June 30, 2017

Honorable Donald J. Trump, President
The White House
1600 Pennsylvania Avenue NW
Washington, DC 20500

Honorable Thomas E. Price, M.D.
U.S. Department of Health and Human Services
Hubert H. Humphrey Building
200 Independence Avenue SW
Washington, DC 20201

Dear Mr. President and Secretary Price:

Citizens’ Council for Health Freedom (CCHF) is pleased that the Trump administration has put on hold the final Common Rule (“Federal Policy for the Protection of Human Subjects”), which was published by the Obama administration on January 19, 2017.

We have one request and two recommendations.

On January 4, 2016, our organization submitted public comments on the proposed rule (with an addendum comment added later). Our concerns included:

- No retention of parent consent requirements for research using newborn DNA
- Need to retain ‘human subject’ designation for newborn DNA

In December 2014, President Obama signed the Newborn Screening Saves Lives Reauthorization Act (NSLRA). It included the language we worked on with the office of Senator Rand Paul and the Senate Steering Committee. The language required parental consent for the use of dried newborn bloodspots for federally-funded research. Hospitals prick the newborn’s heel and send the bloodspots to state public health departments for newborn genetic screening programs. The bloodspots are often stored in perpetuity without parental consent. The 2014 federal law also designated the child’s newborn bloodspot (DNA) as a ‘human subject’ and prohibited all waivers to the parental consent requirement.

The law said this protective language would disappear from federal statute after the final Common Rule was published because – we were told – NIH leadership had committed to include the 2014 statutory language in the final Common Rule.

However, when the rule was finalized, it did not include parental consent requirements or any other part of the protective language of Senator Paul’s NSLRA amendment. In fact, it specifies
that the 2014 NSSLRA language “will no longer apply after the effective date of this rule, January 19, 2018” (page 7152). On page 7261, the definition of “research” specifically excludes “public health surveillance activities, including the collection and testing of information or biospecimens conducted, supported, requested, ordered, required, or authorized by a public health authority.”

We immediately contacted the staff of the Senate Steering Committee to request that the Congressional Review Act (CRA) be used to stop the rule, and thus protect the 2014 consent requirements that enable parents to protect the genetic rights of their children. However, in the flurry of those next 60 days, this procedural stop was not used.

Thus, we are now pleased to learn that the Common Rule has been put on hold.

To underscore the importance of this hold, please be advised that the genetic privacy of the four million children born each year is at stake. Under the final Common Rule, the DNA of newborn citizens could be stored, used, accessed, analyzed and distributed by states without parent consent. These children will grow into voting adults who may or may not learn their genetic privacy rights were lost at birth. As an example of some of the intrusions over the years, newborn DNA has been used for barter (TX), shared with the CDC for research (MN) and sent to the U.S. military to create a national mitochondrial DNA (mtDNA) registry (TX).

CCHF first discovered the unconsented storage, use and sharing of newborn DNA by state health departments in Minnesota in 2003. Storage began in 1997, solely as an executive decision. No law authorized it. Our efforts against “Baby DNA” warehousing have led to three successful parent lawsuits in Texas and Minnesota, changes in laws and rules, coverage by Science and Nature, and a television report disclosing 666 banker boxes of stored newborn bloodspots in Indiana (23 years of newborns), now available to researchers without consent.

But most Americans still have no idea that states are storing, using, and sharing newborn DNA and conducting genetic research on children. These children who later become adults are also unaware. This acquisition of private property happens when new parents are exhausted, exhilarated, in pain, and according to newborn screening research, in a “fog.” They think every lab test is a hospital test. They don’t know their baby’s DNA is being sent to the government.

Most Americans also do not realize that the federal government in 2013 provided $25 million to four institutions for five-year research projects to sequence the genomes of newborn children and study the legal, ethical and social ramifications of genetic detailing at birth.

The Trump administration now has an opportunity to right this wrong at the federal level.

OUR REQUEST:
We ask that the rule be revised to include all the protective parental consent and ‘human subjects’ language of the Newborn Screening Saves Lives Reauthorization Act of 2014.
ADDITIONAL RECOMMENDATIONS:
We also recommend that HHS funding for state newborn genetic screening programs be contingent on the state’s annual attestation that no newborn bloodspots have been stored or analyzed (beyond the child’s newborn screening test) or used, shared or sequenced without the consent of the child’s parents. Consent acknowledges that each individual’s genetic code and genetic traits are private and under the parent’s and, eventually, the adult child’s purview.

Additionally, we recommend HHS require that hospitals make parents aware of the right to have newborn genetic screening done privately. For example, hospitals could inform parents that they are willing to prick the child’s heel and place the newborn’s bloodspot card in private lab test kits for parents to mail to the laboratory. This way, parents can choose whether their child’s DNA ever enters, and thus becomes the property of, a state health department. Not all hospitals are willing to cooperate. We once heard from a New Jersey mother who ordered the private testing kit from PerkinElmer, but the hospital refused to use it.

IMPORTANT NOTE:
Parental consent requirements should not be dissent options. The opt-out option (dissent) puts a burden on parents to find out what happened to their child at the hospital, figure out if they can do something about it, learn where to go to get an opt-out form, fill it out, and send it in—and hope it works. Regardless, they cannot get back whatever privacy their child has already lost.

Opt-out also keeps the “genetic grab” in the dark and gives government first dibs to the newborn’s private property. Opt-out does not recognize the parent’s right of guardianship or the child’s right to keep their genetic information private and away from unwanted dissection and commoditization.

CCHF is dedicated to stopping state government storage, use and sharing of newborn DNA. We know of no other organization working on this issue. We are asking the Trump administration to assist us in protecting the genetic privacy and DNA ownership rights of all citizens – starting at birth.

Please contact me directly with questions or to receive additional information: #651-646-8935 or info@cchfreedom.org.

Thank you for your consideration of this important matter.

Sincerely,

Twila Brase, RN, PHN
President and Co-founder