24 Hour Summary
Microbiology Devices Panel
Advisory Committee Meeting
September 8, 2023

Introduction:

A meeting of the Microbiology Devices Panel ("the Panel") of the Medical Devices Advisory Committee was convened on September 8, 2023, to discuss and provide advice to FDA on in vitro diagnostic devices used in pandemic preparedness and response to satisfy, in part, a requirement under the Food and Drug Omnibus Reform Act of 2022 (FDORA).

The Panel discussed and provided advice to FDA regarding topics related to in vitro diagnostic devices used in pandemic preparedness and response, consistent with the requirements under section 3302 of FDORA.

Panel Deliberations/FDA Questions:

1. How can test developers (including both commercial manufacturers and laboratory test developers) best interact with CDRH when preparing for a future pandemic? What steps can CDRH take to strengthen its communication strategies in future pandemics with test developers, laboratories performing tests, and other stakeholders such as patients and clinicians? Were any methods of communication (town halls, telephone hotline, website FAQ, email boxes for stakeholders, EUA templates) more advantageous than others and what might CDRH consider doing differently in future pandemics?

The Panel believes that the Agency's website is a valuable resource for communication, however, they found it difficult to navigate all the content and recommended an option to search or an index of CDRH's website such that information could be accessed more easily. The Panel found that FDA's methods of communication were useful, notably FDA's IVD town halls and EUA templates. The panel recommends that FDA strengthen its current social media strategies.

The Panel suggests continued collaboration with stakeholders in preparation for future pandemics including Federal Agencies (e.g., CDC) as well as the Association of Public Health Laboratories and the Laboratory Response Network.

The Panel suggests more FDA communications to lay users and healthcare practitioners during a pandemic scenario and to consider employing more graphics and alternative ways to provide or display the information. The Panel cautioned not to remove all current text, but rather offer a variety of information options.

2. What types of educational resources or communications from CDRH would be most valuable to aid test developers with respect to test development in preparation for a future pandemic?

The Panel suggests that to increase transparency and aid in preparation for future pandemics, the Agency should provide test developers with information on what factors the Agency considers in determining prioritization of review and other considerations for test developers.

The Panel suggests that FDA should share information at national meetings and with professional societies. Consider collaborating with public/private entities (i.e., professional societies, public health agencies, academic institutions, large commercial laboratories, test manufacturers, etc.) to form a task force to facilitate discussion and to build relationships.

3. Are there certain types of instrument manufacturers or test component manufacturers with whom CDRH should collaborate with in preparation for a future pandemic response to ensure test availability in a future pandemic. For example, would earlier engagement from CDRH to work with manufacturers of high throughput systems help ensure that well-designed, high-throughput tests can be made available at an appropriate volume to meet the needs of any future outbreak?

The Panel recommends that CDRH should collaborate with certain test developers and certain instrument manufacturers in preparation for a future pandemic response to ensure test availability in a future pandemic. The Panel recommends that there should be broad coverage and diverse mechanisms for prioritization to reduce the number of applications that need to be reviewed for a new test. The Panel suggests a need for redundancy to eliminate the reliance on a single manufacturer or type of test, but that FDA should prioritize instruments and technologies that utilize high throughput systems that have an open channel for use with LDTs as they are often “first responders” in a public health emergency. The FDA should consider pre-authorizing certain manufacturers or certain types of tests by working with those manufacturers to understand how they can quickly mobilize to meet the needs of a public health emergency.

The Panel believes there will likely always be a need for collection devices (e.g., swabs) and transport media (e.g., universal transport media (UTM) so ensuring those are available in any future pandemic will help ensure test availability.

4. Are there certain types of tests or developers that should be prioritized for review in the early stages of a future pandemic? Examples include certain test types (e.g., diagnostic and high throughput), test protocol development for sharing with any laboratory, manufacturing capacity, or experienced test developers.

The Panel cannot identify a single type of test that should be prioritized in a future pandemic as that is likely dependent on the emerging pathogen, however, the panel supports prioritization of EUA requests from experienced developers to ensure the quality of a submission as well as incorporate any EUA requests for open systems that can be applied more broadly across laboratories. The Panel suggests that a solicitation process for interested manufacturers might make sense to assist in the prioritization of device submissions.

The Panel recommends including CDC early on to validate their first line of primers and probes on a variety of platforms, specifically focusing on systems/platforms common in public health laboratories as they are also first responders. Consider systems that are commonly used in large commercial, reference, or central laboratories, and beyond instruments, consider manufacturers that can assist with informatics to ease issues with accessioning and resulting. This would reduce bottlenecking and will allow time and focus to be spent on running the tests.

The Panel recommends that FDA consider equity to ensure that in a future pandemic all persons have access to tests. The Panel recommends that FDA should not only focus on instrumentation or tests that are suitable for reference laboratories, but also consider solutions that are closer to the point of care (i.e., suitable for smaller settings). FDA should consider prioritizing manufacturers whose targets are broad (i.e., pan targets). The Panel recommends that FDA consider the diversity of sample types, for example molecular platforms that can test multiple types of samples, as well as consider solutions for immunocompromised people, particularly if working with antibody based testing or immunological markers. Additionally, when prioritizing instrumentation or tests, the Panel recommends that FDA consider biological plausibility as a consideration and if there are preexisting claims for a self-collection device.

5. What are key features of tests or are there certain test designs that would be helpful in a future pandemic?

The Panel emphasizes the importance of a reference material that is compatible with all assays and continued availability and use of the reference material during a pandemic to ensure standardization of tests and requiring the results of testing with the reference material in the device labeling.

The Panel suggests that FDA work to create user friendly instructions for instruments or tests that are point-of-care or over the counter. They suggest considering a review process with end users and analyze currently authorized COVID-19 tests instructions for use to find useful and not useful commonalities. Instructions should also account for equity, diversity, and inclusion. Additionally, the Panel suggests

that FDA consider creating non-pathogen specific templates for sample collection, handling, and results to aid in the developmental process.

6. What other lessons from the recent COVID-19 pandemic and mpox emergencies might CDRH take into consideration in preparing for future pandemics?

The Panel suggests that FDA consider how the Agency can quickly adapt to an increased workload that might be observed in any future pandemic. The Panel suggests the use of third-party reviewers or a group of external experts (possibly FDA retirees or persons familiar with the Agency) that might obviate the need to bring on many inexperienced staff. In addition, the Panel suggests a full-time pandemic response team at the Center to assist in preparation for future pandemics.

The Panel suggests that FDA should consider populations that will be hit the hardest by another pandemic and apply lessons learned from past pandemics, particular the COVID-19 pandemic.

The Panel suggests more transparency surrounding the Agency's efforts during a pandemic based on the numerous efforts undertaken by FDA during the COVID-19 pandemic of which the panel was not aware.

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Transcripts:

Transcripts may be downloaded from:
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