ASSOCIATION FOR MOLECULAR PATHOLOGY

Providing global expertise in molecular testing that drives patient care

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Dockets Management
Food and Drug Administration
5630 Fishers Lane, Rm 1061
Rockville, MD 20852

Submitted electronically at https://www.regulations.gov

RE: Docket FDA-2024-D-0083, Enforcement Policy for Certain In Vitro Diagnostic Devices for Immediate Public Health Response in the Absence of a Declaration under Section 564

To Whom It May Concern:

On behalf of the Association for Molecular Pathology (AMP), thank you for the opportunity to submit these comments in response to "Enforcement Policy for Certain In Vitro Diagnostic Devices for Immediate Public Health Response in the Absence of a Declaration under Section 564". AMP is an international medical and professional association representing approximately 2,900 physicians, doctoral scientists, and medical laboratory scientists (technologists) who perform or are involved with laboratory testing based on knowledge derived from molecular biology, genetics, infectious disease and genomics. Membership includes professionals from the government, academic medicine, private and hospital-based clinical laboratories, and the in vitro diagnostics industry. Many of AMP's members are molecular laboratory professionals who were on the frontlines of responding to the COVID-19 pandemic and Mpox outbreak. AMP maintains that laboratory-developed tests (LDTs) are not medical devices and thus, should not be subject to FDA's policies. However, we provide these comments to ensure that FDA's thinking is supportive of robust and effective public health responses to chemical, biological, radiological, or nuclear (CBRN) agents as the conversation on LDT regulatory policy continues.

It is critical that the same policy failures that were experienced during the COVID-19 and Mpox public health emergencies are not repeated in future infectious disease outbreaks. One such failure was not leveraging the diversity of clinical laboratories in the United States and their ability to provide timely diagnostic services. As such, AMP is concerned that FDA's intent to limit enforcement discretion to certain tests and certain laboratories, such as those that are U. S. government laboratories (USG), state or local public health laboratories, laboratories that have USG agreements or have already taken a test through FDA authorization, could result in an inadequate testing capacity to meet the needs of the country and subsequently, delayed return of results, created long lines to access testing, decreased access to testing and more. The involvement of a wide range of clinical laboratories was essential in response to the COVID-19

pandemic as laboratories dealt with local surges, supply chain disruption, limited capacity and long turnaround times for testing that was outsourced to large reference laboratories. For example, community and hospital clinical laboratories are optimally positioned to meet the testing capacity needs in their local area due to their physical proximity to patients. Additionally, community and hospital clinical laboratories are often able to provide the faster turnaround times necessary to manage patients who need immediate care. **AMP strongly urges FDA to consider how to involve each facet of the laboratory community, including public health, hospital, academic medical center, community, reference laboratories, and others, regardless of whether those laboratories have a formal or informal agreement with the USG.**

To better inform policymaking efforts, AMP surveyed its members multiple times over the course of 2020 and collected hundreds of responses from molecular laboratory professionals to understand the successes and hurdles they experienced when providing the crucial and timely diagnostic services that patients needed.[1] One tremendous challenge at the beginning of the COVID-19 pandemic was a result of FDA's policy requiring emergency use authorization (EUA) for laboratory developed testing procedures prior to using them clinically. This negatively affected the ability of clinical laboratories and developers to offer high quality SARS-CoV-2 molecular diagnostic tests and for the country to have enough capacity in diagnostics to adequately respond as the virus continued to spread. Once the FDA provided more flexibility in its EUA guidance, laboratories were able to quickly offer validated tests for clinical use and provide innovative solutions to respond to patient needs, despite challenges such as the disrupted supply chain. One critical flexibility was the ability of laboratories to develop methods that allowed patients to collect their own specimens to circumvent the need for scarce personal protective equipment. AMP is concerned that the guidance fails to recognize the important role patient self-collection plays in the nation's ability to respond to pandemics and infectious disease outbreaks. **AMP encourages FDA to expand the application of this enforcement discretion policy to tests with self-collection or at-home tests.**

The guidance document also requires that tests must be appropriately validated on the test systems (including instruments and reagents) intended for clinical use. This policy fails to take into account the likelihood of laboratory testing supply shortages during an emergent situation. In AMP's surveys of its members during the COVID-19 pandemic, it was reported that supply chain interruptions were the biggest barrier to increasing testing capacity. AMP members provided SARS-CoV-2 testing using a variety of testing platforms and methods. One reason for this was to address severe supply shortages, including pipette tips, reagents, and test kits. As currently written, the guidance document would prohibit laboratories from making necessary adjustments to account for supply chain issues without notifying the FDA. **Thus, AMP encourages the FDA to provide more flexibility to this requirement in the event of supply chain issues in order to avoid decreases in testing capacity**. **Additionally, AMP believes the requirement of 30 negative and 30 positive samples for clinical evaluation, while reasonable in a non-emergent situation, may delay the availability of tests, especially at the outset of an**

[1] https://www.amp.org/advocacy/sars-cov-2-survey/

infectious disease outbreak when obtaining characterized samples may be difficult. We strongly encourage FDA to provide more guidance and flexibility on this matter.

Lastly, AMP also requests that when a 564 declaration is issued, FDA provide a longer timeline of at least 30 days for laboratories to prepare an EUA submission. Twenty-one days is an unrealistic timeline for laboratories to submit for an EUA, especially considering that molecular professionals are focused on performing tests and caring for patients – not paperwork – as an infectious agent spreads in communities. Laboratory professionals were under great strain during the COVID-19 pandemic and this was exacerbated by workforce shortages. According to AMP's surveys, over 70 percent of respondents reported that they faced workforce issues during the COVID-19 pandemic and unfortunately, we do not believe these shortages will be remedied any time soon. Thus, imposing such a rapid turn-around time for submitting EUA applications may further inhibit a laboratory's ability to offer testing during a critical time in a response effort.

Thank you for the opportunity to provide these comments for your consideration. AMP appreciates your continued leadership and efforts to improve our nation's preparedness for and response to public health emergencies and disasters. Should you have any questions or wish to discuss these issues further, please do not hesitate to contact Annie Scrimenti, AMP Associate Director, Public Policy and Advocacy at AScrimenti@amp.org.

Sincerely,

Maria E. Arcila, MD

President, Association for Molecular Pathology