AMA
AMERICAN MEDICAL ASSOCIATION

JAMES L. MADARA, MD
EXECUTIVE VICE PRESIDENT, CEO

ama-assn.org
t (312) 464-5000

December 17, 2019

David J. Karp
Senior Counsel
Office of Legal Policy
U.S. Department of Justice
950 Pennsylvania Avenue, NW
Room 4234
Washington, DC 20530

Re: DNA-Sample Collection from Immigration Detainees, Docket Number OAG-164

Dear Mr. Karp:

On behalf of the physician and medical student members of the American Medical Association (AMA), I welcome the opportunity to provide comment on the Department of Justice's (DOJ) proposed rule concerning DNA-Sample Collection from Immigration Detainees. During the AMA's recent Interim Meeting of our House of Delegates, which includes representatives of state and specialty medical societies, a resolution was adopted in opposition to the collection and storage of DNA from refugees, asylum seekers, and undocumented immigrants for nonviolent immigration-related crimes without informed consent that is not coerced. The AMA therefore urges the DOJ not to expand the use of DNA-sample collection as it undermines fundamental and long-standing accepted ethical conventions related to privacy and consent, as well as due process requirements when the federal government collects health information absent a compelling public health or public safety need.

We are also concerned that the proposed rule was issued with less than 30 days for comment and without any basis provided for the truncated deadline, in violation of the standard procedural requirements of the Administrative Procedures Act. Furthermore, the AMA is concerned with the accuracy and reliability of the DNA-sampling methods and conditions under which testing would occur. This latter issue has implications for a broader scope of individuals who are biologically related to individuals who are subject to government mandated DNA testing.

Overview and Procedural History

On October 22, 2019, the DOJ proposed to amend regulations that require DNA sample collection from individuals who are arrested, facing charges, or convicted, and from non-U.S. citizen persons who are detained under the authority of the U.S. The proposed amendment would strike a provision of 28 CFR §28.12(b)(4) authorizing the Secretary of the Department of Homeland Security (DHS) to exempt from the sample-collection requirement certain immigrants from whom collection of DNA samples is not feasible because of operational exigencies or resource limitations. Thus, the proposal would make the collection of DNA samples mandatory for all non-U.S. citizen persons who are detained under the authority of the U.S., except for the following: 1) immigrants lawfully in, or being processed for lawful admission to, the U.S. (i.e., lawful visitors from other countries); 2) immigrants held at a port of entry

during consideration of admissibility and not subject to further detention or proceedings (e.g., immigrants briefly held up at airports during routine processing or taken aside for secondary inspection); and 3) immigrants held in connection with maritime interdiction, because collecting DNA samples in maritime interdiction situations may be unnecessary and practically difficult or impossible.

The population impacted by the proposal includes immigrants without any criminal history, including minor children, who present themselves at a U.S. port of entry to legally apply for protection from persecution in their home country and are subject to detention (e.g., those individuals presenting with credible fear claims). According to the DOJ, assuming the population subject to DNA collection under the rule remains at this level, DHS would be expected to submit an additional 748,000 samples annually. Thus, the population to whom this proposed rule would apply is expansive.

Under the proposed rule, regardless of whether individuals are deemed criminal arrestees or immigration detainees, the use of collected DNA samples is the same by the federal government. The profiles are searched against the Federal Bureau of Investigation's Combined DNA Index System (CODIS), which includes DNA profiles derived from biological residues left at crime scenes (e.g., the DNA of a murderer found on an item he/she left or touched in committing the crime). Reportedly, the Attorney General will review DHS's capacity to implement DNA-sample collection from non-U.S. person detainees as required by the regulation. The DOJ will then work with DHS to develop and implement a plan for DHS to phase in that collection potentially over the next three years.

Compliance with the Administrative Procedure Act (APA)

The 20-day notice period provided for the proposed rule runs afoul of legal requirements governing federal agency rule-making. The APA requires agencies to give at least 30 days for public comment on major new policies, 5 U.S.C. § 553(c)–(d), a requirement designed to "foster the fairness and deliberation that should underlie a pronouncement of such force." *United States v. Mead Corp.*, 533 U.S. 218, 230 (2001). Here, the DOJ unilaterally imposed a shorter notice period without providing the legally required justification.

Given the large volume of proposed rules and sub-regulatory guidance issued by the federal government, providing adequate public notice and opportunity to comment is essential to ensure that all impacted stakeholders with substantive expertise and impacted interests have the ability to respond. The number of important health related proposed rules and draft guidance issued in any given month, 12 months of every year is significant. As an organization committed to advancing the health and wellness of the nation, the AMA, while having a finite number of resources, must carefully consider when to provide comment consistent with AMA policy after reviewing and considering what are often lengthy proposed rules and guidance documents. In addition, the AMA must carefully consider the expert opinion of a number of internal and, frequently, external experts to provide evidence-based and constructive recommendations and comment. When a federal agency arbitrarily limits the number of days allowed for comment without a pressing public health, public safety, or other emergency or need as specified in the APA and regulation, the federal agency is deprived of input that would better inform public policy and the functioning of the federal government programs and impacted individuals and organizations are denied due process.

In the case of this proposed rule, which presents a significant precedent that could impact the privacy of health information for a far larger category of individuals beyond individuals here legally under color of law and those who are not, *including U.S. citizens*, the input of stakeholders like the AMA with expertise

has been limited without any basis as a result of the reduced comment period. Thus, the proposed rule is procedurally defective and, at a minimum, must be reissued to remedy the lack of legal enforceability. However, given the issues that the AMA outlines below, we strongly urge DOJ not to reissue the proposed rule, but instead consider alternative less intrusive, more cost-effective, and accurate methods of identification that do not involve the collection of health information of an individual as well as the individual's biological relatives.

DNA: Health Information of Individual and Biologically Related Individuals

DNA is the genetic information that a person carries throughout life. An individual's genetic code influences the expression of nearly all health traits, such as susceptibility to heart disease and diabetes, as well as response to medications. As a result, access to genetic data can unlock a wealth of health information that is clinically actionable, impacting all medical specialties and all facets of patient health. For an individual, DNA is also inherently personally identifying. In fact, it is increasingly recognized that genetic data cannot be de-identified. Today, the identities for many if not most Americans can be revealed from a DNA profile, even if that individual has not already undergone genetic testing. Based on the significant fraction of DNA shared with biological relatives, one or more of whom may already populate DNA databases, individual identity can be inferred from genetic data. Furthermore, forensic DNA profiles may be linked to other genetic data, revealing health and other sensitive information about a person without their prior knowledge.

Privacy, Notice, Consent and Health Information

Privacy, Notice, Consent

Any entity seeking access to an individual's health information must pass the stringent test of showing why its professed need should override the individual's most basic right in keeping his or her own information private. Moreover, individuals deserve a full and open discussion of exactly who wants their health information and for what purpose. Only then may the true balancing of interests take place. This is the basis of AMA policy and we believe should be the basis for government collection of one of humankind's most sensitive sources of information: DNA.

The AMA's approach to privacy is governed by our Code of Medical Ethics and long-standing policies adopted by our policymaking body, the House of Delegates, which support strong privacy protections. AMA policy and ethical opinions on privacy and confidentiality provide that an individual's privacy should be honored unless waived by the individual in a meaningful way, de-identified, or in rare instances when strong countervailing interests in public health or safety justify invasions of privacy or breaches of confidentiality. 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 entities and individuals as possible to achieve the necessary end.

Risk of Expansion of Intended Uses for Unauthorized Purposes

Health care information, including genomic information, is one of the most personal types of information an individual can possess and generate. While the DOJ states its intent to use the collected DNA samples to screen for matches in the FBI's CODIS, it fails to consider the potential downstream consequences of

the mass collection of genetic information, particularly for individuals who may have committed no previous crime. Such consequences may include re-identification of individuals through de-identified (or partially de-identified) data, embarrassment or stigma resulting from an unwanted disclosure of information or from fear of a potential unwanted disclosure, perceived and real risks of discrimination including future employment and loss of access to or increased costs of insurance, and law enforcement accessing data repositories beyond their intended scope.

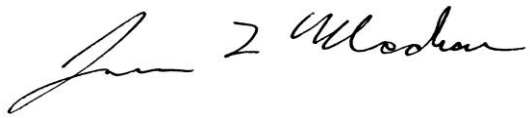
Methods and Conditions of DNA-Sampling Impact Accuracy and Suitability for Intended Use

The AMA has had significant involvement in policy and clinical discussions concerning the quality and accuracy of genetic testing over the past decade. The AMA has focused not only on genetic testing in the context of clinical care, but also direct-to-consumer genetic testing. The DOJ should be aware that the Centers for Medicare & Medicaid Services (CMS) and commercial payers have called into the question the quality and accuracy of genetic testing even when performed consistent with the Clinical Laboratory Improvement Act (CLIA), as amended, and by *trained* health care professionals. While the AMA strongly supports the quality of such testing where health care professionals are extensively trained and have established protocols for the collection of specimens, performing tests, and returning results (including identifying the limitations of the testing), we have strong concerns where DNA collection, testing, and return of results are not undertaken by trained health care professionals under CLIA-like rigorous protocols. Why? Because errors (including contamination, incorrect procedures, and misinterpretation) undermine the quality and accuracy of the DNA testing and can have negative consequences on health as well as an individual's ability to obtain life insurance and long-term care.

Furthermore, in the case of this proposed rule, it can adversely impact one's status in the U.S. and has implications for one's putative biological relatives. There is unanimity among all major health care stakeholders that it is essential that trained and qualified personnel should be involved in genetic testing where established policy, procedures, and regular proficiency testing occurs. Reportedly, the current personnel, policies, and procedures that would be used for this proposed DNA testing fall well short of these minimum requirements. This is particularly problematic if the uses of this data go beyond intended uses or are subject to security breaches as outlined above.

We appreciate the opportunity to comment, urge the DOJ to rescind the current proposed rule, and welcome the opportunity to share our views further. If you have any questions, please contact Margaret Garikes, Vice President for Federal Affairs, at margaret.garikes@ama-assn.org, or by calling 202-789-7409.

Sincerely,



James L. Madara, MD