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U.S. Department of Health and Human Services (HHS)
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RE: HHS Request for Public Comments on “Considerations and Recommendations for National Guidance Regarding the Retention and Use of Residual Dried Blood Spot Specimens after Newborn Screening,” – a Briefing Paper issued April 26, 2010 by HHS through the Secretary’s Advisory Committee on Heritable Disorders in Newborns and Children.

Public Comments on HHS Recommendations for Storage and Secondary Use of Newborn DNA

Citizens' Council on Health Care (CCHC) is a non-profit health care policy organization supporting patient and doctor freedom, medical innovation and the right to a confidential patient-doctor relationship. We submit the following comments on the Secretary’s Advisory Committee’s Recommendations for storage and secondary use of newborn blood specimens (DNA) under the following sub-headings:

- Summary of Concerns
- Consent Requirements Dismissed
- Deception Supports DNA Dissection
- Government Wants DNA on File
- Trust & Transparency in Tatters
- Why Consent is Critical – One Example
- Risks, Realities & Rights
- Conclusion

Summary of Concerns

The Advisory Committee’s recommendations are an attempt to establish and support government banking and ownership of citizen DNA at birth through the creation of 50 state government DNA warehouses for nationwide genetic research on the American public without the informed written consent of citizens. Specifically, the Secretary’s Advisory Committee on Heritable Disorders:

- Fails to recommend informed written consent requirements for the storage and use of newborn DNA for research and other purposes.
- Recommends the Committee simply “Develop national guidance for consent or dissent for the secondary use of specimens...” (p. 20)
- Asserts a public claim on the DNA of newborn citizens. (p. 1)
- Claims that newborn blood is necessary for “population surveillance.” (p. 3)
- Claims that newborn screening test development is not research. (p. iv)
- Does not support the 22 state genetic privacy laws and the 5 state genetic ownership laws that may or do require consent. (p. 8)
- Does not include compelling statistics from the Univ. of Michigan study that found the public appalled by unconsented government storage and research (p. 12).
- Recommends parent education instead of informed parent consent requirements that would enforce such education. (p. iv)
- Claims that state screening programs are charged with “stewardship” of newborn DNA samples—‘ensuring appropriate use’—when they are actually charged with simply testing each newborn. (p. 6)
- Fails to acknowledge the constitutional Fourth Amendment genetic privacy and property rights of individuals.

Thus, the Secretary’s Advisory Committee on Heritable Disorders in Newborns and Children has done an extraordinary disservice to the parents, children and citizens of the United States, advocating for the expansion of government power over the individual’s most intimate property and the reduction of constitutional rights of individual citizens.

HHS Secretary Kathleen Sebelius should require her Advisory Committee on Heritable Disorders to withdraw these recommendations and issue a new set of recommendations that comply with the legal individual rights and informed written consent requirements that are secured by the Fourth Amendment privacy and property protections of the United States Constitution.

Consent Requirements Dismissed

Experts in the field of newborn screening agree that State banking of newborn blood is on shaky legal, ethical and moral ground because the banking of the child’s DNA is primarily intended for research purposes and States do not seek or obtain parent consent prior to banking.

In 2006, Dr. Bradford L. Therrell, Ph.D wrote that “nineteen states/territories have statutes and regulations that permit researchers to access and use newborn screening information for scientific studies, and 10 of these have laws or regulations that include specifically access to specimens.” He wrote about the following about the banking of newborn blood specimens (“*Status of Newborn Screening Programs in the United States, PEDIATRICS, May 2006*):

“Whereas previously these specimens were viewed as primarily useful for program quality assurance...they have become increasingly important as possible sources for genetic research. This is of particular importance because newborn screening specimens represent the **most comprehensive population testing program** currently in operation, and specimens are obtained from essentially every newborn. ...” *[emphasis added]*

“[G]enerally the specimens that are stored for long periods (beyond a few months) are not considered useful for quality assurance regarding the original screening tests (with limited exceptions). Therefore, **it is agreed generally that specimens stored for long periods are of interest primarily for their potential research use.** This use is made more complex by the fact that most newborn screening programs do not need to obtain

consent for testing; therefore, the use of specimens beyond the newborn screening procedure itself **raises various legal and ethical questions.**" [emphasis added]

"...[T]he potential for research use of population screening specimens is extensive. The CDC, in cooperation with APHL, convened a small working conference in September 2002 to discuss the possibilities for research use of these specimens, including the possibilities for consolidating specimens from programs to provide larger collections of available specimens for possible research...it may be possible to create a **virtual national centralized specimen management system** that would be useful for various types of research." [emphasis added]

Despite the compelling evidence that parents believe such government storage is "unlawful" (*"The Public's Perceptions Related to Uses of Newborn Screening Dried Blood Spots," Sharon Kardia, Ph.D., University of Mich., Sept 23, 2009 presentation*) and that parents want parent consent requirements for storage and research (*"Not Without My Permission," Dr. Beth Tarini, M.D. et. al., Public Health Genomics, July 11, 2009*), and that parents believe specific consent requirements for each research project is critical even if blood spots are de-identified (*Sharon Kardia presentation*), the Advisory Committee does not acknowledge parent consent as critical for government storage and use of newborn blood spots (DNA) for research or other purposes.

While the Committee recommends the "establishment of a voluntary U.S. national repository," (p. 8), and the Committee's 4th recommendation give cursory mention of consent, opting out of research and destruction of blood samples, there are no recommendations to require fully-informed written parent consent. Nor are there any recommendations for written informed consent requirements for the children who grow up to become adults whose DNA is owned by state government, shared broadly and warehoused in government biobanks since birth. Instead the Committee advises mere consideration of consent:

"[E]ach state should consider whether separate or blanket consent/dissent processes for approved studies is required from parents, legal guardians or individuals screened upon the age of majority for the use of residual newborn screening specimens.

Nor do the recommendations acknowledge the Fourth Amendment rights of citizens, including the newborn and his or her parents right to prohibit government collection, storage, use, and dissemination of newborn citizen DNA. This right was underscored recently in the court decision that forced the Texas Department of Health to destroy illegally retained newborn bloodspots.

In fact, rather than acknowledging newborn DNA (blood spots) as the most personal and unique private property of America's youngest citizens, the Advisory Committee recommends the waiver (dismissal) of parent consent:

[Recommendation 5]: "**If residual blood specimens are to be available for any purpose other than the legally required newborn screening process for which they were obtained, an indication of the parents' awareness and willingness to participate should exist in compliance with federal research requirements, if applicable.** Depending on the purposes for which specimens will be used, a parental consent (opt-in) or a dissent (opt-out) process may meet this requirement, if necessary, or a waiver of consent may be appropriate." (p. iv)

This recommendation has several concerns beyond the recommended waiver of parent consent requirements.

First, several years ago, a change in the federal research requirements allowed researchers to avoid patient consent requirements if they simply coded the patient's human tissue/blood/organ in a manner that removed the identity of the patient but allowed the tissue to be linked back to the patient—and if everyone promised through data agreements not to re-identify the individual even if they could. This change in federal research policy eliminated the previous requirement that tissues be completely anonymized (unable to ever go back and identify the individual) and enables patients to be reidentified through the linkage code despite the current federal prohibition to do so.

As noted in the Committee's recommendations, this linkage to individual data is common:

“All newborn screening programs retain residual newborn screening specimens for some period of time, usually with at least one identification numbers. Linkage to demographic information usually continues until de-identification may be initiated.” (p. 16)

Second, this supposed “indication of parent awareness and willingness to participate,” which the Committee did not detail, does not qualify as consent. Consent is a legal transaction. Consent forms are legal documents that inform patients of risks, rights, and benefits prior to securing the patient's signature (consent). Since “indication” is not defined, this “indication” could simply be wrapped into the broad ‘consent for treatment’ form signed by the expectant mother upon admission to the hospital. This type of consent is also not a valid consent for government storage, use and dissemination of the newborn's blood and DNA for genetic research and other purposes.

If a State does choose to require consent, the Advisory Committee appears to recommend a consent that is squishy— not ironclad, written or informed:

“Commentators have noted that the best way to ensure new tests are introduced in a rational manner and promote appropriate communication with families, is to rely on a research approach that is *flexible* with respect to (1) how parental permission is acquired; and (2) methods for the rigorous evaluation of harms and benefits associated with screening. It also has been noted that fundamental ethical concerns around individual and societal risk should ultimately drive *how research regulations are interpreted* and used. *A balanced consideration of concerns justifies waiving informed consent* for population-based newborn screening research using de-identified specimens when a clinically well-defined test and an effective therapy are present.” [emphasis added] (p. 12)

Deception Supports DNA Dissection

We are very concerned about the Advisory Committee's assertion that “new test development or refinement” is not research and is one of the “valid components of the public health newborn screening programs and therefore, should not require additional consent.” (p. iv)

First, as noted in the paper, most newborn genetic screening programs have no consent requirements (p. 2). Second, the development of newborn tests (using newborn blood samples) for the purpose of screening children in the future for new conditions not currently screened through newborn screening is research.

Those who claim it is not research, as asserted in Minnesota by the Minnesota Department of Health, often refer to this type of research as newborn screening studies or public health studies. Whatever the term, these studies are research on human subjects. Newborn screening test development often uses both the stored newborn blood spots of children who *have* the condition

for which health officials wish to screen all newborns and the stored newborn blood specimens from children who have *not* been diagnosed with the condition.

The Committee's recommendations are contradictory on this issue. While the paper regularly dismisses the need for parent consent, the Committee actually agrees that research is taking place as soon as they bank newborn blood that will later be used to develop new newborn tests and thus "some form of consent or formal IRB waiver of consent" is needed:

"Some form of consent or formal IRB waiver of consent appears to be necessary if newborn screening specimens are to be placed into a repository for research purposes since **creation of a research repository is, in and of itself, research.**" *[emphasis added]* (p. 12)

Dr. Francis Collins, director of the National Institutes of Health (NIH), has publicly stated that newborns may soon have their genome completely sequenced at birth through newborn screening. Thus, this Committee's recommendation against parent consent requirements for the development of new newborn tests supports the development of a government screening program that will eventually conduct comprehensive genomic sequencing of every citizen at birth.

Government Wants DNA on File

Recommendation #1, regarding the drafting of state policy, is an attempt to persuade state legislators to keep newborn DNA on file with the government—and available for research:

"Policymakers should consider the value of the specimens as a promising resource for research..." (p. iii)

Furthermore, the Secretary's Advisory Committee on Heritable Disorders suggests use of the newborn's sample for ongoing research without consent or institutional oversight:

"If the research study does not require that donors be re-contacted or identified, some have suggested that existing medical records and stored specimens containing identifying information can be made available for research without explicit individual consent or ethical review board approval." (p. 13)

The Committee further claims that these recommendations will "encourage an approach to future policymaking that enables residual specimens use to advance science and clinical care for newborns." The paper also "calls upon policymakers, the public health community, health care providers and families to work together to **protect this valuable resource for the public good.**" (p.1) *[emphasis added]*

There are no recommendations to protect the *private, individual good of citizens* including, the right to keep their DNA out of the hands of government and researchers unless, through fully-informed written consent, they so choose to have their DNA on file and available.

Furthermore, this is the DNA of newborn citizens who cannot yet choose to give or deny their consent. Rather than addressing the constitutional and property interests and rights of these newborn citizens, the Committee asserts a "public" interest in citizen DNA sufficient for government to lay claim to the DNA of all babies for the "public good."

No such "public good" exists in law, and in fact, individual rights under the Fourth Amendment of the U.S. Constitution, as asserted in the March 12, 2009 [parent lawsuit](#) against the Texas

Department of Health and [upheld by the court](#) in a December 2009 decision, protect individuals from such unconsented DNA takings by government.

Trust & Transparency in Tatters

After stating in the body of the paper that only 57% of States have internal written policies for specimen usage, (p. 4) and that only 12 states include mention of specimen storage in their newborn screening educational pamphlets (p. 10), the Committee claims, “State processes for residual newborn specimen storage strive to secure the specimens, protect the privacy of the newborn and their families, and promote public trust. State policies also emphasize transparency of administrative practices, and create supporting information that encourages informed public participation.” (p. 1)

That is not the experience of parent in Minnesota or Texas. In Minnesota, the Minnesota Department of Health has gone out of its way to make sure parents are not informed—beginning the collection without public notice or statutory authority, not informing hospital of parent’s legal opt-out rights secured in 2003, hiding the opt-out information in a fancy brochure tucked amidst baby formulas coupons in the birth packet, and trying to undo the informed consent requirements of the state genetic privacy law (2007, 2008, 2009).

In Texas, the Texas Department of Health has commodified the newborn’s DNA by trading the specimens to secure laboratory equipment, as reported by the *Austin American-Statesman*. The Texas DOH also disseminated newborn bloodspots to the U.S. military to create a DNA database for law enforcement, as reported by the *Texas Tribune*. These activities were done without parent consent or knowledge, leaving the public’s trust and the integrity of both Departments in tatters.

Why Consent is Critical - One Example

Citizens’ Council on Health Care has been instrumental in protecting the genetic privacy and DNA property rights of newborns and their families since we discovered the existence of a Minnesota baby DNA warehouse and the Minnesota genetic registry of newborn genetic testing results during the debate over a Minnesota newborn screening bill in 2003.

The Minnesota genetic registry began retaining newborn screening test results July 1, 1986 and the baby DNA warehouse began storing baby DNA on July 1, 1997. At the end of 2009, the test results of 1,639,028 children were in the State genetic registry and the blood spots of 891,673 children were in the State baby DNA warehouse. As we now know, State health officials made executive decisions and began these collections without statutory authority or parent consent.

The proposed 2003 legislation would have authorized the state health commissioner to genetically test every newborn at her own discretion, for as many conditions as she chose. No specific statutory approval or parent consent was to be required.

Although the bill moved forward with the Commissioner’s authority to expand newborn genetic testing intact, our efforts secured Minnesota parents the right to opt-out of the testing or to agree to the testing but require the State to destroy the blood samples and the genetic test results.

However, the Minnesota Department of Health (MDH) did not choose to update the newborn screening rules to include the provisions of the 2003, or to inform parents or hospitals of these new legal rights.

Seven years later, many parents of newborns, informed by CCHC of their options, still have to fight for their rights at the hospital where doctors and nurses remain unaware of these rights and

believe the parents are attempting to violate the screening law. **This example demonstrates why opt-out (dissent) should not be the legal standard. Only opt-in (consent) requires hospitals, hospital staff, and parents to be fully informed of their legal choices.**

In 2006, the state legislature passed a state genetic privacy law requiring informed written consent for the collection, storage, use and dissemination of genetic information. When an administrative law judge charged MDH with violation of the 2006 state genetic privacy law, MDH unsuccessfully sought to exempt the newborn screening program from the genetic privacy law in the last days of the 2007 legislative session, appealed, lost the appeal, and then withdrew their proposed revision to the newborn screening rule. They tried again at the 2008 and 2009 legislative session, unsuccessfully, but to this day, MDH continues to collect, store, use and disseminate newborn blood specimens for genetic research.

Nine Minnesota families sued MDH on March 11, 2009. The appeal was heard June 8, 2010 and no decision has yet been issued.

Meanwhile, in Texas, a news reporter, staying abreast of our organization's efforts in Minnesota, researched the policies and practices surrounding newborn DNA in Texas and discovered a baby DNA warehouse going back to 2002, also established and populated without parent consent. After writing a major article on the issue, a lawsuit was filed (March 12, 2009), legislators changed the law to allow parents to opt-out, and in December 2009, a judge ordered the Texas Department of Health to destroy blood spots stored prior to the May 2009 change in Texas law.

Risks, Realities & Rights

Legitimate genetic research respects the legal, ethical, and moral rights of individuals to be informed and not coerced or forced to participate in government DNA storage and genetic research initiatives. Parents and grown children must be fully informed about the testing, the research, the risks, the benefits, and their rights. Only then should they be asked if they wish to provide written consent. *Such information on risks, realities and rights must include, at a minimum:*

- 1) Newborn screening is newborn genetic testing.
- 2) State government, not the hospital, conducts the genetic testing.
- 3) If held by government, the baby's blood (DNA) becomes government property.
- 4) Future legislatures may decide to claim the DNA held by government for purposes of law enforcement or other uses that parents and their grown children may object to.
- 5) Research is voluntary and requests for storage and use of newborn DNA for research may be refused.
- 6) If consent is given, the government will warehouse newborn DNA.
- 7) Such government or private genetic research may be objectionable.
- 8) DNA cannot be anonymized, according to genetic experts. (p. 13)
- 9) Newborn DNA may hold information about the baby and the parents that the baby and/or the parents do not wish to know themselves or divulge to doctors, government or researchers.
- 10) Individuals have a right "Not to Know" what their genes may say.
- 11) Genetic findings are merely predictive, but induce emotional or other harm.
- 12) Individuals have the right to refuse to become subjects of genetic research.
- 13) False-positive screening results may cause long-term anxiety for parents.
- 14) All genetic test results are reported to the child's doctor for placement in the child's permanent medical record.

- 15) Newborn screening findings, including genetic traits that will not produce actual physical symptoms, may negatively impact the future employment, insurance and reproductive options of the child (despite supposed protections of the GINA law).
- 16) As the paper notes, screening data placed in the child's medical records may be accessed without parent or individual consent by government and others for analysis, tracking, research and under purposes under the so-called HIPAA "privacy" rule. (p. 9)
- 17) The baby's DNA is the property of the baby, protected until adulthood by the baby's parents and protected from government 'search and seizure' through the Fourth Amendment of the U.S. Constitution.
- 18) Private newborn genetic testing is an option for parents who do not wish to have government conduct genetic testing on their child through newborn screening.
- 19) If the parents give consent and later wish to reconsider their consent, they have the freedom to opt-out of further research in the future.
- 20) If parents provide consent for storage of their child's DNA, it will not be used for any research project, including public health studies or newborn screening studies, without the additional written consent of the parents.
- 21) Children, once they reach adulthood, may not be pleased that their parents handed over their DNA to the government for research and other uses.

Conclusion

The Advisory Committee's recommendations are an attempt to establish and support government banking and ownership of citizen DNA at birth through the creation of 50 state government DNA warehouses for nationwide genetic research on the American public without the informed written consent of citizens. The Advisory Committee has dismissed the critical need for consent requirements. Thus, policymakers should dismiss these recommendations by the Secretary's Advisory Committee on Heritable Disorders in Newborns and Children.

HHS Secretary Kathleen Sebelius should require her Advisory Committee to withdraw these recommendations, which are based on dismissal of individual rights and the biased assertions of state and federal government officials and Advisory Committee appointees. The Committee should write and submit recommendations for the storage and use of newborn DNA that acknowledge the consent, privacy, parent, and DNA property rights of individual citizens, including especially the rights of newborns who are America's youngest citizens.