still on file at the State health department—is vulnerable to government DNA sequencing and genetic profiling through State access to stored DNA, the State registry of genetic test results, or a combination of the two.

Each newborn citizen could eventually find their name tied to a genetic sequence—a unique string of predictive code comprised of the four letters that make up DNA — G, A, T, C. Each child could thus be registered at birth with a government-issued genetic profile ("genetic ID") that could potentially be used for eugenic purposes. This "ID" could also become a source of discrimination—as was portrayed in the troubling, but forward-thinking, 1997 movie, *Gattaca.*

Profiling Technology Advances

The process of examining the entire genome of each newborn to predict the child's every genetic defect and potential weakness is well on its way. According to minutes from a 2004 meeting held by the March of Dimes and The Hastings Center in Washington D.C. (*Using DNA-based Technologies in Newborn Screening*), "the ability to use DNA as a primary test in NBS [newborn screening] will depend on the quality of arrays, accuracy, automation, and content."[46]

The plan to use DNA sequencing for newborn genetic screening aligns with recent genome sequencing activities at the national level:

> "The National Human Genome Research Institute *[genome.gov]*…has announced the goal of reducing the cost of sequencing an individual human genome first to $100,000 and then to $1,000. At this last price point, thought to be reachable **by 2014, an individual's full genome could be added to his or her medical file as part of routine medical care**—to supplement and in some ways to supersede the patient's family medical history…In the meantime, it is already feasible, using 'gene chips,' microbeads, and other state-of-the-art multiplex technologies, to test an individual's DNA for the presence of hundreds of thousands of distinct single nucleotide polymorphisms (SNP) [pronounced "snips"] which are minute variations in the DNA sequence that can affect how…the individual develops disease and responds to pathogens, drugs, vaccines, and so forth." [47]

DNA sequencing at birth would produce vast amounts of data,[48] predicting a child's risk of not only rare childhood diseases, but also common childhood conditions (e.g. infantile colic and asthma – *see bottom of p. 22*) and catastrophic or chronic diseases that are not expected to emerge until the infant becomes an adult, such as osteoporosis and cardiac disease *(see top of p. 22)*. Even the baby's potential for behavioral problems and political proclivities could become a part of the government's sequenced—and recorded—findings.[49]

CCHC, 1954 University Ave W. Ste. 8, St. Paul, MN 55104 p 651-646-8935 f 651-646-0100 www.cchconline.org

Not Private Data

The government's newborn genetic test results are not private. They become part of a government record in some if not all States. The results are also sent to the baby's physician for entry into the child's permanent medical record—likely to be electronic and available online.[50]

In addition, the results are available, under the so-called federal HIPAA "privacy" rule,[51] to more than 600,000 entities, including government agencies.[52] Private insurers and Medicaid officials—who may be responsible for reimbursing hospitals for the cost of newborn genetic screening—may also have access to the test results. Furthermore, although most parents don't realize it, the child's newborn genetic screening results can disclose a portion of the *parent's* genetic profile, including some indication of whether the parent is a carrier of one or more genetic traits.[53]

The HIPAA "privacy" Rule provides more than 600,000 entities with access to medical records without patient consent.

It is not hard to imagine the day when any discovered but non-symptomatic condition could become a "pre-existing condition" for which private insurers would not pay.[54] The eugenic implications are obvious. Thus, the growing collection of genetic test results and newborn DNA could easily enable a eugenic agenda on the part of government agencies and private industry.

Not Without Consent

As noted above, most parents do not want government or other researchers to store their children's blood. Nor do they want their children to become the subjects of genetic research without their consent. Adults think similarly about storage and use of their own blood.

The Centers for Disease Control and Prevention (CDC) conducted a survey that included questions on research and storage of blood. Here are the responses of the 2,621 individuals who responded to questions specific to research and storage of blood (84% of everyone surveyed):

- 10% of respondents stated they would be willing to donate blood but not have it stored for long-term studies.
- 27% indicated they would not be willing to donate blood for genetics research, even with assurance of confidentiality and anonymity.
- 21% would not be willing to donate blood or have it stored for genetics research under any circumstances.[55]

The public clearly has reservations about government storage of citizen DNA. These findings, however, worry CDC government officials who are apparently expecting to rely on the use of donated human biological specimens and DNA for their government research projects.[56]

CCHC, 1954 University Ave W. Ste. 8, St. Paul, MN 55104 p 651-646-8935 f 651-646-0100 www.cchconline.org

Violating the Public's Trust

There may be many reasons why Americans prefer to keep their DNA out of government hands and their genetic secrets firmly ensconced within their own blood cells. One of those reasons could be the unsavory history of eugenics—too often done in the name of public health.[57] Another could be parents simply exercising the 'right to *not* know' and the 'right to not *be* known." In short, they may be exercising the rights of self-determination and privacy. A third reason may be a lack of trust in State public health agencies and research institutions.

Not all State agencies or researchers have a good record with the public. The Minnesota Department of Health (MDH), for example, has refused to comply with statutory written informed consent requirements for the storage, use, and sharing of newborn DNA—even after an administrative law judge ruled that the Department is in violation of the Minnesota Genetic Privacy Law.[58] Instead, MDH has tried over three successive legislative sessions to secure an exemption of these State activities from the state genetic privacy law and its informed consent requirements. For this reason, nine Minnesota families have sued the State.[59] The chart below shows the newborn data and DNA (blood) already collected and used without parent consent:

Table 5. Minnesota Department of Health Storage and Use of Genetic Test Results and Newborn Blood as of December 31, 2008 [60]

Number of Children	Action Taken by MN Department of Health *without* Parent Consent
819,282	Newborn Dried Blood Spot Samples Stored since July 1, 1997.
52,519	Newborn Blood Used for Research *(most without consent)* since 1997.
1,567,133	Individual Child Records of Genetic Test Results Stored since July 1, 1986.

The Mayo Clinic, which has a multi-million dollar contract with MDH to do part of the testing, supports MDH's legislative efforts. The MDH contract gives Mayo researchers access to 2 of the 5 newborn blood spots for their own test development research.[61] The Mayo Clinic distributed a letter to State legislators asking them to pass a bill that if enacted would eliminate consent requirements related to retention of newborn DNA, test result storage, and genetic research.[62]

Informed Consent Requirements Needed

Consent requirements are critical to preventing eugenics and protecting individual human rights. Written informed parent consent would provide needed protection for newborn citizens and for their exhausted, excited, and harried parents at the hospital. However, as demonstrated in Minnesota, state agencies[63] and newborn screening advocates such as the March of Dimes[64] and the Mayo Clinic,[65] are strongly opposed to parent consent requirements. *(see quotes in footnotes)*

CCHC, 1954 University Ave W. Ste. 8, St. Paul, MN 55104 p 651-646-8935 f 651-646-0100 www.cchconline.org

Yet, Lainie Friedman Ross, M.D., Ph.D. calls for mandatory informed parent consent requirements. She writes, "The time required does not need to be excessive…and is justified by its value in educating women about medical tests that can promote their child's well-being. If the consent is perfunctory, that does not argue against the need for consent, but is a criticism of the physicians who are not fulfilling their role in the consent process."[66]

Dr. Ross adds, "the arguments in favor of parental consent are persuasive. Parental consent serves several important functions. First, parental consent is sought for all medical care of children to promote their well-being and to protect them from harm. Consent serves as a symbol of respect for the family…Second, procuring parental consent serves a valuable educative role. By requiring consent, parents must be educated about the purpose and limitations of screening, which may give them an incentive to follow up on abnormal screening results." Dr. Ross supports the repeal of mandatory testing laws in favor of passing laws that require fully informed parent consent.[67]

George Annas, JD, MPH, Chair of Health Law at the Boston University School of Public Health, agrees with parent consent requirements saying, **"I encourage policies which require parental consent for all genetic testing of children, even in the newborn nursery."**[68]

Conclusion

In light of the continued expansion of State newborn genetic screening programs, State retention of newborn DNA, government registration of newborn genetic test results, and concerns about the re-emergence of eugenics, informed written parent consent requirements are needed for the protection of all citizens, including newborn citizens. Prior to expanding State newborn genetic screening programs to include genetic testing of babies for common conditions and adult-onset diseases, State legislators must protect citizens from eugenic strategies in and outside of State government. Specific protective strategies include:

- Allow parents to choose the conditions for which their child is tested;
- Destruction of current State newborn DNA repositories
- Before newborn blood is taken, require informed written consent for:
    - Newborn genetic screening
    - Government storage of test results and newborn DNA
    - Research using newborn DNA and newborn genetic test results.

Finally, State legislatures should privatize newborn genetic screening programs to protect citizens from State genetic registries, State ownership of citizen DNA, government research projects, and intrusive government interference in private family and medical decisions.

Twila Brase, RN, PHN, is president of Citizens' Council on Health Care, a national free-market health care policy organization located in Saint Paul, Minnesota.

Eugenic Concerns — Newborn Genetic Screening – Published Evidence

Title	Author	Publication	Date	Quote
"Private and Public Eugenics: Genetic Testing and Screening in India"	J.A. Gupta	*Journal of Bioethical Inquiry,* pp 217-228.	Nov. 22 2007	"I then discuss the recently launched newborn screening programme as an example of **public eugenics**."
"Questioning the Consensus: Managing Carrier Status Results Generated by Newborn Screening"	Fiona Alice Miller, PhD et al	*American Journal of Public Health, Vol 99(2), pp.210-215.*	Feb 2009	"However, newborn screening is a classic public health intervention in which.... carrier status information might be accused of a **subtle form of eugenics**."
"Testing Children and Adolescents"	Dorothy Wertz	A Companion to Genethics, (Wiley-Blackwell)	2002	"The child will be **labeled for life,** even if not told, and will be deprived of the right to decide about whether to be tested."
Legal and Ethical Issues in Newborn Screening	James E. Bowman MD	*PEDIATRICS* Vol. 83, No.5, pp. 894-896.	May 1989	"The development of techniques for newborn screening and for prenatal diagnosis of sickle hemoglobin and other hemoglobinopathies will have a profound effect on public health policy to a greater extent than did mass population testing that was initiated in the early 1970s… **Arguments for and against these procedures are reminiscent of debates about the use of the limited tools of the old eugenics to prevent the birth of children who were considered to be physically, mentally, or socially defective."**
"Designing Babies"	Debora L. Spar	The baby business, (Harvard Business Press) p.109	2006	**"unlike its eugenics cousin, the science of genetics was detached from any political or social implications:** researchers strove to understand life, but not necessarily to change it. **As the science advanced, however, this once fine line began to blur.** The starting point was 'genetic counseling,' a small cottage industry that emerged from the medical side of genetics. By the 1950s several of the doctors who studied genetic deformities among their patients began small sideline businesses in prenatal consulting, helping worried parents determine whether their offspring were at risk for genetic disorders…"
"Eugenics and Genetic Discrimination	Neil Holtzman and Mark Rothstein	*American Journal of Human Genetics 50(3): 457-59 (taken from http://bioethics.georgetown.edu/publications/scopenotes/sn28.htm*	Mar. 1992	"**The threat of eugenics and genetic discrimination** comes not only from meddlesome social commentators and political demagogues but from the increasing **economics pressures** on our employment system that remains largely responsible for access to private health insurance and health care."
"Genetics and Genetic Technology"	David H. Smith and Cynthia B. Cohen	A Christian Response to the New Genetics, (Rowman & Littlefield), p 132	2003	"After a long hiatus, the field of public health is once again working in what is now known as **'public health genetics,"** but in that area experts are particularly careful to support only programs, such as newborn screening, designed to lead to better medical care…**Nonetheless, it is not hard for critics to see potentially eugenic purposes behind some contemporary uses of genetics."**
"F30. On the Draft of the Proposed W.H.O	Akiko Nobe, The	*Bioethics in Asia,* pp. 439-	2000	"It is repeatedly stressed that genetics services should not be provided coercively, and that genetic counseling should not be

Guidelines on Ethical Issues in Medical Genetics and the Provision of Genetics Services"	Parents' Association of Children with Malformation in Extremities (Japan)	444, Eubios Ethics Institute		directive. And yet, frankly speaking, I suspect that the **Guidelines suggest a grand family-plan project: that is, a project for the eradication of hereditary disease.** "It is when we admit the genetic diversity of humanity that we can protect the human rights of an individual. Whatever genetic characteristics a person has, his/her human dignity and rights should be protected. In medical genetics, too, genetics services should be provided in the framework of this essential and fundamental understanding; and **they should never encourage the idea of eliminating hereditary diseases from society as if they were some form of evil.** I sincerely hope genetic medicine will respect the genetic diversity of the individual person and **protect the rights and happiness of the weak.**"
"Mapping the Human Genome"	George J. Annas, JD, MPH, Professor of Health Law	A Companion to Genethics, Wiley-Blackwell	2002	"[T]wo major legal issues are implicit in all genetic screening programs: autonomy and confidentiality. **Autonomy requires that all screening programs be voluntary, and that consent to them is sought only after full information concerning the implications of a possible finding is disclosed and understood."**
"Informed Consent and the Use of Archived Tissue Samples" Excerpts from presentation given at the CORN Conference on Genetic Services, Washington, DC February 16-17, 1996	Mary Z. Pelias, Ph.D., JD	"Newborn Screening-New Dilemmas" http://www.circ.uab.edu/sergg/current/win96-1.htm	Feb. 1996	Geneticists have been quick to realize that collections of tissue samples may be immensely valuable in research on gene structure and in research on gene frequencies in the populations. **Particularly tempting are the collections of blood spots that are gathered from the newborn population as part of state-funded programs** to detect and treat phenylketonuria, sickle cell anemia, congenital hypothyroidism, and a few other early onset diseases. …The genetic community enthusiasm has been tempered by skepticism on the part of some about the propriety of using stored samples. One major concern is the issue of informed consent in newborn screening, and the fact that there are often few provisions for obtaining a parent's prior permission for the participation of a newborn in a screening program. Alternatively, some geneticists have argued that the consent of parents is unnecessary if the stored samples are used 'anonymously' in research projects, but there is no consensus about what actually constitutes anonymous use…**What is singularly lacking in provisions for informed consent is explicit permission for future use of samples that are stored away after newborn testing is complete."**
"Newborn Screening, Genomic Medicine and Eugenics"	The President's Council on Bioethics (Washington, D.C.)	The Changing Moral Focus of Newborn Screening, p. 52-53.	Dec. 2008	**The $1,000 genome may arrive sooner than even this optimistic projections would suggest**…in the fall of 2008, a company in California announced plan to begin offering complete human genome sequences for $5,000, starting in the spring of 2009. In the meantime, it is already feasible, using 'gene chips,' microbeads, and other state-of-the-art multiplex technologies, to **test an individual's DNA** for the presence of hundreds of thousands of distinct single nucleotide polymorphisms (SNP), which are minute variations in the DNA sequence that can affect how (or correlate with other DNA variations that affect how) the individual develops disease and responds to pathogens, drugs, vaccines, and so forth."
"Mandatory PKU Screening: The Other Side of the Looking Glass"	George J. Annas, JD, MPH	*American Journal of Public Health,* 72: 1401-1403.	1982	*Regarding false-positive tests:* "A recently concluded study of the parents of 60 infants in Massachusetts who were retested in a newborn screening program found that…36 per cent of the parents of these normal infants reported heightened concern about the health of their infant because of the repeat testing. The authors could not

				determine how long these concerns would last, or what actions they would take**…This may not strike one as an adequate reason for refusing PKU screening. But look into the future when we will be able to screen for 1,000 more diseases. Suppose, for example, a computerized screening test for 1,000 conditions…Each infant screened will then be diagnosed initially as suffering from 10 disorders, even though he/she suffers from none.** If the false positive rate is 5 per cent per test, he/she will appear to have 50 disorders…"
"Eugenics and Public Health"	Abby Lippman, Ph.D. Dept of Epid. & Biostatistics, McGill University (Quebec, Canada)	American Journal of Public Health 93(1): 11	2003	[State-supported programs of prenatal genetic screening and testing] seem to be based on an underlying (implicit) assumption that people with disabilities not only cannot have a satisfying life, but are not welcome in society—and that parents will want to avoid their birth. Tightening the connection is a further assumption that there are important public health cost savings if people with disabilities are never born…these persisting false assumptions about the 'costs,' social and financial, of disabilities **perpetuate pronatalist eugenics in this century**."
"Fun With Eugenics."	Ross	*Unenlightened Commentary. – blog*	Feb. 20, 2009	"**On the subject of how eugenics is socially acceptable as long as you don't call it eugenics**: 'A March of Dimes report released today says all 50 states and the District of Columbia now require newborn screening for 21 or more so-called core disorders recommended for testing. These core disorders, 29 in all, include many rare but potentially disabling or fatal metabolic disorders. Although all states have rules or laws requiring the screenings, Pennsylvania and West Virginia have yet to implement their expanded programs, according to the organization.'" (*The New York Times*, "Screening for Rare Genetic Disorders Now Routine in Newborns," Feb. 18, 2009)
"Eugenics and Public Health"	Abby Lippman, Ph.D. Dept. of Epid. & Biostatistics, McGill University (Quebec, Canada)	American Journal of Public Health 93(1): 11	2003	Public funding of prenatal screening programs, which necessarily reflects the state-sponsored use of some genetic variation alone to value one group more than another, raises such issues. Whatever else this may be, **this kind of valuation illustrates eugenics**. And though 'healthy' may have replaced 'better' as the contemporary goal for babies, we need to be vigilant to ensure that today's public health programs do not violate fundamental principles of human rights and social justice in the course of improving the health of babies and their mothers."
"Genetics and Society"	Dr. Anthony Wynsha W-Boris, CBB Human Genetics	*http://www.ratsteachgenetics.com/Genetics_pdfs/Lecture_18_slides.pdf*	n.d.	*Prenatal Genetic Testing:* **"[I]s testing and abortion for disabilities, mental retardation, deafness and blindness justified? Probably, although some with these disorders would argue no**…" **"****Ethical dilemma: balancing respect for autonomy of a patient's reproductive decision making vs. whether their decisions are fair or beneficial."
"Francis Galton: and Eugenics Today"	Galton DJ, Galton CJ, Dept of Metabolism and Genetics, London	*Journal of Medical Ethics* 24(2): 99 – 105	April 1998	"**Eugenics can be defined as the use of science applied to the qualitative and quantitative improvement of the human genome**…Its scope has increased enormously since the recent revolution in molecular genetic**. Genetic files can be easily obtained for individual either antenatally or at birth**…"
Backdoor to Eugenics	Troy	Published by	1990	"Genetic research and the screening for genetic disorders have

	Duster	Routledge		the potential for doing great amounts of good, and **great amounts of harm**."
"Genetics and Genetic Technology"	David H. Smith and Cynthia B. Cohen	A Christian Response to the New Genetics, (Rowman & Littlefield) p. 141	2003	"Before prenatal genetic tests were available, a couple who had a child with extreme and special needs could **count upon some measure of social sympathy and support. But today the birth of a child with a genetically linked affliction may seem like a deliberate act on the part of the parents**, who either decided to forget the test that would have told them about the condition or decided to have the child despite the known diagnosis. Either way, somehow, the birth of the afflicted child is their fault, or at least their responsibility, and they are then expected to live with the consequences.'"
"Newborn Screening, Genomic Medicine and Eugenics"	The President's Council on Bioethics (Washington, D.C.)	The Changing Moral Focus of Newborn Screening, p. 78.	Dec. 2008	If the putative benefit to the family is to be realized by preventing the birth of siblings with the detected genetic defect, then it would make more sense to screen for the defect prenatally, so that the family is not burdened with even one defective child. Putting it so callously highlights the morally problematic character of screening for family planning. If we test an infant, not in the hope of providing treatment for his or her condition, but with a view to making sure that no further children come into the family with the same defect, are we not in effect telling the child that he or she was, in some ways, **a regrettable mistake**—that, had we known his or her genetic makeup in advance, we would have tried to prevent his or her birth? **To the affected child, family planning in this sense means not 'limiting the incidence of a defective gene' but 'preventing the birth of any more kids like me.'** Here the laudable goal of reducing the incidence of genetic disease comes into collision with the wish and the obligation to treat every family member as a being with inherent and equal worth."
"Genetic Counseling and Risk Communication Services of Newborn Screening Programs"	Michael H. Farrell, MD et.al	*ARCH PEDIATRIC ADOLESC MED,* VOL. 155	Feb. 2001	"**Children can be inadvertently harmed by the efforts of newborn screening programs, just as they can experience benefits**. The potential for psychosocial harm has been apparent for decades but there have been only limited efforts to prevent problems such as the **vulnerable child syndrome**."
"Genetic Counseling and Risk Communication Services of Newborn Screening Programs"	Michael H. Farrell, MD et. al	*ARCH PEDIATRIC ADOLESC MED,* VOL. 155	Feb. 2001	"We were struck by the large number of respondents [primarily state follow-up coordinators] agreeing with the statement about the **'suitability for reproduction' of the patient.** During development of the survey, we included this quaint wording with the expectation that most respondents would disagree with the phrasing **reminiscent of eugenics.**"
"Newborn Screening. Saving Lives the Molecular Way"	Suzanne Kennedy Director of R&D, CA biotech firm	*Bitesize Bio* - Blog	Nov. 26, 2007	"As medicine becomes more personalized, the next wave of testing may very well be **whole genome sequencing at birth** followed by real-time PCR to test for the presence of specific mutations."
"Genetic screening with the DNA Chip: a new Pandora's box?"	Dr. Wolfram Henn, Institute for Human Genetic, Univ. of Saarland	*Journal of Medical Ethics 25(2)*	1999	"After cost-effectiveness analyses have proven that genetic screening can produce considerable savings even for rather rare disease which require expensive therapies for affected patients, there is little doubt that health insurers will support extensive screening programmes. The widening of the diagnostic spectrum may also reinforce the already widespread public opinion that the birth of handicapped children should be prevented. Ultimately, the **exclusion of prenatally testable conditions from health**

	(Germany)			**insurance cover might serve as a sanction instrument for a new kind of economically motivated negative eugenics** that may well become popular in an era of declining prosperity."
"Genetic and metabolic screening of newborns: must healthcare providers seek explicit parental consent? (Canada)"	Wildeman, Sheila: Downie Jocelyn	*Health Law Journal*	Jan. 1, 2001	"Somewhat to our surprise, we concluded that the current approach to parental consent to newborn screening--again, **an approach based on the understanding that explicit consent is not required--is not legally defensible."**
"Bioethics and American Children"	Norman Fost MD, MPH, Director, Program in Medical Ethics, Univ. of Wisc. Hospital	*Presentation to the President's Council on Bioethics*	Dec. 8 2005	"So we now already have many states including Wisconsin, that does routine testing without consent, without prior research, for dozens of conditions using tandem mass spectrometry. And I predict, unless there is some dramatic change in the way we think about these things, the way we do these things, that multi-array DNA testing will occur within the next few years, as soon as the cost comes down to make it efficient to do it. This, to me, is **a calamity involving every child in America. The amount of mischief. The amount of harm, psychosocial harm that will occur to families and children, not to mention medical harm**, is, in my view, going to be quite extensive."
"PHG-1 Public Health Genetics Policy Statement"	ASTHO (Assn. of State and Territorial Health Officials	*http://www.sboh.wa.gov/Goals/Past/Genetics/GTF2002_04-12/documents/Tab04-ASTHO_PHGPolicyStatement.pdf*	Oct 26, 2001	"Population-Based Genetic Screening: State health agencies have been leaders in population-based screening for conditions which happen to be of genetic etiology for over a quarter century via newborn screening programs**.** These programs have led to the early diagnosis of mostly rare disorders…As the genetic nature of common diseases is better understood and the ability to predict the occurrence of these diseases becomes more precise, public health will need to address the **integration of genetic testing into screening procedures for common diseases**."
"The Future of Newborn Screening: Clouds on the Horizon? Staff Discussion Paper."	Adam Schulman, Ph.D.	*Discussed at the March 2008 meeting of the President's Council on Bioethics*	n.d.	"If we test an infant, not in the hope of providing treatment for his condition but with a view to making sure that no further children come into the family with the same defects, aren't we in effect telling the child that he was in some ways a regrettable mistake—that, had we known his genetic makeup in advance, we would have tried to prevent his birth?" The blameless intention to diagnose and treat our children's illnesses will have drifted into the rather more sinister project of purifying future generations of their undesirable members. **The specter of 'eugenicide' hovers over the eagerly anticipated marriage of newborn screening with genomic medicine."**
"The Future of Newborn Screening: Clouds on the Horizon? Staff Discussion Paper."	Adam Schulman, Ph.D.	*Discussed at the 3/08 meeting of The President's Council on Bioethics*	n.d.	"…**Why prevent the disease when it would be simpler to prevent the patient?"**
"Aren't we all Eugenicists? - Commentary on Paul Lombardo's "Taking Eugenics Seriously"	Mary B. Mahowald	*Florida State University Law Review* Vol 30: 219	2003	"[S]ociety, through its policy makers and those who influence public opinion, **really does want to reduce the number of people who are mentally retarded in the general population**; it may focus on Down syndrome because its presence is more easily recognizable than other conditions associated with mental retardation. In general**, it wants to "improve the stock" and perhaps avoid the costs of care** by eliminating or at least reducing the numbers of a particular group of people by encouraging testing in women and supporting the abortion of fetuses that test positive for Down syndrome."

"Chinese Geneticists' Views of Ethical Issues in Genetic Testing and Screening: Evidence for Eugenics in China"	Xin Mao, Division of Genetics, West China Univ. of Medical Science, China	*The American Journal of Human Genetics*, 63: 688-695.	Aug.21, 1998	"Sixty-five percent agreed with the statement that **'an important goal of newborn screening is to identify and counsel parental carriers before next pregnancy'**…The majority of respondents agreed that partners should know each other's genetic status before marriage (92%), that **carriers of the same defective gene should not mate with each other** (91%)…In their comments, almost all respondents said that the goal of human genetics was "improvement of the population quality, decrease of the population quantity, and **furtherance of eugenic principles**" and agreed that "an important goal of genetic counseling is to **reduce the number of deleterious genes in the population."**
"Clinical Ethical Issues"	Marcia Sue DeWolf Bosek, Teresa A. Savage	The Ethical Component of Nursing Education: Integrating Ethics into Clinical Experience, (Lippincott Williams & Wilkins)	2006	"[Peter] Singer, whose appointment as a professor in philosophy at Princeton was vigorously protected by disability activists, **has long maintained that it should be morally permissible to kill a newborn who has disabilities.** Because certain disabled newborns lack the capability of becoming sentient, Singer believed that their parents should have the option of killing them."
"The Groningen Protocol – Euthanasia in Severely Ill Newborns"	Eduard Verhagen, MD, JD and Pieter J.J. Sauer, MD, PhD	*The New England Journal of Medicine,* Volume 352: 959-962, No. 10	Mar. 10, 2005	"Legal control over euthanasia in newborns is based on physicians' own reports, followed by assessment by criminal prosecutors… [W]e developed a protocol, known as the Groningen protocol, for cases in which a decision is made to **actively end the life of a newborn…**there are infants with a hopeless prognosis who experience what parents and medical experts deem to be unbearable suffering. Although it is difficult to define in the abstract, this group includes patients who are not dependent on intensive medical treatment but for whom a very poor quality of life, associated with sustained suffering, is predicted. For example, a child with the most serious form of spina bifida will have an extremely poor quality of life, even after many operations. This group also includes infants who have survived thanks to intensive care but for whom it becomes clear after intensive treatment has been completed that the quality of life will be very poor and for whom there is no hope of improvement."
"Historical and Theoretical Overview of the Eugenics Movement	Ellen A Brantlinger	Sterilization of People with Mental Disabilities (Greenwood Publishing Group), p. 3	1995	**"Eugenics created and gave scientific and social meaning to new objects of study—unfit or 'dysgenic' groups'"**
"Genetics and Society"	Dr. Anthony Wynsha W-Boris, CBB Human Genetics	*Powerpoint Slide: http://www.ratsteachgenetics.com/Genetics_pdfs/Lecture_18_slides.pdf*	n.d.	**"Problem of Dysgenics** • Dysgenics: deterioration of the health and well-being of a population by practices allowing the accumulation of deleterious alleles • Medical treatment may allow incidence of harmful genes to increase: could be great effect for severe X-linked and AD disorders, as well as common complex disorders • Genetic counseling, genetic testing and parental decisions to limit reproduction may have large effect on incidence some diseases • Prenatal diagnosis may lead to pregnancy termination for

				serious disease, unclear what effect this may have on gene frequencies • Carrier screening programs may reduce numbers of affected individuals in population (Tay-Sachs, β-thalessemia)"
"Newborn Screening"	Mary Ann Baily, The Hastings Center, NY	*From Birth to Death and Bench to Clinic: The Hastings Center Bioethics Briefing Book for Journalists, Policymakers, and Campaigns,* ed. Mary Crowley, pp 125-128.	2008	"A dramatic expansion of newborn screening programs is under way, with most states testing for about 29 core conditions, up from fewer than 10 several years ago…**The expansion of newborn screening raises ethical controversies about its cost, evidence of its efficacy, and parental informed consent…** Because parental consent is the ethical standard, the mandatory status of public newborn screening has always been controversial…The ACMG report argued that it was appropriate to depart from this [treatment-focused] criterion and **consider benefits to the family or society, rather than to the infant**. For example, early diagnosis of an untreatable genetic condition may allow parents to plan ahead for the time when the child's symptoms appear and perhaps **to alter their reproductive decisions to avoid the birth of another affected child."**
"Historical and Theoretical Overview of the Eugenics Movement	Ellen A Brantlinger	Sterilization of People with Mental Disabilities (Greenwood Publishing Group), p. 16	1995	"The **growing repertoire of new genetic technologies related to reproduction, although not developed under the rubric of eugenics, often focuses on detecting flaws in genes**. Ultimately, then, many are eugenic in that they incorporate the thinking that better genes make better people. Furthermore, the new genetics identifies some genes, and some people, as unfit. According to Spallone (1989), the growth of reproductive technologies is based on an 'arrogant belief in scientific and social control' and 'a desire to assert more social/biological control over women, pressuring them to have **the perfect baby**.'"
"Newborn Screening"	Mary Ann Baily, The Hastings Center, NY	*From Birth to Death and Bench to Clinic: The Hastings Center Bioethics Briefing Book for Journalists, Policymakers, and Campaigns,* ed. Mary Crowley, pp 125-128.	2008	"The United States has sturdy societal values respecting the rights of individuals to decide what treatments they will have, whether they will participate in research, and what can be done with their personal information and their bodily tissues, including blood samples**.** (Because only a fraction of each blood sample taken for newborn screening is used in the screening, the remainder is a valuable potential resource for research and program evaluation.) Since parents are normally considered the appropriate people to make decisions on behalf of their children, **parental informed consent is ethically required for the medical treatment of children and for the involvement of children in research."** **"[T]here is an urgent need to clarify the ethical requirements with respect to parental consent for using leftover blood spots** for newborn screening quality improvement, research related to newborn screening, and research on questions not directly related to newborn screening. The use of newborn screening blood spots is simply a specific instance of the larger issue of achieving a societal consensus on the ethical rules that should govern the use of bodily tissues for social purposes."
"Addressing the Fallout of Newborn Screening"	Shirley S. Wang	*The Wall Street Journal*	Oct. 30, 2007	"Hayward Genetics Center at Tulane University in New Orleans, for example, sees about **seven false positives for every one baby with a true metabolic defect**…"
"Effect of expanded newborn screening for biochemical genetic disorders on child outcomes and parental stress?"	Susan E. Waisbren Ph.D et. al	*http://www.aphl.org/profdev/conferences/proceedings/Documents/2008%20_APH*	Nov. 19, 2003	"[F]alse-positive screening results may place families at risk for increased stress and **parent-child dysfunctions."**

		L_NBS_and_Genetics_Testing_Symposium/027%20-%20Matern%204.pdf		
"Eugenics roots impact health policies today"	Heather Lutz	*Cleveland Jewish News,* reporting on 11/13/07 Prof. Maxwell J. Mehlman lecture (Case Western Univ. School of Law)	Dec. 6, 2007	**"The U.S. government even encourages some eugenics-related programs**, such as offering tax breaks for families who have several children and putting caps on welfare benefits for poor families with a certain number of children… Additionally, some hospitals are beginning to **incorporate more tests into routine newborn screening.** Mehlman criticized the fact that this testing is often done for diseases with very little prevalence in the population and without the informed consent of parents."
"Influences on the proposed UN Declaration on the Rights of Disabled People"	John Forman, ED, NZ Organisation for Rare Disorders	*PowerPoint Presentation*	Feb 2003	"…to **talk of eliminating disease and disability** (as the first [UN] draft so boldly and callously put forth **as the ethical underpinning of gene research**) was to make not a scientific decision but a value judgment on some people…" – Marcia Rious, President, Roeher Institute, Canada, *Inclusion News*, May 1998.
"Microarrays"	John F. Palma, PhD, Director, Molecular Diagnostics R&D, Affymetrix, Inc.	"Using DNA-based Technologies in Newborn Screening," Conference by The Hastings Center and the March of Dimes, Loew's L'Enfant Plaza Hotel Washington, DC	Sept 1, 2004	*Conducting DNA Sequencing:* "Dr. Palma proceeded to describe the products that his company offers. Invented over a decade ago using photolithography, it involves a glass wafer that can be diced up into tens, hundreds, and even thousands of individual square chips, also called arrays. Each square is packaged into a cartridge, and the sample is then hybridized to the array. **Each array contains millions of DNA probes…**The company has developed an assay by which, in a single tube, it is possible to query 100,000 SNPs at one time and hybridize an array that will provide the profiles for all 100,000 SNPs**.** Over the next year this technology will be scaled to represent 500,000 SNPs…**The company also has developed a number of resequencing methods that will be critical to the NBS community.**"
"Questioning the Need for Informed Consent: A Case Study of California's Experience with a Pilot Newborn Screening Research Project"	Lisa Feuchtbaum, et al, CA Dept of Health Services, Genetic Disease Branch	*Journal of Empirical Research on Human Research Ethics,* Vol 2(3) pp 3-14.	Sept 2007	"The Genetic Disease Branch (GDB) mission is 'to serve the people of California by **reducing the emotional and financial burden of disability and death caused by genetic and congenital disorders in children.'"**
"Science and Society—Genetic Testing. Uses and the Risk of Abuse"	Halldor Stefansson, Science and Society Officer, EMBL	*http://www.embl.de/training/ells/teachingbase/project1/uses_abuses.pdf* (Denmark)	n.d.	"Areas of focus in genetic testing include: pre-implantation genetic diagnosis (PGD), prenatal diagnosis, **newborn screening**, carrier screening, susceptibility screening and forensic testing… Disability advocates and feminists, for instance, have criticized genetic screening because they think it **fosters intolerance for "less than perfect people…**The introduction of laws prohibiting marriages between those deemed "unfit" to produce offspring involves the elimination of unfit or undesirable genes by prohibition on sexual relations. **We must ask ourselves if we are entitled to play the role of 'The Creator'?"**
"NIH Data Sharing Policy	Steven	*http://www.aphl.*	May	"The **major genetic risk factors for common diseases** such as

for Genome-wide Association Studies ("GWAS")	Hirschfeld, MD, PhD, National Institute of Child Health and Human Development, NIH	*org/profdev/conferences/proceedings/Documents/2007_NBS_and_Genetic_Testing_Symposium/NIH_Data_Sharaing_Policy.pdf*	10, 2007	**heart disease,** diabetes, some forms of cancer, hypertension, asthma, Alzheimer's disease, **osteoporosis**, **autism**, and mood disorders are **likely to be identified in the near future**."
Sickle Cell Screening for Students in Manchester	Jamaica Ministry of Health & Environment	*http://www.jis.gov.jm/health/html/20090317T220000-0500_18881_JIS_SICKLE_CELL_SCREENING_FOR_STUDENTS_IN_MANCHESTER.asp*	Mar 17, 2009	"According to [Professor Graham Sergeant, Chairman of the Sickle Cell Trust], the project, which is in collaboration with the Ministry of Health, with support from the Alcoa Foundation and the National Health Fund, will help to detect persons with the genes, which could result in babies being born with sickle cell. 'This is followed **by counseling to influence reproductive decisions** leading to reduction in the number of babies born with the sickle cell disease. Such a reduction is vital to reduce the distress to families and the cost to the health services,' he said."
"Eugenics is nothing to be scared of"	Cabalamat (British)	*Amused Cynicism* - blog	Aug 10, 2008	"**I propose that the least intelligent 20% of the population be discouraged from breeding.** I'm agnostic how we would define who falls in this category — maybe it could be an IQ test… As well as discouraging the least intelligent from breeding, the state could intervene at the top end too, by having a **pool of sperm and egg donors, who would all be of high intelligence, in good mental and physical health, and not genetically prone to diseases**…Clever people are better for the economy. Were the steam turbine, the jet engine, the computer, or the world wide web invented by clever people or stupid people?"
Amazon.com, Editorial Reviews	Kirkus Reviews, Kirkus Associates, LP	DEATH AND DELIVERANCE: Euthanasia in Germany 1900 – 1945, Michael Burleigh		"Scientists approved the sterilization of some 400,000 people between 1934 and 1945 to **eradicate ``degenerative heredity'' in order to 'improve the race.'"**
Buck v. Bell, 274 U.S. 200, 207 (1927)	Supreme Court Justice Oliver Wendell Holmes	Quote taken from: "Mapping the Human Genome, George Annas, A Companion to Genethics, (2002)	1927	**"We have seen more than once that the public welfare may call upon the best citizens for their lives. It would be strange if it could not call upon those who already sap the strength of the State for these lesser sacrifices often not felt to be such by those concerned, 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."
"Newborn Screening Translation Research Initiative"	Website page	CDC FOUNDATION: http://www.cdcfoundation.org/programs/nstri/index.aspx	Accessed on Apr. 17, 2009	"The Newborn Screening Translation Research Initiative (NSTRI) … will provide laboratory support and a knowledge base for a wide array of conditions such as lysosomal storage disorders, **autism spectrum disorders, immune deficiency disorders, infantile colic, diabetes, cystic fibrosis, asthma, and infectious diseases** such as toxoplasmosis…"
"A Vision of the Future of Newborn Screening"	Duane Alexander (NIH) and Peter C. van Dyck	*PEDIATRICS,* 117: 350, 352.	2006	"[a]rguments for considering broader benefits from the early diagnosis that only newborn screening can provide include... knowledge on which to base **reproductive decision-making years before a disease would be diagnosed for the affected child.**"

	(HRSA)			
"DNA Fingerprinting"	Sarah Don (Australia)	*http://www.scribd.com/doc/11337826/DNA-Fingerprinting*	2008	"Over 4 million newborns in the U.S. each year undergo genetic testing for diseases such as cystic fibrosis, phenylketonuria (a metabolic disorder caused by a deficiency in the enzyme phenylalanine hydoxylase) and sickle cell anaemia**. Comparing all the DNA samples from these genetic tests by collecting them in a DNA biobank could assist researchers in identifying associated genes."**
"China Aims to Improve Health of Newborns by Law"	Richard Tomlinson	*British Medical Journal*, 309 (6965): 1319 [Described in "Eugenics", SCOPE NOTE 28, NRCBL]	Nov. 19, 1994	"Brief details are provided on new Chinese legislation regarding marriage and the prevention of unhealthy births…[T]he Chinese government requires premarital genetic evaluations, testing for contagious diseases, and is some cases **requires persons carrying "serious" genetic defects to agree to sterilization or long-term contraception before obtaining permission to marry**."
"Introduction"	Justine Burley, John Harris	A Companion to Genethics, (Wiley-Blackwell)	2002	**"Genetics has grown up with the legacy of the eugenics movement of the last century and with the specter of Nazi atrocities. This history has colored many people's thinking about genetics**, and we explore this legacy and its lessons for the future. Following the Second World War, many international conventions and protocols attempted to prevent future abuse by setting out guidelines for the ethical conduct of future research. The cornerstone of these and indeed of much contemporary thinking about the ethics of scientific research is the notion of informed consent. People are generally presumed to be the best guardians of their own interests and hence their fully **informed consent to involvement in research is an obvious first safeguard."**
"GenEthics": Ethical Issues in Medical Genetics"	Javad Tavakkoly Bazzaz MD, PhD, Tehran Univ. of Medical Sciences	2nd International Congress of Medical Ethics in Iran, Tehran	Apr 16 - 18, 2008	**"Eugenics is directed against whole populations**, whereas the work of today's clinical geneticists is directed towards individuals and families. However, it is important to be aware that collective results of individual decisions could lead to social policies that discriminate against the minority who make different decisions and especially against persons with disabilities. **In a democratic society this result could occur by virtue of majority vote to restrict services."**
"In the name of Eugenics: Genetics and the Uses of Human Heredity"	Daniel J. Kevles	http://bioethics.georgetown.edu/publications/scopenotes/sn28.htm	1985	"How the public or politically powerful coalitions, will respond to the **steady pressure of problems raised by the advance of genetics** depends upon what reconciliation society chooses to make between the ancient antinomies—social obligations as against individual rights and reproductive freedom and privacy as against the requirements of public health and welfare."

[1] Jeffrey R. Botkin, MD, MPH. [Department of Pediatrics and Medical Ethics, University of Utah, Salt Lake City, Utah]. "Research for Newborn Screening: Developing a National Framework." *PEDIATRICS*. Vol 116 (4). October 2005. pp. 862-871.

[2] Nancy S. Green M.D. [March of Dimes Birth Defects Foundation] et. al. "Newborn Screening: Complexities in Universal Genetic Testing." *American Journal of Public Health*. Vol 96 (11). November 2006.

[2] Bradford L. Therrell, PhD et al. "Status of Newborn Screening Programs in the United States. *PEDIATRICS* Vol. 117 (5), May 2006. pp. S212-S252.

[3] Ibid.

[4] The Changing Moral Focus of Newborn Screening: An Ethical Analysis by the President's Council on Bioethics. The President's Council on Bioethics. December 2008. p. 78.

[5] War Against the Weak. Edwin Black. p. 418.

[6] "Nazi Persecution of the Mentally and Physically Disabled – Forced Sterilization" online at the Jewish Virtual Library. http://www.jewishvirtuallibrary.org/jsource/Holocaust/disabled.html

[7] Michael H. Farrell, MD et.al. "Genetic Counseling and Risk Communication Services of Newborn Screening Programs." *ARCH PEDIATRIC ADOLESC MED,* Vol 155. February 2001.

[8] Halldor Stefansson [Science and Society Officer, Office of Information and Public Affairs, European Molecular Biology Laboratory (EMBL)]. "Science and Society—Genetic Testing. Uses and the Risk of Abuse." http://www.embl.de/training/ells/teachingbase/project1/uses_abuses.pdf

[9] War Against the Weak. Edwin Black. p. 398.

[10] *Buck v. Bell,* 274 U.S. 200, 207 (1927).

[11] Ellen A. Brantlinger. Sterilization of People with Mental Disabilities: Issues, Perspectives and Cases (Greenwood Publishing Group, 1995) p. 33.

[12] Twila Brase RN, PHN [President, Citizens' Council on Health Care]. *The Untold PKU Testing Story…and Why it Challenges Government-Mandated Newborn (Genetic) Screening.* September 2008. [PKU is lack of a protein enzyme.]

[13] "Newborn Screening Program." Wadsworth Center, New York State Department of Health. n.d. http://www.cdph.ca.gov/programs/nbs/Documents/NBS-ListOfDisordersProvDisclaimer20070716.pdf

[14] Heartland Regional Collaborative. Strategic Plan 2006 – 2008. http://www.heartlandcollaborative.org/documents/RegionalPlan_000.pdf

[15] Søren Holm. "Testing Children and Adolescents." A Companion to Genetics. 2002.

[16] Nicholas Wake. "Genes Show Limited Value in Predicting Diseases." *The New York Times*. April 15, 2009.

[17] Bruce Jennings and Elizabeth Heitman. "Genetics and Genetic Technology." A Christian Response to the New Genetics (Rowman & Littlefield). Authors: David H. Smith and Cynthia B. Cohen. page 138.

[18] George Annas. "Mapping the Human Genome." A Companion to Genetics. 2002. p. 133.

[19] Willet Hays, president of the American Breeders Association, writing in the *American Breeders Magazine* in a 1912 article titled "Constructive Eugenics." [quote taken from War Against the Weak (Edwin Black, author), page 40.]

[20] Cited in Duster, Troy. Backdoor to Eugenics (New York, Routledge 1990) The Center for Bioethics and Human Dignity presents Genetic ethics: do the ends justify the genes? (Wm. B. Eerdmans Publishing 1997)

[21] Steven Rose. "The Rise of Neurogenetic Determinism." *Thinking about Evolution: Historical, Philosophical, and Political Perspectives.* Rama Shankar Singh et.al (Cambridge University Press). 2000. p. 416.

[22] "New testing regime to aid sickle-cell detection." *Jamaica Gleaner*. October 15, 2008.

[23] Ibid.

[24] http://www.sicklecellsociety.org/information/resrep/Res21.htm. Accessed April 20, 2009.

[25] The Changing Moral Focus of Newborn Screening. The President's Council on Bioethics. December 2008. p. 8.

[26] "States expand newborn screening for life-threatening disorders" (Press Release). March of Dimes. February 18, 2009.

[27] "Disorders Detectable by NBS Program as of July 16, 2007." California Department of Health Services. n.d.

[28] S. 1858, Public Law No: 110-204. Found at http://www.govtrack.us/congress/billtext.xpd?bill=s110-1858.

[29] Susan Bachrach, Ph.D. "In the Name of Public Health – Nazi Racial Hygiene." *The New England Journal of Medicine*. 351(5), July 29, 2004. pp. 417-420.

[30] Philip Reilly. "Eugenics and the Misuse of Genetic Information to Restrict Reproductive Freedom, Board of Directors of the American Society of Human Genetics." *The American Journal of Human Genetics*, Vol 64(2) February 1999. pp 335-338.

[31] Mary Ann Roser. "Texans unknowingly donate children's blood to research." *American-Statesman*. February 22, 2009. ALSO: http://www.health.state.mn.us/newbornscreening/research.html

[32] Mary Ann Baily. "Newborn Screening." From Birth to Death and Bench to Clinic: The Hastings Center Bioethics Briefing Book for Journalists, Policymakers, and Campaigns. edited by Mary Crowley, pp 125-128.

[33] Beth A. Tarini, MD, MS [Assistant Professor of Pediatrics, Child Health Evaluation and Research Unit, University of Michigan]. "Not Without Consent: Parents' Willingness to Permit Use of NBS Sample for Research & Storage." Powerpoint Presentation from 2008 Newborn Screening and Genetics Testing Symposium, November 5, 2008.

[34] "State by State Government Newborn Blood & Baby DNA Retention Practices." Citizens' Council on Health Care. 2009. http://www.cchconline.org/pdf/50_States-Newborn_Blood_Retention_Policies_FINAL.pdf

[35] Robert F. Weir, Robert S. Olick, Jeffrey C. Murray. The Stored Tissue Issue: Biomedical Research, Ethics, and Law in the Era of Genomic Medicine. (Oxford University Press US 2004) p. 25.

[36] Tarini, op.cit.

[37] Tarini, op.cit.

[38] John Stein, Minnesota Department of Health. Testimony at Minnesota House Civil Justice Committee. March 23, 2009.

[39] "Minnesota Department of Health Comments to the 2009 Genetic Information Report," December 15, 2008. p. 1. http://www.cchconline.org/pdf/MDH%20Genetic%20Info%20Response%2012_2008.pdf

[40] Quote by Piero Rinaldo, MD, Ph.D. researcher and geneticist at the Mayo Clinic in Rochester Minnesota ("Screening newborns poses research/privacy debate." Heather J. Carlson. *Post-Bulletin*. March 26, 2009).

[41] "Development of Newborn Screening Test for Adrenoleukodystrophy" The Myelin Project (TX), 3/7/08. Accessed online.

[42] Lisa Feuchtbaum et al. "Questioning the Need for Informed Consent: A Case Study of California's Experience with a Pilot Newborn Screening Research Project." *Journal of Empirical Research on Human Research Ethics*. Vol 2(3) September 2007. pp 3-14.

[43] Wikipedia – Compulsory Sterilization: "California sterilized more than any other state by a wide margin."

[44] *Bearder, et.al. v. State of Minnesota and Minnesota Department of Health*, filed March 11, 2009.

[45] "Texas A&M Named in Blood Storage Lawsuit." *KBTX.com*. March 13, 2009.

[46] "Microarrays." John F. Palma, PhD, Director, Molecular Diagnostics R&D, Affymetrix, Inc. "Using DNA-based Technologies in Newborn Screening" (Minutes from meeting). The Hastings Center and the March of Dimes conference at Loew's L'Enfant Plaza Hotel Washington, D.C. September 1, 2004.

[47] The President's Council on Bioethics. "Newborn Screening, Genomic Medicine and Eugenics." The Changing Moral Focus of Newborn Screening. Dec. 2008. pp. 52-53.

[48] Nancy S. Green and Kenneth A. Pass. "Neonatal screening by DNA microarray: spots and chips." *Nature Reviews Genetics* Vol 6 February 2005. p. 147-151.

[49] Anna Jo Bratton. "Political-Genetic Theory Is Studied." *Associated Press*. November 2, 2006.

[50] The "HITECH Act" within the American Recovery and Reinvestment Act of 2009 (Economic Stimulus, p. 117) signed by Congress requires the "utilization of an electronic health record for each person in the United States by 2014."

[51] 45 CFR Parts 160 and 164. "Standards for Privacy of Individually Identifiable Health Information" August 14, 2002.

[52] Deborah C. Peel, MD. Patient Privacy Rights. Letter to Congressmen Daniel Akaka and Edward Kennedy. February 6, 2007: "The consent provisions were replaced with 'regulatory permission for over 600,000 covered entities to use and disclose personal health information for treatment, payment, and health care operations.'"

[53] For example, "Testing for sickle cell disease also detects infants with sickle cell trait. Although an infant with sickle cell trait does not have the problems of sickle cell disease, his or her parents could have another child who does have sickle cell disease." (Wadsworth Center, http://www.wadsworth.org/newborn/babhealth.htm#listing) As the Wisconsin Department of Health and Social Services' Sickle Cell Trait brochure notes, "Babies inherit sickle cell trait from their parent…Your baby inherited hemoglobin A from one parent and hemoglobin S from the other parent (AS=Sickle Cell Trait)."

[54] Bruce Jennings and Elizabeth Heitman. op.cit.

[55] Sophia Wang et al. "Public Attitudes Regarding the Donation and Storage of Blood Specimens for Genetic Research." *Community Genetics* 4(2001): pp.18, 20.

[56] Ibid. p.19.

CCHC, 1954 University Ave W. Ste. 8, St. Paul, MN 55104 p 651-646-8935 f 651-646-0100 www.cchconline.org

[57] Anne-Emanuelle Birn, ScD, MA and Natalia Molina, PhD, MA. "In the Name of Public Health [Editorial]" *American Journal of Public Health.* Vol 95(7). July 2005. pp. 1095-1097.

[58] Barbara L. Neilson, ALJ. Report of the Administrative Law Judge. Minnesota Office of Administrative Hearings. March 23, 2007; *and* Raymond R. Krause, Chief Administrative Law Judge, Minnesota Office of Administrative Hearings, in letter to MDH on July 3, 2007: "[R]econsideration of Finding 67 of the ALJ Report is denied."

[59] http://www.cchconline.org/pr/pr031109.php

[60] Email to author from Mark McCann, Supervisor, Public Health Laboratory. Minnesota Dept. of Health, January 12, 2009.

[61] State of Minnesota Professional and Technical Services Contract, CFMS Contract No.A-61671, Total amount of Contract $6,985,000. Dated June 14, 2004 – September 30, 2008. Accessed 4/22/09 through http://nathanmhansen.blogspot.com/ at: http://www.hansenlawoffice.com/MDH/Contract%20with%20Mayo%20for%20Screening%2004%20to%2009.pdf

[62] http://www.cchconline.org/pr/mayo_letter_2009pdf080.pdf

[63] McCann: "Mr. Chair, Senator Hann, I don't think my response indicated that there wasn't a law, just not a current practice for us to have written informed consent to operate a newborn screening program within the boundaries of program operations, our interpretation of current law." Stein: "Were we to operate that on the basis of informed consent, we believe that it would compromise our ability to effectively operate the program." *(Testimony by MN Dept. of Health officials Mark McCann and John Stein, Minnesota Senate Health, Housing and Family Security Committee hearing on proposed legislation to exempt newborn screening program from the state genetic privacy law's informed written consent requirements, March 16, 2009).*

[64] "There's a difference between informed consent and public health. We have a number of laws in this state in which the public's interest takes precedent over the individual's privacy…If parents don't want it than they have the ability to opt out, but the child never has the right to opt out. There's that prevailing government interest we think is a broad one. And regarding saving this material, we at the March of Dimes believe that material can be used for a lot longer time to try and improve the health of individuals and the health in society. These specimens are good for up to 20 years for doing research....Most importantly we use these to come up with new tests [test development]...we would urge you strongly to continue this program. *(Testimony by Phil Griffin, lobbyist for March of Dimes, Minnesota Senate Health, Housing and Family Security Committee hearing on proposed legislation to exempt newborn screening program from the state genetic privacy law's informed written consent requirements, March 16, 2009).*

[65] "We urge you to pass this bill and resist efforts by opponents using fear tactics about the DNA that could be identified from the blood spot. The protection of our children is of paramount importance and outweighs any speculative harm that might occur if the program is made voluntary as that diminishes the need for this program*." (Letter to MN House Health Care and Human Services Policy and Oversight Committee, Franklin W. Iossi, Director, State Government Relations, Mayo Clinic and Mayo Health System, March 17, 2009)* Note: Mayo Clinic receives two of the five blood spots taken from Minnesota children at birth. The $6 million contract with the Minnesota Department of Health authorizes Mayo Clinic to conduct genetic research using those blood spots without parent consent.

[66] Lainie Friedman Ross, MD, Ph.D. "Genetic Testing of Children." A Companion to Genethics (Wiley-Blackwell 2002).

[67] Ibid.

[68] George J. Annas, JD, MPH, Professor of Health Law. "Mapping the Human Genome." A Companion to Genethics (Wiley-Blackwell 2002) p. 133.

Presentations
To request a presentation on this topic:
651-646-8935; info@cchconline.org

CCHC MISSION
Citizens' Council on Health Care is committed to supporting patient and doctor freedom, medical innovation, and the right to a confidential patient-doctor relationship.