

Good morning. My name is Frank Iossi, Director of State Public Affairs for Mayo Clinic Rochester. I am speaking today instead of Kathy Meyerle, one of Mayo's participants on the Genetic Information Work Group that made its report to you earlier this year. She is out of the state and unable to be here today.

Mayo is pleased to be able to comment on the report and the three bills that have been introduced that address the collection, storage and use of genetic information. Mayo Clinic supports the principles of protection of privacy and confidentiality set out in the Genetic Information report but urges the state not to take action that will have the effect of creating Minnesota as an island where health care delivery becomes more administratively burdened, medical research becomes impractical and our population suffers as a consequence.

The Work Group report has both specific and general recommendations. While Mayo generally has no objection to the recommendations in the report, the report does not go into sufficient detail to address many important considerations that surround the regulation of the creation and use of genetic information. These three bills in trying to provide more of this detail create significant problems for health care in general and health care research in particular. The sections of the bills dealing with the collection, storage and use of genetic information are much more restrictive than federal law and regulation or laws in other states in the area of protecting genetic information. In addition more protections were added in May 2008 with Congressional passage of GINA, the Genetic Information Nondiscrimination Act. Passage of the proposed sections relating to collection, storage and use would make Minnesota an outlier and significantly impact the work of Minnesota's health care providers as well as researchers.

We urge consideration of laws that protect against use that would harm an individual rather than regulating the front-end collection and storage of information or material that contains or refers to genetic information. Storage should be permitted but the use limited to those purposes authorized by law or with patient consent. The proposals in the bills all burden the health care system at the point of collection and we think this is the wrong approach and puts an unnecessary burden on the health care system.

Proposed amendments to the state Cancer Surveillance System, Three-degree pedigrees and use of Bureau of Criminal Apprehension specimens are acceptable to Mayo Clinic. These three specific recommendations are contained in HF 1821 first. Mayo does not have any objection to the recommendations regarding the state cancer surveillance system, creation of three-generation pedigrees and the handling of DNA specimens by the Bureau of Criminal Apprehension. These very discrete issues were discussed thoroughly by the Work Group and the recommendations are sufficiently narrow and focused on the use of this type of genetic information to provide a balance between the risk of harm and privacy interests of the individual and the needs of the programs.

First I'd like to give you several examples of how the bills would impact day-to-day clinic and hospital practice.

Testimony given May 1, 2009 hearing, MN House

How does it do this? The definitions of genetic information include a family history about a particular disease or disorder that is known to have a genetic component if that information might be used in providing medical care to that individual. It is standard medical practice to ask a patient for a family medical history. Questions that are asked include those about a family history of diseases, some of which have genetic origins. If a patient has a parent or other relative with a genetic form of cancer such as colon or breast cancer and provides this information to a doctor, it appears the bills would require the written informed consent of the relative in addition to the patient. We think this is not reasonable or necessary.

These bills would prohibit the creation of a medical record, unless prior to the creation of that record, a very specific written consent form was signed. We know of nowhere in this country that written informed consent is required to create a medical record. Under one of the bills, in fact, this consent would need to be renewed annually. We find this requirement to be an unnecessary measure to protect genetic information contained in an individual's medical record given the protections that already exist in state and federal law concerning use and disclosure of medical records.

The bills would require a written consent form for virtually any laboratory test. Mayo Clinic performs over 7000 laboratory tests each working day. Under these bills the drawing of blood, collection of urine or removal of any tissue for a diagnostic test would be considered the collection of genetic information since some of the proposed bills define the biological material as genetic information in and of itself. For the tests that are specifically looking for a genetic component, discussion of the need for the test and consent to perform the test are a routing part of the clinical practice. Obtaining a consent form to draw blood to perform a cholesterol or blood sugar test is simply unnecessary.

Some language would prevent routine quality improvement and equipment calibration and testing. Certification and accrediting agencies require quality improvement and calibration activities. By prohibiting the storage of biological materials without a written consent form specifying the uses of the material required and routine quality practices would be impaired or made much more difficult. The retention and use of a specimen without any identifier on it or information recorded in any way that could be linked to the individual presents no risk of harm to that individual.

Second, I'd like to explain how these bills will significantly impact the research and business operations of Mayo Clinic other than its direct patient care.

The bills put an important Mayo Clinic business at a competitive disadvantage with its national competitors, none of whom are in Minnesota and would be unaffected by the law. Mayo Medical Laboratories receives specimens in Rochester each day from all over the United States and the world. MML is a growing reference laboratory business that has created new jobs and provides tax revenue to the state of Minnesota. Each day [#] of diagnostic tests, 90% of which originate outside Minnesota, come to Rochester to

be processed and the reports sent back to the doctors ordering these tests. How many of those doctors are going to continue to collect and send specimens to Minnesota if MML has to require that a specific consent form be signed and sent along with these specimens? I would suggest to you that MML's business would virtually disappear.

The bills, in fact, fail to address one of the larger risks for release of genetic information and that is by businesses, not health care providers, selling whole genome screening over the internet for anyone who will spend the money to have the screening done. Nothing in this bill would restrict how these businesses, which are not health care providers, collect, report or use the information they obtain on specifically identifiable individuals.

Mayo Clinic's ability to compete with other academic health centers around the United States for grants from the National Institutes of Health and other private funding sources would be impaired. These bills would impose a unique set of burdens on Mayo and its presence in Minnesota that other competing researchers do not face. In some cases it means research involving large collections of specimens may not even be able to be carried out in Minnesota.

Many research projects require large collections reflecting entire communities that would be unavailable if selective consent was required. Much important research is performed on existing records and material that has been collected for some other purpose. The federal research regulations recognize that when information is collected in this way and the data is recorded such that there is no way to relate the information back to the source, no harm is presented to the individual and no additional consent is required. Questions that involve looking for patterns or diseases that affect a very small percent of the population, but can have significant impact on an affected individual would not be able to be answered if large portions of a population could not be contacted or declined to respond to a request for consent to use their information.

I can give you one very specific example that is eerily reflective of what is on the front pages of all our papers this week – the need to determine the cause of side effects from a flu vaccine. In the 1970s when the last influenza epidemic took place and there were mass immunizations across the country, many people became ill with a disease called Guillian-Barre Syndrome. It was the epidemiologists at the Mayo Clinic, looking at the medical records of the residents of Olmsted County, what we call the Rochester Epidemiology Project, who were able to determine the relationship between the flu vaccine and the disease. Without the ability to look at the medical records and biological specimens of a large population, it would not have been possible for this connection to be made. Genetic research has significant implications for protecting the public health.

I could provide more examples but these illustrate my point that these bills would have immediate and significant on Minnesota's largest private employer.

Mayo Clinic suggests that existing law concerning release of medical records is adequate to protect the interests of the individual. The privacy interest that an individual has in his or her medical record is the same interest that is to be honored in the collection, testing

and use of biological specimens from which genetic information might be obtained. These bills would simply create incredible burdens without providing significant increased protection beyond what is already in federal and state law.

Thank you for giving me the opportunity to present our concerns.