

December 1, 2014

RE: HR 1281

Dear Senator,

Founded in 1983, the Council for Responsible Genetics is the oldest national bioethics organization in the United States. We helped lead the successful efforts to enact the federal Genetic Information Nondiscrimination Act and CRG has supported every state and federal genetic privacy initiative in the last thirty years. We are founders of the Genetic Privacy Network and the Forensic Genetics Policy Initiative and have produced many influential books and reports including *Genetic Explanations* and *Biotechnology in our Lives*. Our Board of Directors includes leading scientists and public policy professionals.

We stand in strong opposition to HR 1281 as currently drafted. We believe Section 9 of this bill is against the interests of parents in making a truly informed choice about whether states shall permanently retain and use their children's personal genetic information.

Before they are even a week old, ninety-eight percent of the 4.3 million babies born annually in the United States have a small sample of blood taken from their heels. These newborn bloodspots (NBS) are then screened for a variety of inherited conditions and are often later stored in state-operated databases. Newborn screening itself is an important public health program and some have described these residual sample "biobanks" in equally positive terms. Although there are concrete benefits of newborn testing, there are also troubling consent and privacy issues raised by the screening, storage, and use of the samples.

With respect to sample storage and use, there is little transparency regarding storage procedures or the use of the samples after they have been screened. Indeed, not only do most parents never realize they have "consented" to storage of their children's biological material, they fail to understand that the actual state government (as opposed to the hospital) is the entity in possession of this sample. This issue would be compounded if/when states share this information with the U.S. government.

Several studies have shown that the vast majority of parents want the choice as to whether the state should maintain their child's sample after screening is completed and most oppose the indefinite storage of such



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samples.¹ Even though parents want informed consent to store and use the samples, most states do not have clearly articulated policies about consent for the storage and use of samples, do not effectively communicate these policies to parents and do not offer parents a truly informed choice about whether to participate in storage procedures.

The concern of parents that states retain their children's biological information is heightened because storage procedures and security at these state facilities are arcane and we still have few laws that truly protect the privacy of genetic information.

We are at a critical time in the development of medicine: the mapping of the human genome has provided powerful new tools to understand the genetic basis of disease and genetic tests can help diagnose genetic conditions, guide treatment decisions, help predict risk of future disease, inform reproductive decision-making, and assist medication selection. Americans are enthusiastic about the promise of genetic medicine; but are understandably fearful about how this powerful information can be abused. The sheer amount of genetic data being generated today, and its commercialization, raises serious medical privacy concerns.

Many individuals are legitimately concerned that their genetic information will be used against them and are unwilling to participate in medical research or be tested clinically, even when they are at risk for serious disease. They simply do not trust insurers, employers and other entities with incentives to improperly acquire and use genetic information. The government has not classified the collection and use of newborn screening data as research and its unclear whether the Common Rule, which requires informed consent for human subject research, would apply. This lack of clarity leaves newborn data ripe for misuse.

The lack of a formal informed consent procedure raises multiple problems. One critical problem is the ambiguity posed by silence. As applied to the case of newborn screening, a parent who does not voice objection to the screening program may still approve of the program and consent to screening and storage even if s/he does not express affirmative consent. On the other hand, that same parent may disapprove of newborn screening but s/he is either uninformed about or unaware of the program and therefore does not express explicit refusal. In both cases, however, the outcome is the same: the infant will undergo screening and their sample will be stored. The reality is that many parents are not well informed about screening programs or consent, due to inopportune methods and timing of information dissemination and the lack of adequate training for medical professionals responsible for communicating the information. Parents, understandably, want to be actively involved in decision making regarding their children's personal health information.

Finally, affirmative consent for storage is crucial because it promotes greater governmental transparency. Such transparency is especially important because newborn screening and storage is often exempted from state genetic privacy laws. Researchers and administrators working with these samples know very well how alarming newborn blood spot biobanking can sound to most people, which explains why many of these clinicians, researchers and state labs would prefer these projects to keep a low profile. However, public health officials' desire to avoid controversy must be balanced against parental interest in being informed about the storage and use of their children's bloodspots.

How many parents, having just had a baby and still in the hospital truly understand what the state may or may not be telling them? Thus, the only way to be sure that someone is truly consenting is to obtain his or her affirmative consent, as required by the opt-in model.

¹ See, for example, Erin Rothwell et al., Policy Issues and Stakeholder Concerns Regarding the Storage and Use of Residual Newborn Dried Blood Samples for Research, POLICY POLITICS NURSING PRACTICE, 2010 at 5, 5-6. and A. Tarini et al., Not without my Permission: Parents' Willingness to Permit Use of Newborn Screening Samples for Research, PUB. HEALTH GENOMICS, 2010, at 125, at 126.

HR 1281, as currently drafted, employs a mechanism for storage of newborn bloodspots that stands in direct opposition to recommendations by the Task Force on Genetic Screening, the Newborn Screening Task Force, and the President's Council on Bioethics. All three organizations propose that the storage of residual bloodspots should be implemented as an opt-in model of consent.² Numerous studies have also supported this position.³

The absence of clearly articulated and communicated consent policies is particularly problematic because of the mismatch between the promise of maintaining residual sample databases and the actual benefits generated by such storage. As mentioned above, public health officials and patient groups often emphasize the value that these databases represent, but the actual benefits generated are much less dramatic than their statements would suggest. Across the country, state stored blood spots are used almost exclusively for formulating screening tests and ensuring that existing tests meet certain quality standards. While these are beneficial applications of storage, they do not require the scale of current sample storage and can often be done even more effectively in appropriate research facilities. They certainly fall far short of the too often claimed promises of elucidating disease characteristics and generating earlier interventions.

Newborn screening is one of the few forms of genetic testing to which almost everyone is exposed. Yet parental knowledge of newborn screening and storage practices is extremely limited. As the National Institutes of Health (NIH) and other distinguished bodies move toward developing better and more informed consent procedures, HR 1281 would be moving in the opposite direction; against historical trends and even more importantly the desires of American parents.

Section 9 of HR 1281 must be amended to require states who receive federal money for the purpose of newborn screening to provide an opt-in model of consent for the continued storage and use of newborn DNA beyond what is required for the initial screening procedures. Such consent must be fully informed and acquired at a time when the parents can truly make an informed decision

We strongly encourage you to oppose HR 1281 until it reflects the desires of American parents for privacy and informed consent.

Sincerely,

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² Lainie Friedman Ross, Mandatory versus Voluntary Consent for Newborn Screening?, KENNEDY INST. ETHICS J., Dec. 2010, at 299, 300.

³ See, for example, Jeffrey R. Botkin et al., Public Attitudes Regarding the Use of Residual Newborn Screening Specimens for Research, PEDIATRICS, Feb. 2012, at 231, 234 and L. McKechnie & A. B. Gill, Consent for neonatal research, ARCHIVES DISEASE CHILDHOOD FETAL NEONATAL ED., 2006, at F374, F374.