ILLINOIS STATE MEDICAL SOCIETY

Resolution 01.2019-11
(A-19)

Introduced by: David J. Palmer, M.D. and A. Jay Chauhan, D.O., ISMS Members

Subject: Direct-to-Consumer Genetic Tests

Referred to: Medical Legal Council

Whereas, direct-to-consumer genetic testing, such as 23andMe and AncestryDNA.com, is publicly promoted and commercially available to bring personal insight into ancestry, genealogy, and inherited traits by means of a genetic blueprint (Personal Genome Service or PGS); and

Whereas, the genetic testing may or may not reveal variants associated with a higher risk of certain diseases such as Alzheimer's, Parkinson's, or Macular Degeneration, which may not have clinical merit, but could result in emotional distress upon discovery; and

Whereas, the PGS is deemed a medical device by the FDA (1), but is also a mechanism for massive information-gathering whereby personal, self-disclosed, information, including a person's genome, can be used by the company or third parties for selling the consumer products and services; and

Whereas, PGS companies have different policies regarding managing and disseminating information for research purposes, including academic institutions, non-profit foundations, and pharmaceutical companies for journal publications, and some have indicated that their database-sifting scientific work does not constitute research on human subjects (1); and

Whereas, some genetic testing companies have direct financial relationships with pharmaceutical (GlaxoSmithKline, Pfizer) and biotechnology (Genentech) companies and universities (University of Chicago) to name a few (2); and

Whereas, privacy breaches have occurred by hackers with a genetic testing company, MyHeritage, affecting 92,000,000 individuals (3), with the potential for other abuse by governments, companies, criminals with either company-direct or indirect access (hackers, sold by unauthorized persons, released by disgruntled employees); and

Whereas, data breaches are a potential risk for re-identification in up to 12-18% of the consumers using information on recreational genetic genealogy databases followed by internet sources using metadata such as their date of birth and state of residence (4); and

Whereas, the Health Information Portability and Accountability Act (HIPAA) allows the transfer of date of birth and state of residence without penalty; and

Whereas, the Genetic Information Non-Discrimination Act (GINA, 2008) (5) prevents discrimination by health insurance companies and employers, but not life, disability, or long-term care insurance companies, based on acquired genetic information, possibly causing some insurance company application rejections; and

Whereas, 17 states have additional laws restricting the use of genetic information in determining life and disability insurance coverage, and eight states for long-term care insurance, excluding Illinois; and

Whereas, genetic information and research continues to evolve resulting in technology advancements whereby past user information may be used negatively against those individuals; therefore, be it

RESOLVED, that ISMS endorse the American Medical Association (AMA) (6), Federal Trade Commission (FTC), Federal Drug Administration (FDA), and Centers for Disease Control (CDC) recommendations (7, 8) establishing clear policies for data-sharing, educating participants about the risks and benefits of genetic studies by each genetic testing company. These include choosing what genetic information may be shared and what genetic health reports are desired to prevent emotional stresses based on the results, permission to delete the account and collected data anytime, giving permission to third parties to collect web-based information regarding PGS company-generated services for marketing and social media, and understanding that data breaches can re-identify the user whose information can be used against their interests; and be it further

RESOLVED, that ISMS and the AMA regard research using consumer genome data derived from saliva or cheek swab samples as research on human subjects requiring consents in compliance with the Health and Human Services (HHS) Office for Human Research Protection (OHRP) (9). An “opt in” option is recommended to allow more consumer choice in the consent process; and be it further

RESOLVED, that ISMS provide amendments for review to the AMA Patient Privacy and Confidentiality Statement, H-315.983, to align with current research and privacy infringement findings (see attached) since the ISMS BOT review in 2012. The proposed amendments are in the following sections:

1. e. …where care is received, ***while working with the Department of Health and Human Services (HHS) to stop the transfer of birthdates and state of residence by genetic testing companies and their affiliates, unless there is explicit user approval, to prevent re-identification of the test user by way of surname inference methods.***

7. …informed consent of the tested individual. ***Our AMA regards studies using consumer genome data derived from saliva, cheek swab, or other human tissue samples as research on human subjects requiring consents in compliance with the HHS Office for Human Research Protections (OHRP). An "opt in" option is recommended to allow more consumer choice in the consent process.***

17. …against discrimination on the basis of genetic testing. ***The AMA will work with Congress and HHS to modify the Genetic Information Nondiscrimination Act of 2008 (GINA), which bans genome-based policy and hiring decisions by health insurance companies and employers, by adding Long-Term Care, Life Insurance, and Disability Insurance to the Act to prevent applicant rejection based on their genetic makeup.***

18. a. (added section):
Our AMA supports privacy standards that would prohibit pharmaceutical companies, biotechnology companies, universities, and all other entities with financial ties to the genetic testing company from sharing identified information with other parties without the consent of the user. If a data security breach occurs with the Direct-To –Consumer genetic company or its collaborators, then the company has the responsibility to inform all users of the breach and the impact of the unprotected private data on those individuals; and be it further

RESOLVED, that the ISMS request the AMA to work with HIPAA to modify the rules to prevent genetic testing entities from transferring the date of birth and state of residence to third parties which may result in the re-identification of the user based on surname inference (4); and be it further

RESOLVED, that ISMS lobby the Illinois state legislature and the AMA work with Congress and HHS to extend the consumer protections of the Genetic Information Non-Discrimination Act (GINA) of 2008 by adding long-term care, disability insurance, and life insurance to the Act modeled after other states' laws, such as California (10).

Bibliography

1. Seife, Charles, "23andMe is Terrifying, but Not for the Reasons the FDA Thinks", Scientific American, 11/27/2013, https://www.scientificamerican.com/article/23andme.
2. Schencker, Lisa, "Planning to give 23andMe of AncestryDNA kits this Christmas? Read this first," Chicago Tribune, December 14, 2018.
3. Brown, Kristen V, Bloomberg Technology, 6/5/18.
4. Gymrek, M, McGuire, AL, Golan, D, Halperin, E, and Yaniv, E, "Identifying Personal Genomes by Surname Inference," Science, (339) Jan 18, 2013, 321-324.
5. NIH, National Human Genome Research Institute, "The Genetic Information Non-Discrimination Act of 2008, https://www.genome.gov/27568492/the-genetic-information-nondiscrimination-act-of-2008, accessed 12/29/18.
6. AMA Genetic Research Policy statement
7. Federal Trade Commission (FTC) Consumer Information, "Direct-to-Consumer Genetic Tests," https://www.consumer.ftc.gov/articles/0166-direct-to-consumer-genetic-tests, accessed 12/29/18.
8. Fair, Lesley, FTC Consumer Information, "DNA test kits: Consider the privacy implications", https://www.consumer.ftc.gov/blog/2017/12/dna-test-kits-consider-privacy-implications, December 12, 2017.
9. NIH, National Human Genome Research Institute, "Informed Consent for Genomics Research," https://www.genome.gov/27026588/informed-consent-for-genomics-research, accessed 12/29/18.
10. California Legislative Information, Insurance Code, Division 2: Classes of Insurance, Part 2: Life and Disability Insurance codes 10140-10143. http://leginfo.legislature.ca.gov/faces/codes, accessed 1/3/19.

ADDENDUM

AMA genetic privacy protection policy with recommended modifications for the ISMS to discuss and AMA to consider. Changes to the original document are in red, italicized, and bold.

ISMS
Genetic Testing
ISMS supports consistent oversight of genetic testing, including a requirement of proficiency testing, to ensure that this field is used in the best interest of patient care. (HOD 2010; Last BOT Review 2012)

AMA
Direct-to-Consumer Marketing and Availability of Genetic Testing D-480.987
Our AMA:

(1) recommends that **genetic testing** be carried out under the personal supervision of a qualified health care professional;

(2) encourages individuals interested in obtaining **genetic testing** to contact a qualified healthcare professional for further information;

(3) will work with relevant organizations to develop criteria on what constitutes an acceptable advertisement for a direct-to-consumer **genetic** test;

(4) encourages the U.S. Federal Trade Commission, with input from the U.S. Food and Drug Administration and the Centers for Medicare and Medicaid Services, to require that direct-to-consumer advertisements for **genetic testing** are truthful and not misleading; such advertisements should include all relevant information regarding capabilities and limitations of the tests, and contain a statement referring patients to physicians to obtain further information;

(5) will work to educate and inform physicians regarding the types of **genetic** tests that are available directly to consumers, including information about the lack of scientific validity associated with some direct-to-consumer **genetic** tests, so that patients can be appropriately counseled on the potential harms.

Our AMA: (1) acknowledges the increasingly important role of genomic-based personalized medicine applications in the delivery of care, and will continue to assist in informing physicians about relevant personalized medicine issues; (2) will continue to develop educational resources and point-of-care tools to assist in the clinical implementation of genomic-based personalized medicine applications, and will

continue to explore external collaborations and additional funding sources for such projects; and (3) will continue to represent physicians' voices and interests in national policy discussions of issues pertaining to the clinical implementation of genomic-based personalized medicine, such as **genetic** test regulation, clinical validity and utility evidence development, insurance coverage of **genetic** services, direct-to-consumer **genetic testing**, and privacy of **genetic** information.

4.1.3 Third-Party Access to Genetic Information
The rapid pace of development and dissemination of **genetic testing** has made it possible to generate information about individuals across a wide and growing spectrum of **genetic** variations associated with disease risk. The prospect of access to and use of such information by third parties who have a stake in an individual's health raises ethical concerns about confidentiality and potentially inappropriate use of **genetic** information.

Patients who undergo **genetic testing** have a right to have their information kept in confidence, and a variety of state and federal laws prohibit discrimination by employers, insurers, and other third parties based on **genetic** information they obtain about an individual.

Physicians who provide and interpret **genetic** tests, or who maintain patient records that include the findings of **genetic** tests, have professional ethical obligations to:
(a) Maintain the confidentiality of the patient's health information, including **genetic** information.
(b) Release a patient's **genetic** information to third parties only with the patient's informed consent.
(c) Decline to participate in **genetic testing** at the request of third parties (for example, for purposes of establishing health care or other benefits or coverage for the individual) except when at the patient's request and with their informed consent.

Patient Privacy and Confidentiality H-315.983
1. Our AMA affirms the following key principles that should be consistently implemented to evaluate any proposal regarding patient privacy and the confidentiality of medical information: (a) That there exists a basic right of patients to privacy of their medical information and records, and that this right should be explicitly acknowledged; (b) That patients' privacy should be honored unless waived by the patient in a meaningful way or in rare instances when strong countervailing interests in public health or safety justify invasions of patient privacy or breaches of confidentiality, and then only when such invasions or breaches are subject to stringent safeguards enforced by appropriate standards of accountability; (c) That patients' privacy should be honored in the context of gathering and disclosing information for clinical research and quality improvement activities, and that any necessary departures from the preferred practices of obtaining patients' informed consent and of de-identifying all data be strictly

controlled; (d) That any information disclosed should be limited to that information, portion of the medical record, or abstract necessary to fulfill the immediate and specific purpose of disclosure; and

(e) That the Health Insurance Portability and Accountability Act of 1996 (HIPAA) be the minimal standard for protecting clinician-patient privilege, regardless of where care is received***, while working with Department of Health and Human Services (HHS) to stop the HIPAA transfer of birthdates and state of residence by genetic testing companies and their affiliates, unless there is explicit user approval, to prevent re-identification of the test user by way of surname inference methods.***

2. Our AMA affirms: (a) that physicians and medical students who are patients are entitled to the same right to privacy and confidentiality of personal medical information and medical records as other patients, (b) that when patients exercise their right to keep their personal medical histories confidential, such action should not be regarded as fraudulent or inappropriate concealment, and (c) that physicians and medical students should not be required to report any aspects of their patients' medical history to governmental agencies or other entities, beyond that which would be required by law.

3. Employers and insurers should be barred from unconsented access to identifiable medical information lest knowledge of sensitive facts form the basis of adverse decisions against individuals. (a) Release forms that authorize access should be explicit about to whom access is being granted and for what purpose, and should be as narrowly tailored as possible. (b) Patients, physicians, and medical students should be educated about the consequences of signing overly-broad consent forms. (c) Employers and insurers should adopt explicit and public policies to assure the security and confidentiality of patients' medical information. (d) A patient's ability to join or a physician's participation in an insurance plan should not be contingent on signing a broad and indefinite consent for release and disclosure.

4. Whenever possible, medical records should be de-identified for purposes of use in connection with utilization review, panel credentialing, quality assurance, and peer review.

5. The fundamental values and duties that guide the safekeeping of medical information should remain constant in this era of computerization. Whether they are in computerized or paper form, it is critical that medical information be accurate, secure, and free from unauthorized access and improper use.

6. Our AMA recommends that the confidentiality of data collected by race and ethnicity as part of the medical record, be maintained.

7. **Genetic** information should be kept confidential and should not be disclosed to third parties without the explicit informed consent of the tested individual***. Our AMA regards studies using consumer genome data derived from saliva, cheek swab, or other human tissue samples as research on human subjects requiring consents in compliance with the HHS Office for Human Research Protections (OHRP). An "opt in" option is recommended to allow more consumer choice in the consent process.***

8. When breaches of confidentiality are compelled by concerns for public health and safety, those breaches must be as narrow in scope and content as possible, must contain the least identifiable and sensitive information possible, and must be disclosed to the fewest possible to achieve the necessary end.

9. Law enforcement agencies requesting private medical information should be given access to such information only through a court order. This court order for disclosure should be granted only if the law enforcement entity has shown, by clear and convincing evidence, that the information sought is necessary to a legitimate law enforcement inquiry; that the needs of the law enforcement authority cannot be satisfied by non-identifiable health information or by any other information; and that the law enforcement need for the information outweighs the privacy interest of the individual to whom the information pertains. These records should be subject to stringent security measures.

10. Our AMA must guard against the imposition of unduly restrictive barriers to patient records that would impede or prevent access to data needed for medical or public health research or quality improvement and accreditation activities. Whenever possible, de-identified data should be used for these purposes. In those contexts where personal identification is essential for the collation of data, review of identifiable data should not take place without an institutional review board (IRB) approved justification for the retention of identifiers and the consent of the patient. In those cases where obtaining patient consent for disclosure is impracticable, our AMA endorses the oversight and accountability provided by an IRB.

11. Marketing and commercial uses of identifiable patients' medical information may violate principles of informed consent and patient confidentiality. Patients divulge information to their physicians only for purposes of diagnosis and treatment. If other uses are to be made of the information, patients must first give their uncoerced permission after being fully informed about the purpose of such disclosures.

12. Our AMA, in collaboration with other professional organizations, patient advocacy groups and the public health community, should continue its advocacy for privacy and confidentiality regulations, including: (a) The establishment of rules allocating liability for disclosure of identifiable patient medical information between physicians and the

health plans of which they are a part, and securing appropriate physicians' control over the disposition of information from their patients' medical records. (b) The establishment of rules to prevent disclosure of identifiable patient medical information for commercial and marketing purposes; and (c) The establishment of penalties for negligent or deliberate breach of confidentiality or violation of patient privacy rights.

13. Our AMA will pursue an aggressive agenda to educate patients, the public, physicians and policymakers at all levels of government about concerns and complexities of patient privacy and confidentiality in the variety of contexts mentioned.

14. Disclosure of personally identifiable patient information to public health physicians and departments is appropriate for the purpose of addressing public health emergencies or to comply with laws regarding public health reporting for the purpose of disease surveillance.

15. In the event of the sale or discontinuation of a medical practice, patients should be notified whenever possible and asked for authorization to transfer the medical record to a new physician or care provider. Only de-identified and/or aggregate data should be used for "business decisions," including sales, mergers, and similar business transactions when ownership or control of medical records changes hands.

16. The most appropriate jurisdiction for considering physician breaches of patient confidentiality is the relevant state medical practice act. Knowing and intentional breaches of patient confidentiality, particularly under false pretenses, for malicious harm, or for monetary gain, represents a violation of the professional practice of medicine.

17. Our AMA Board of Trustees will actively monitor and support legislation at the federal level that will afford patients protection against discrimination on the basis of **genetic testing.** ***The AMA will work with Congress and HHS to modify the Genetic Information Nondiscrimination Act of 2008 (GINA), which bans genome-based policy and hiring decisions by health insurance companies and employers, by adding Long-Term Care, Life Insurance, and Disability Insurance to the Act to prevent applicant rejection based on their genetic makeup.***

18. Our AMA supports privacy standards that would require pharmacies to obtain a prior written and signed consent from patients to use their personal data for marketing purposes.

18a. Our AMA supports privacy standards that would prohibit pharmaceutical companies, biotechnology companies, universities, and all other entities with financial ties to the genetic testing company from sharing identified information with

other parties without the consent of the user. If a data security breach occurs with the Direct-To –Consumer genetic company or its collaborators, then the company has the responsibility to inform all users of the breach and the impact of the unprotected private data on those individuals.

19. Our AMA supports privacy standards that require pharmacies and drug store chains to disclose the source of financial support for drug mailings or phone calls.

20. Our AMA supports privacy standards that would prohibit pharmacies from using prescription refill reminders or disease management programs as an opportunity for marketing purposes.

21. Our AMA will draft model state legislation requiring consent of all parties to the recording of a physician-patient conversation.

Fiscal Note:

N/A

Existing ISMS policy related to this issue:

ISMS supports consistent oversight of genetic testing, including a requirement of proficiency testing, to ensure that this field is used in the best interest of patient care. (HOD 2010; Last BOT Review 2012)

Declaration of Professional Responsibility, Medicine's Social Contract with Humanity Preamble Never in the history of human civilization has the well being of each individual been so inextricably linked to that of every other. Plagues and pandemics respect no national borders in a world of global commerce and travel. Wars and acts of terrorism enlist innocents as combatants and mark civilians as targets. Advances in medical science and genetics, while promising great good, may also be harnessed as agents of evil. The unprecedented scope and immediacy of these universal challenges demand concerted action and response by all. As physicians, we are bound in our response by a common heritage of caring for the sick and the suffering. Through the centuries, individual physicians have fulfilled this obligation by applying their skills and knowledge competently, selflessly and at times heroically. Today, our profession must reaffirm its historical commitment to combat natural and man-made assaults on the health and well being of humankind. Only by acting together across geographic and ideological divides can we overcome such powerful threats. Humanity is our patient. Declaration We, the members of the world community of physicians, solemnly commit ourselves to: I. Respect human life and the dignity of every individual. II. Refrain from supporting or committing crimes against humanity and condemn all such acts. III. Treat

the sick and injured with competence and compassion and without prejudice. IV. Apply our knowledge and skills when needed, though doing so may put as at risk. V. Protect the privacy and confidentiality of those for whom we care and breach that confidence only when keeping it would seriously threaten their health and safety or that of others. VI. Work freely with colleagues to discover, develop, and promote advances in medicine and public health that ameliorate suffering and contribute to human well-being. VII. Educate the public and polity about present and future threats to the health of humanity. VIII. Advocate for social, economic, educational, and political changes that ameliorate suffering and contribute to human well-being. IX. Teach and mentor those who follow us for they are the future of our caring profession. We make these promises solemnly, freely, and upon our personal and professional honor. Adopted by the House of Delegates of the American Medical Association in San Francisco, California on December 4, 2001 (HOD 2003; Last BOT Review 2012)