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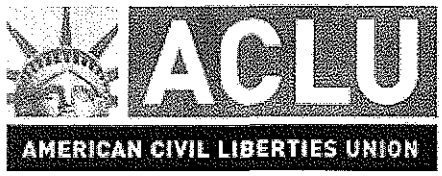

May 14, 2010

Advisory Committee on Heritable Disorders
in Newborns and Children
5600 Fishers Lane, Room 18A19
Rockville, Maryland 20857

Comments of the American Civil Liberties Union

Re: *The Retention and Use of Residual Dried Blood Spot Specimens after Newborn Screening*

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The American Civil Liberties Union (ACLU) welcomes the opportunity to comment on the retention and use of dried blood spot specimens collected in the course of newborn screening for inherited disorders. The ACLU is a nationwide, non-partisan organization with more than 500,000 members dedicated to protecting the principles of liberty, freedom, and equality as set forth in the Bill of Rights to the United States Constitution. For almost ninety years, the ACLU has sought to preserve and strengthen privacy and self-determination in all aspects of American life.

Last month, the Advisory Committee on Heritable Disorders in Newborns and Children ("Advisory Committee") issued a draft set of recommendations to the Secretary of the U.S. Department of Health and Human Services in the form of a briefing paper entitled *Considerations and Recommendations for National Guidance Regarding the Retention and Use of Residual Dried Blood Spot Specimens after Newborn Screening*. The briefing paper contains praiseworthy suggestions for improving newborn screening programs.[1] However, the Advisory Committee falls short when it fails to recommend that states obtain express, informed consent to the retention of samples beyond the completion of newborn screening and to the subsequent use and dissemination of samples. Instead, the Advisory Committee ambiguously asserts that states "should consider whether consent or dissent from families is necessary for uses other than newborn screening and, if so, under what circumstances."[2] In other words, the Advisory

[1] The ACLU supports the Advisory Committee's recommendations that newborn screening programs develop strategies to educate health care providers and that both providers and state newborn screening programs themselves should take affirmative steps to ensure that families understand newborn screening, including possible future research uses of newborn blood samples. Briefing Paper at iv.

[2] Briefing Paper at iii.

Committee leaves the issue of informed consent to state-by-state experimentation, and accepts the possibility that consent may be dispensed with entirely.

The ACLU recognizes the importance of newborn screening. Even absent consent, we support screening for identifiable conditions which would result in substantial impairment of a child if not immediately detected and promptly treated, and for which there is available effective ameliorative therapy that is in fact offered to the child regardless of ability to pay. This is the rare circumstance in which the state's interest in protecting newborn health is so compelling that it trumps countervailing privacy and autonomy interests.

The ACLU believes that, in all other cases, informed consent is required. This includes retaining newborn blood spots after completion of the screen and research use of the samples by states and third parties. Proceeding with such uses in the absence of express, informed consent is not only improper, but also risks undermining the public trust and goodwill upon which newborn screening programs depend.

The Advisory Committee's Proposal Represents a Radical Departure from Traditional Practice.

Even in its original form, newborn screening was unusual because it is a population screening program subjecting virtually all of those born in the U.S. to the collection and analysis of their tissue. From its beginnings in the 1960s until recently, the exceptionally broad reach of this government-mandated intervention was justified and cabined by the seriousness and immediacy of the health concerns at issue.[3] In recent years, this has begun to change. States are increasingly using newborn blood samples for medical research, some of which is calculated to improve newborn screening, and some of which is completely unrelated to screening.

In short, the Advisory Committee has endorsed a fundamental transformation of newborn screening. The Committee seeks to convert a program developed for the benefit of the child whose blood is taken into one benefitting medical research. It would change the program from one in which the impact of the program is finite and known into one in which infants' blood may be used for a broad array of purposes, possibly including some not currently imagined, by unidentified people, for an undetermined length of time into the future.

The Retention and Use of Newborn Blood Samples Implicates Important Privacy and Self-Determination Interests.

The ACLU acknowledges that newborn blood samples are useful for medical research. Yet not everyone shares the Advisory Committee's opinion that the samples are a "public good." Indeed, some parents view the samples, which contain their newborn child's DNA, as deeply personal and private. Even some of those who are willing to donate their child's blood for research uses oppose a regime which requires them to relinquish all control over the future uses of the blood.

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[3] President's Council on Bioethics, *The Changing Moral Focus of Newborn Screening* p. 2, 21 (Dec. 2008)(approving screening in cases where "the targeted condition is an important health problem, whose natural history is well-understood, and whose symptoms are amenable to early intervention and effective treatment.)

There are many reasons for these views. For some, they reflect deeply held religious beliefs. Other individuals legitimately fear discrimination because of their genetic profiles, for example because they possess a gene that predisposes them to certain types of disease.[4] Others may wish not to know, or to keep secret, otherwise unapparent genetic conditions that testing of blood specimens can reveal.[5] Others might consent to the use of their tissue for some research uses but find others profoundly objectionable.[6] Still others may simply believe that their genetic information is nobody's business, and certainly not the government's business. Others are justifiably concerned about the future potential for law enforcement or other forensic uses of the samples.[7]

That some individuals object to the use of newborn samples without notice or consent is not a matter of conjecture. Parents in Texas sued their state's newborn screening program for taking newborn blood samples and storing them indefinitely for undisclosed research purposes.[8] In describing the harm to their children that they perceived, the parents cited many of the above privacy concerns. They told the court that "blood spots contain deeply private medical and genetic information" and they were "concerned about the potential for misuse of that information and fear the possibility of discrimination against their children and perhaps even relatives through the use of such blood samples and research activity thereon."[9]

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[4] The Genetic Information Nondiscrimination Act represents a step toward addressing this concern, but by no means eliminates it. Pub. L. No. 110-233, 122 Stat. 881 (2008).

[5] Such conditions include the potential for diseases such as Huntington's disease and Alzheimer's disease.

[6] For example, The Havasupai Indians provided researchers with DNA samples for the purpose of studying the tribe's high rate of diabetes. Tribe members were astonished to discover that their DNA had been used for other purposes, including studying the tribe's origins in a way that cast doubt on their ancestral stories. Amy Harmon, *Indian Tribes Win Fight To Limit Research Of Its DNA*, New York Times (Apr. 21, 2010). They sued, and recently won a settlement that included return of their DNA samples. Other individuals might object to having his or her genetic information used for research on the link between race and violence. Henry T. Greely, The Uneasy Ethical and Legal Underpinnings of Large-Scale Genomic Biobanks 8 Annual Review of Genomics and Human Genetics 343 (September 2007).

[7] The ability to access DNA is of interest to law enforcement, as is obvious from the continuing expansion of the Federal Bureau of Investigation's Combined DNA Index System (CODIS). FBI Website, CODIS Combined DNA Index System. http://www.fbi.gov/hq/lab/html/codisbrochure_text.htm. In Sweden, the police have already used newborn screening biobanks in a criminal case. Lori Andrews, *Should Infant DNA Later Be Used In Forensics*, On The Edges Of Science And Law, http://blogs.kentlaw.edu/islat/2009/06/should-infant-dna-later-be-used-in-forensics.html.

[8] Beleno v. Texas Department of States Health and Human Services, Case No. 09-cv-00188, First Amended Complaint (filed 9/29/2009).

[9] Beleno v. Texas Department of States Health and Human Services, Case No. 09-cv-00188, First Amended Complaint at 4 (filed 9/29/2009).

In other words, people care about the ways in which their genetic material is used. When the government collects, stores, and uses blood samples pursuant to a mandatory program, it must take these concerns seriously.

"Anonymization" Does Not Negate Civil Liberties Concerns Surrounding the Use of Newborn Blood Samples.

Some argue that secondary uses of newborn blood samples raise no privacy or consent issues because they can simply be anonymized. Because the samples contain DNA, however, it cannot be assumed that such de-identification is possible. It is unarguable that individual identification is currently possible in cases where a reference sample is available, and it has been estimated that such unique identification is possible with as few as 75 single-nucleotide polymorphisms (SNPs).[10] Moreover, recent developments in genetic testing to predict ethnicity and facial characteristics[11] indicate that it is quite conceivable that genotype alone may one day be sufficient for identification.[12]

To the extent phenotypic information accompanies DNA samples, the risk of individual identification is increased.[13] Logic dictates, and experience has shown, that most meaningful research cannot occur on samples unaccompanied by at least some phenotypic information, and some research requires extensive demographic, medical history, or other information. Finally, even to the extent that DNA and other personal information are delinked, the power to relink information can be abused—either by researchers themselves or by rogue employees or hackers.[14]

In sum, it is simply insufficient to assert that secondary uses are permissible, or that individuals' privacy and autonomy concerns are addressed, because samples are "anonymized." Such a position is out of step with forensic DNA technology as it exists currently and as it will likely develop in the very near future.

Express, Informed Consent Requirements Are Essential to Reconciling Public Health Research with Individuals' Rights of Privacy and Self-Determination.

The way to take civil liberties concerns seriously is by requiring that informed consent be obtained for essentially all collection, storage, use and dissemination of newborn blood spots. The only exception to this requirement should be the narrow set of circumstances previously described, in which the individual child would be harmed by inaction and significantly benefitted by medical intervention. In all other cases, and especially with regard to the expanding array of

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[10] Lin, Z., A.B. Owen and R.B. Altman, "Genomic Research and Human Subject Privacy," Science, Vol. 305, no. 5681 (9 July 2004), p. 183.
[11] *See* Cho, M.K. and P. Sankar, "Forensic Genetics and Ethical, Legal and Social Implications Beyond the Clinic, *Nature,* Vol. 36, no. 11 (November 2004), pp. S8-S12. *See also* "Retinome," DNA Witness, available at: http://dnaprint.humid.e-symposium.com/dnawitness/retinome.html
[12] McGuire, A.L. and R.A. Gibbs, "No Longer De-Identified," Science, Vol. 312 (21 April 2006).
[13] Greely 8 Annual Review of Genomics and Human Genetics at 351.
[14] *Id.* at 350-51.

secondary uses to which newborn blood is put, express and informed consent must be obtained. To date, these uses have occurred without public knowledge, exploiting the trust and goodwill parents extend to the newborn screening program. This state of affairs cannot continue.

Advances in medical and especially DNA technology do not, as some would assert, obviate the need for informed consent. On the contrary, true informed consent is now more important than ever, in light of the abundance of information that can be extracted from a single blood sample, and the ease with which the information can be disseminated.

Specifically, "informed" consent in this context means that each parent consenting to secondary uses of his or her infant's blood knows:

(1) what tissue being collected and what information can be extracted from that tissue;
(2) the period of time over which the sample and any derivative information will be stored;
(3) any and all purposes for which the sample and derivative information will be used; and
(4) to whom and under what circumstances the sample or any data drawn from it may be released to third parties.

In addition, an individual can only be said to have given his or her informed consent if he or she is provided with appropriate privacy notifications sufficiently in advance of the collection of the information so that needed deliberation and consultation can occur prior to the point when a decision must be made. Moreover, each individual must be informed of their right to learn at a later point in time whether and to whom the sample and associated information has been disclosed, and by what means they may later withdraw their consent.

Fortunately, this is not a situation in which there is inherent tension between advancing public health and respecting parents' decisions. A consent process will enable the small percentage of parents who wish to opt out of certain uses of their children's blood spots to do so, while allowing the others to donate their children's blood spots to public health research. When, as in the newborn screening context, tissue and the information it contains is collected from an individual for one purpose but subsequently used for another purpose, it is especially important that the secondary uses be disclosed to the individual. For the state to fail to do so is, simply put, a violation of the public trust.

The Risks of Foregoing Express, Informed Consent Outweigh Any Perceived Benefits.

The more newborn screening programs deviate from express, informed consent, the more they run the risk of losing the public support on which their success depends. Although the public's awareness of the secondary uses of newborn screening samples is currently minimal, it will not remain this way for long. The newborn screening program has come unmoored from its roots in clinical interventions benefitting individual children, and the government has failed to respond to this development with heightened protections for the fundamental rights of individual children and their families. As a consequence, media attention and the concern of organizations like the ACLU are increasingly drawn to this issue.

As individuals increasingly feel that their babies' blood is being taken for one purpose and then used against their will and beyond their control for other unspecified purposes, there is a real risk that the public will lose trust in the newborn screening program. The program saves lives. It would truly be tragic if the expanding use of newborn blood for unconsented-to research were to result in parents declining to have their infants screened in the first instance. Public sentiment that samples are being misused, or that individuals are being misled or not given a say in their use could lead to a political backlash undermining the support upon which those very research projects ultimately depend.

Sincerely,

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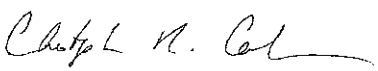

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