Re: Opposition to SB 2199

Madam Chair Larson, esteemed committee members,

This bill is way ahead of our times. We're not there yet.

The bill's sponsors envision a state where **mind concepts like gender identity** can be distinctly spelled out somewhere along the almost 20,000 genes in the human genome. This concrete idea: we have a simple test for a complex issue – has been at the crux of many famous discrimination tragedies of humankind: the Arian nation in Nazi Germany, the "healthy Greeks" in ancient Athens and Sparta and, more recently, in numerous states' eugenics policies: Indiana 1907, etc.

Figure 1 Human Genome

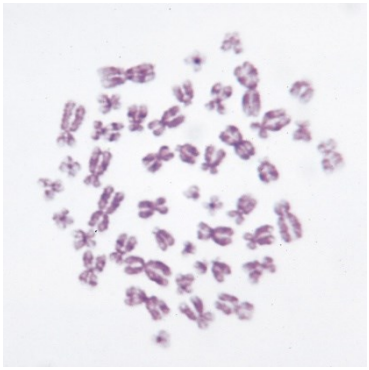

Figure 2 Human chromosomes

There is a federal law to prevent exactly this type of **discrimination based on genetics**: The Genetics Information Nondiscrimination Act of 2008 signed by President Bush[1](GINA 2008)

We've been there before: the behavior of institutions, private citizens, state, will change depending on the results of this genetic testing. The very definition of **eugenics**. And this is the basis of GINA 2008:

1. Office of the Federal Register, National Archives and Records Administration. (2009, January 2). 122 Stat. 881 - Genetic Information Nondiscrimination Act of 2008. [Government]. U.S. Government Publishing Office. https://www.govinfo.gov/app/details/STATUTE-122/STATUTE-122-Pg881
"The early science of genetics became the basis of State laws that provided for the sterilization of persons having presumed genetic "defects" such as mental retardation, mental disease, epilepsy, blindness, and hearing loss, among other conditions. The first sterilization law was enacted in the State of Indiana in 1907. By 1981, a majority of States adopted sterilization laws to "correct" apparent genetic traits or tendencies. Many of these State laws have since been repealed, and many have been modified to include essential constitutional requirements of due process and equal protection. However, the current explosion in the science of genetics, and the history of sterilization laws by the States based on early genetic science, compels Congressional action in this are Congress has collected substantial evidence that the American public and the medical community find the existing patchwork of State and Federal laws to be confusing and inadequate to protect them from discrimination. Therefore Federal legislation establishing a national and uniform basic standard is necessary to fully protect the public from discrimination and allay their

concerns about the potential for discrimination, thereby allowing individuals to take advantage of genetic testing, technologies, research, and new therapies."

And how do we get the testing done? Besides profiling and by violating federal laws like those pertaining to HIPAA – the Health Information and Portability Act – since "**genetic testing is health information**[2]" which[3], furthermore, cannot be undertaken without court order:

Once the hypothetical scenario goes through, say, the legal hoops of obtaining it, we face the fact that we have NO FDA APPROVED GENETIC TESTING[4]

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2 HIPAA privacy regulation (as defined in subsection (b)) so it is consistent with the following: "(1) Genetic information shall be treated as health information described in section 171(4)(B).

3 GENETIC TESTING.—"(1) LIMITATION ON REQUESTING OR REQUIRING GENETIC TESTING.—A group health plan, and a health insurance issuer offering health insurance coverage in connection with a group health plan, shall not request or require an individual or a family member of such individual to undergo a genetic test.

4 " Part of the FDA's mission is to protect public health by ensuring the safety, efficacy, and security of drugs, biological products, and medical devices. The agency considers genetic tests to be a special type of medical device, and therefore these diagnostic tools fall within FDA's regulatory purview. Until recent years, FDA chose to apply "enforcement discretion" to the vast majority of genetic tests. The FDA can use "enforcement discretion" when it has the authority to regulate tests but chooses not to. In the current regulatory landscape, whether FDA regulates a test is determined by how it comes to market. A test may be marketed as a commercial test "kit," a group of reagents used in the processing of genetic samples that are packaged together and sold to multiple labs. Test kit manufacturers must receive approval from FDA before selling their products on the market. More commonly, a test comes to market as a laboratory-developed test (LDT), where the test is developed and performed by a single laboratory, and where specimen samples are sent to that laboratory to be tested. To date, FDA has practiced enforcement discretion for LDTs. This means that LDTs are being used in the clinic without the FDA's assessment of their analytical and clinical validity.

FDA initially applied enforcement discretion on LDTs T because clinical genetic testing was not very widespread in the past - however, due to the rapid advances in next-generation sequencing (NGS) technology, the pervasiveness of clinical genetic testing today, the growth of direct-to-consumer (DTC) genomic testing, and FDA's mounting concern that **unregulated tests pose a public health threat**, FDA is modifying its approach. To this end, FDA has drafted new guidance to describe how it intends to regulate NGS genetic tests and verify their analytical and clinical validity. The agency has also drafted guidance proposing a new regulatory framework for LDTs. FDA "guidance" is different from laws and regulation in that it only represents the FDA's "current thinking" on a topic and is not legally binding for FDA or the parties it regulates. In practice, however, adhering to FDA guidance is beneficial because it can streamline the regulatory process. The draft guidances are listed below. Since they are in draft form, they are not currently being implemented.

Let's say we go through the hoops of genetic testing false positive and false negative consequences. Then we face the real genetic possibility of quagmires like **intersex conditions**: in this author's math, it comes to close to 200 persons in ND:

The issue of intersex

Quiz: is a **Klinefelter** syndrome condition patient person a boy or a girl? The bill's sponsors may want to pay attention to this issue, since statistically affects about 140 persons in ND: 0.2% prevalence[5]. At a 2005 international consensus conference on intersex management, intersex conditions were subsumed under a new standard medical term, "Disorders of Sex Development" (DSD), defined as "congenital conditions in which development of chromosomal, gonadal, or anatomical sex is atypical"

The prevalence of intersex conditions depends on the definition used. Obvious genital atypicality ("ambiguous genitalia") occurs with an estimated frequency ranging from approximately 1:2000— 1:4500 people (Hughes et al., 2007). The most inclusive definitions of DSD estimate a prevalence of up to 1.7% (Blackless et al., 2000).

For instance, androgen insensitivity syndrome (AIS) occurs in approximately 1 in 100,000 46,XY births (Mendoza & Motos, 2013), and classic congenital adrenal hyperplasia (CAH) in approximately 1 in 15,000 46,XX births (Therrell, 2001). Prevalence figures for individual syndromes may vary dramatically between countries and ethnic groups.

Quiz: You have an XY chromosome makeup child who looks like female – testing concludes Androgen Insensitivity Syndrome – is the child female or male[6]?

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5 The term Klinefelter syndrome (KS) describes a group of chromosomal disorder in which there is at least one extra X chromosome to a normal male karyotype, 46,XY. XXY aneuploidy is the most common disorder of sex chromosomes in humans, with prevalence of one in 500 males. Other sex chromosomal aneuploidies have also been described, although they are much less frequent, with 48,XXYY and 48,XXXY being present in 1 per 17,000 to 1 per 50,000 male births. The incidence of 49,XXXXY is 1 per 85,000 to 100,000 male births. In addition, 46,XX males also exist and it is caused by translocation of Y material including sex determining region (SRY) to the X chromosome during paternal meiosis

6 **Androgen insensitivity syndrome**

Androgen insensitivity syndrome (AIS) is when a person who is genetically male (who has one X and one Y chromosome) is resistant to male hormones (called androgens). As a result, the person has some of the physical traits of a woman, but the genetic makeup of a man.

Causes

AIS is caused by genetic defects on the X chromosome. These defects make the body unable to respond to the hormones that produce a male appearance.

The syndrome is divided into two main categories:

- Complete AIS
- Partial AIS

In complete AIS, the penis and other male body parts fail to develop. At birth, the child looks like a girl. The complete form of the syndrome occurs in as many as 1 in 20,000 live births.

In partial AIS, people have different numbers of male traits.

Partial AIS can include other disorders, such as:

- Failure of one or both testes to descend into the scrotum after birth

- Hypospadias, a condition in which the opening of the urethra is on the underside of the penis, instead of at the tip
- Reifenstein syndrome (also known as Gilbert-Dreyfus syndrome or Lubs syndrome)
  Infertile male syndrome is also considered to be part of partial AIS.
  Complete androgen insensitivity syndrome affects 2 to 5 per 100,000 people who are genetically male.
  Partial androgen insensitivity is thought to be at least as common as complete androgen insensitivity.
  Mild androgen insensitivity is much less common.
  Cca 40 persons in ND

IN a small state like ours, careless laws will affect people in communities we know. The science about transphobia and its deleterious effects on the mental health and suicide rates of transgender folk is well documented, by our own state's data[7]. We will see lives lost, communities torn, alienation felt by the very targets of our efforts: children/adolescents, who feel invalidated, see their peers invalidated, see their state profiling itself as a righteous, intolerant community where one either blends in or is cast aside with lethal consequences.

A century's worth of legal soul searching has already happened, why repeat history at the scale of our state, why harm our own children?

In sum: Our great nation has been putting efforts into solving these very issues we face today. We can subscribe to its efforts and think through the well- documented consequences or ignore our own data that aligns with the national stats and go through the documented dire circumstances – to prove what concepts exactly?!

Thank you for your time,

Gabriela Balf