



ASSOCIATION FOR MOLECULAR PATHOLOGY

Providing global expertise in molecular testing that drives patient care
6120 Executive Boulevard, Suite 700, Rockville, Maryland, 20852
Tel: 301-634-7987 | Fax: 301-634-7995 | amp@amp.org | www.amp.org

November 21, 2022
Federal Trade Commission
Office of the Secretary
600 Pennsylvania Avenue NW
Suite CC-5610 (Annex B)
Washington, DC 20580
Re: Commercial Surveillance ANPR, R111004
Comments submitted electronically via <https://www.regulations.gov>

Dear Chair Khan:

On behalf of the Association for Molecular Pathology (AMP), thank you for the opportunity to comment on the Federal Trade Commission (FTC) published Advance Notice of Proposed Rulemaking (“ANPR”) on Commercial Surveillance and Data Security. AMP is an international medical and professional association representing approximately 2,600 physicians, doctoral scientists, and medical laboratory scientists (technologists) who perform or are involved with laboratory testing based on knowledge derived from molecular biology, genetics and genomics. Membership includes professionals from the government, academic medicine, private and hospital-based clinical laboratories, and the in vitro diagnostics industry. As professionals that operate within most CLIA certified clinical molecular pathology laboratories in the United States, we are concerned that there may be unintended consequences of the ANPR that may interfere with routine laboratory practices.

AMP has invested time and resources into developing position statements on the appropriate sharing of data, and we encourage the FTC to consider AMP’s and other professional societies’ policy recommendations on how best to incentivize data sharing to advance medical research and clinical care, while protecting patients’ privacy and sensitive health information. You may access AMP’s data sharing policy here, and below are our responses to specific questions asked in the ANPR.

89. To what extent should trade regulation rules, if at all, require companies to explain (1) the data they use, (2) how they collect, retain, disclose, or transfer that data, (3) how they choose to implement any given automated decision-making system or process to analyze or process the data, including the consideration of alternative methods?

AMP requests that you take into consideration that the sharing of data, samples, and other health information is critical for advancing healthcare and medical research. Health and genetic data may be obtained through entities required to comply with the Health Insurance Portability and Accountability Act (HIPAA) or through entities that do not fall under this privacy law. In the molecular field, the latter often occurs in direct-to-consumer genetic testing companies offering tests for ancestry and wellness. In 2019, AMP updated its position statement on consumer genomic testing,¹ and recommended that consumer genomic testing companies adhere to The Future of Privacy Forum’s “Privacy Best Practices for Consumer Genetic Testing

¹ https://www.amp.org/AMP/assets/File/position-statements/2019/AMP_Position_Statement_Consumer_Genomics_FINAL.pdf?pass=20

Services.¹⁷ We encourage the FTC to consider these established best practices as it considers policies under this rulemaking.

The Genetic Information Nondiscrimination Act (GINA) prevents employers and health insurers from discrimination based on genetic risk. The law included consensus driven definitions of genetic test and genetic information, and AMP encourages the FTC to reference these widely supported definitions when setting policy regarding genetic information.

HIPAA allows for secondary use and sharing of data that has been de-identified by standards in the law. AMP agrees with the standards in HIPAA, and we believe that it appropriately enables data sharing for research and clinical purposes while protecting this sensitive information. Laboratories may share residual clinical samples with other laboratories for quality control purposes. Additionally, supported by AMP's position statement on data sharing, laboratories enter de-identified data on variants within the genome and corresponding phenotypes into databases housed and curated by the National Institutes of Health. One such example is ClinVar, a public archive about variants with supporting evidence, currently, ClinVar contains approximately one and a half million unique variants². This provides a valuable tool for other molecular professionals to understand and interpret a new variant and provide an accurate assessment of the implications of that result for the patient's care. In these instances, all identifiers have been removed from the samples to protect the patient's confidentiality. These practices, which are allowed under HIPAA and supported by evidenced based practice guidelines and federal funding, are instrumental to molecular pathology and are necessary to ensure high quality, safe testing for patients. For these reasons, we strongly recommend that the FTC ensure that data de-identified by standards in HIPAA are allowed to be shared and not subject to additional restrictions under this or future rulemaking.

10. Which kinds of data should be subject to a potential trade regulation rule? Should it be limited to, for example, personally identifiable data, sensitive data, data about protected categories and their proxies, data that is linkable to a device, or non-aggregated data?

AMP would like to note that the existence of privacy laws, such as HIPAA, allow for the sharing of de-identified protected health information (PHI), including allowing public and private organizations to share de-identified genetic variant data in easily accessible databases.³ Sharing of de-identified variant data is essential both for understanding the contribution of genetic and genomic variation to disease and conditions, and for translating that information through the development, validation, and interpretation of clinical testing. AMP is concerned that despite the current availability of public databases, that participation in data sharing among clinical laboratories remains low. **It is crucial that any FTC rulemaking does not add excessive barriers that will further discourage laboratories from sharing needed de-identified data for the advancement of science.** AMP encourages its members to pursue variant data sharing practices at their institutions in compliance with currently established law that offer the greatest protection for this sensitive health information.

2. Which measures do companies use to protect consumer data?

In the practice of molecular pathology, the sheer amount and sensitivity of data produced by genomic tests calls for advances in data storage infrastructure, security, and standardization. Across organizations, there are different data storage practices. This includes increased use of cloud-based storage systems, which have significant advantages for storing genetic data due to their low per-GB prices and minimal fixed costs. These systems may be a good choice for many laboratories to store data⁴ however, ensuring compliance with

² <https://www.ncbi.nlm.nih.gov/clinvar/submitters/> Date Accessed November 15, 2022

³ https://www.amp.org/AMP/assets/File/advocacy/AMP_Position_Variant_Data_Sharing_7_29_2021.pdf?pass=24

⁴ <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7276491/>

HIPAA and related regulations is complex⁵. **When developing guidance on measures for protection of consumer data, AMP suggests that the FTC take into account this type of storage process and any steps performed by institutions to ensure compliance within any possible rulemaking.**

Thank you for your efforts to ensure that consumers are not harmed by commercial surveillance and data security practices. AMP believes that any FTC rulemaking on Commercial Surveillance and Data Security should consider existing policies such as HIPAA and GINA and align any future rulemaking to existing privacy policies, including the use of de-identified protected health information, to avoid any confusion and unintended consequences for research and clinical care. AMP hopes that the FTC will take all forementioned information into account for any concurrent rulemaking. Should you have any questions or wish to discuss these issues further, please do not hesitate to contact Sarah Thibault-Sennett, Director, Public Policy & Advocacy at sthibaultsennett@amp.org.

Sincerely,
Laura J. Tafe, MD
President, Association for Molecular Pathology

⁵ <https://www.nature.com/articles/gim201392>