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FOOD AND DRUG ADMINISTRATION

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CENTER FOR DEVICES AND RADIOLOGICAL HEALTH

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MICROBIOLOGY DEVICES PANEL OF THE MEDICAL DEVICES ADVISORY

COMMITTEE (MDAC)

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Contents

Call to Order and Introductions.....	5
Conflict of Interest Statement.....	8
FDA Presentation: IVDs Used in Pandemic Preparedness and Response Overview — Dr. Timothy Stenzel & Dr. Kristian Roth.....	10
Clarifying Questions for FDA.....	19
FDA Questions	34
Question One	34
Question Two	60
Question Three	69
Question Four	102
Question Five	107
Question Six	116
Closing Comments	122
Adjournment	124

Call to Order and Introductions

Dr. Van Der Pol: Hello. I'd like to call this meeting of the Microbiology Devices Panel to order. I'm Dr. Barbara Van Der Pol, and I'm the chairperson of this panel. I'm a professor of medicine and public health at the University of Alabama at Birmingham, and I have a focus on evaluation of diagnostic products for detection of STIs and other infectious diseases. I note for the record that voting members present constitute a quorum as required by 21 CFR Part 14. I would also like to add that the panel members participating in today's meeting have received training in FDA device law and regulations.

For today's agenda, the panel will discuss and provide recommendations to the FDA regarding topics related to in vitro diagnostic devices, used in pandemic preparedness and response consistent with the requirements under Section 3302 of FDORA. Before we begin, I would like to remind the public and the panelists that this is a non-voting meeting and ask our distinguished committee members and the FDA attending virtually to introduce themselves. Committee members, please turn on your video monitors, if you've not already done so, and unmute yourself as you're called on. I will call your name and then please state your area of expertise, your position, and affiliation. This morning we're going to start with Dr. Ricardo La Hoz.

Dr. La Hoz: Hi, good morning. This is Ricardo La Hoz. I'm a director of Solid Organ Transplant Infectious Diseases at the University of Texas Southwestern. I'm also an associate professor of medicine and my area of expertise is adult transplant ID.

Dr. Van Der Pol: Thank you. Dr. Thomas Moore.

Dr. Moore: Good morning. My name is Tom Moore. I'm an infectious disease physician in Wichita, Kansas, clinical professor at the University of Kansas in Wichita.

Dr. Van Der Pol: Thank you. Dr. Cathy Petti.

1 Dr. Petti: Cathy Petti, CEO of HealthSpring Global, board-certified infectious diseases
2 and medical microbiologist. Areas of expertise are diagnostics and digital health.

3 Dr. Van Der Pol: Dr. Emily Blumberg.

4 Dr. Blumberg: Good morning. Emily Blumberg, professor of medicine, Director of Transplant
5 Infectious Disease in the Infectious Disease Fellowship at the University of Pennsylvania, and
6 my expertise is transplant infectious disease.

7 Dr. Van Der Pol: Dr. Camille Kotton.

8 Dr. Kotton: Good morning. Camille Kotton, I'm the Clinical Director of Transplanting
9 Immunocompromised Host Infectious Diseases at Massachusetts General Hospital, and my
10 area is within adult infectious disease. Nice to be here again. Thank you.

11 Dr. Van Der Pol: Dr. Angie Caliendo.

12 Dr. Caliendo: Good morning. I'm Angie Caliendo. I'm a professor of medicine at
13 Brown, an adult infectious disease physician, and my expertise is in molecular diagnostics.

14 Dr. Van Der Pol: Dr. Marcus Pereira.

15 Dr. Pereira: Good morning. Marcus Pereira, associate professor of medicine at Columbia
16 University Medical Center and medical director of the Transplant Infectious Disease Program.

17 Dr. Van Der Pol: Dr. Valerie Ng.

18 Dr. Ng: Good morning. I'm Valerie Ng. I'm a professor emeritus of the University of
19 California, San Francisco. I am the lab director of the clinical laboratories at Alameda Health
20 System, and my area of expertise, I'm a lab generalist. Thank you.

21 Dr. Van Der Pol: Dr. Peggy Honein.

22 Dr. Honein: Yeah, good morning. This is Peggy. I'm the Director of CDC's Division of
23 Infectious Disease Readiness and Innovation in the National Center for Emerging and Zoonotic

1 Infectious Diseases. I'm an epidemiologist by training and my expertise is in public health
2 emergency response.

3 Dr. Van Der Pol: Dr. Nicolas Wentzensen.

4 Dr. Wentzensen: Good morning. I'm a senior investigator at the National Cancer Institute.
5 I'm a clinical epidemiologist with a focus on infectious diseases and cancer associations and
6 gynecologic cancers.

7 Dr. Van Der Pol: Thank you. Mr. Brad Spring.

8 Mr. Spring: Yes, hi, Brad Spring. I'm with Roche Diagnostics and I head up our global
9 regulatory policy and intelligence team, and I am the industry rep.

10 Dr. Van Der Pol: Dr. Roblena Walker.

11 Dr. Walker: Good morning. I'm Dr. Roblena Walker, CEO and research scientist for
12 EMAGAHA Inc. Areas of expertise are microbiology and infectious diseases, and I also serve
13 as a consumer representative.

14 Dr. Van Der Pol: Ms. Jennifer Schwartzott.

15 Ms. Schwartzott: Hi, I'm Jennifer Schwartzott. I'm the patient representative. I also serve
16 with the NIH and the NCI on the Seronet task force and have specialties in Covid.

17 Dr. Van Der Pol: Dr. Tim Stenzel.

18 Dr. Stenzel: Thank you. And good morning and welcome to everyone, particularly patients
19 and other members of the public who are present on the panel or tuning in today. I am Dr. Tim
20 Stenzel, and I direct the Office of In Vitro Diagnostics at the FDA. I'm board certified in
21 molecular pathology. My expertise is in infectious disease, cancer, and genetics. Thank you.

22 Dr. Van Der Pol: Thank you. Dr. Kris Roth.

23 Dr. Roth: Morning. I'm Kris Roth. I'm a Deputy Director in the Division of Microbiology.

24 Dr. Van Der Pol: Thank you. Dr. Uwe Scherf.

1 Dr. Scherf: Yeah, good morning. My name is Uwe Scherf. I'm the Director of the Division
2 of Microbiology Devices and have been in this position for almost 10 years. And it's a pleasure
3 to take care of pandemics since 2009. Thank you.

4 Dr. Van Der Pol: Thank you. And now, Candace Nalls is our Designated Federal Officer
5 for today's Microbiology Devices Panel, and she will make some introductory remarks.

6 **Conflict of Interest Statement**

7 Ms. Nalls: Good morning. I will now read the conflict-of-interest statement. The Food and
8 Drug Administration, FDA, is convening today's meeting of the Microbiology Devices Panel of
9 the Medical Devices Advisory Committee, under the authority of the Federal Advisory
10 Committee Act, FACA, of 1972. With the exception of the industry representative, all members
11 and consultants of the panel are special government employees or regular federal employees
12 from other agencies and are subject to federal and conflict of interest laws and regulations. The
13 following information on the status of this panel's compliance with federal ethics and conflict
14 of interest laws covered by, but not limited to, those found at 18 USC Section 208, are being
15 provided to participants in today's meeting and to the public. FDA has determined that
16 members and consultants of this panel are in compliance with federal ethics and conflict of
17 interest laws. Under 18 USC Section 208, Congress has authorized FDA to grant waivers to
18 special government employees and regular federal employees who have financial conflicts,
19 when it is determined that the agency's need for a particular individual's services outweighs his
20 or her potential financial conflict of interest.

21 Related to the discussions of today's meeting, members and consultants of this panel
22 who are special government employees or regular federal employees have been screened for
23 potential financial conflicts of interest of their own, as well as those imputed to them, including

1 those of their spouses or minor children, and for purposes of 18 USC Section 208, their
2 employers. These interests may include investments, consulting, expert witness testimony,
3 contracts, grants, credits, teaching, speaking, writing, patents and royalties, and primary
4 employment. For today's agenda, the panel will discuss and provide recommendations to FDA
5 regarding topics related to in vitro diagnostic devices used in pandemic preparedness and
6 response, consistent with the requirements under 3302 of the Food and Drug Omnibus Reform
7 Act of 2022.

8 Based on the agenda for today's meeting and all financial interest reported by the panel
9 members and consultants, a conflict-of-interest waiver has been issued in accordance with 18
10 USC Section 208 B3 to Dr. Angela Caliendo. Dr. Caliendo's waiver addresses her stock
11 holdings and affected firms. The combined holdings are currently valued between \$500,001 and
12 \$725,000. The waiver allows this individual to participate fully in the panel deliberations.
13 FDA's reasons for issuing the waiver are described in the waiver documents, which are posted
14 on FDA's website at <http://www.fda.gov/advisorycommittees/default.htm>. Copies of the waiver
15 may also be obtained by submitting a written request to the agency's Division of Freedom of
16 Information, at 5630 Fishers Lane, room 1035, Rockville, Maryland, 20857.

17 Dr. Bradford Spring is serving as the industry representative, acting on behalf of all related
18 industry. Dr. Spring is employed by Roche Diagnostics Corporation. We would like to remind
19 members and consultants that if the discussions involve any other products or firms not already
20 on the agenda for which an FDA participant has a personal or imputed financial interest, the
21 participants need to exclude themselves from such involvement and their exclusion will be
22 noted for the record. FDA encourages all other participants to advise the panel of any financial
23 relationships they may have with any firms at issue. A copy of this statement will be available
24 for review and will be included as part of the official transcript. Thank you.

1 For the duration of the Microbiology Devices Panel Meeting on September 8th, 2023,
2 Dr. Roblena Walker and Ms. Jennifer Schwartzott have been appointed to serve as temporary
3 non-voting members. For the record, Dr. Walker serves as consumer representative to the
4 Antimicrobial Drugs Advisory Committee at the Center for Drug Evaluation and Research,
5 CDER. Ms. Schwartzott serves as a patient representative consultant to the Cellular Tissue and
6 Gene Therapies Advisory Committee at the Center for Biologics Evaluation and Research,
7 CBER. These individuals are special government employees who have undergone the
8 customary conflict-of-interest review and have reviewed the materials to be considered at this
9 meeting. The appointments were authorized by Russell Forney, director of the advisory
10 committee oversight and management staff, on 7/25/2023.

11 Before I turn the meeting back over to Dr. Van Der Pol, I'd like to make a few general
12 announcements. In order to help transcribe or identify who is speaking, please be sure to
13 identify yourself each and every time that you speak. The press contact for today's meeting is
14 James McKinney. Thank you very much. Dr. Van Der Pol.

15 Dr. Van Der Pol: I would like to invite the FDA to start the presentation. I would like to
16 remind the public observers that this meeting is open for public observation. Public attendees
17 may not participate, except at the specific request of the panel chair. FDA, you may now begin
18 your presentation.

19 **FDA Presentation: IVDs Used in Pandemic Preparedness and Response Overview — Dr.**

20 **Timothy Stenzel & Dr. Kristian Roth**

21 Dr. Stenzel: Hello, I am Tim Stenzel, Director of the Office of In Vitro Diagnostics at the
22 FDA. Welcome to our meeting today, into this presentation. My colleague, Kris Roth, will be
23 assisting. I will start the presentation and turn it over about halfway through. So, today the

1 presentation is on Microbiology Devices Panel of the Medical Devices Advisory Committee, to
2 discuss IVD pandemic preparedness and response. Here is our agenda for this talk. Explain the
3 purpose, the background, and finally end up with the panel questions for discussion during the
4 panel meeting. So, I wanted to talk about preparing for pandemics, and the lessons learned. The
5 lessons learned by CDRH from the Covid-19 pandemic, as well as the impacts, emergency and
6 outbreak, can be applied to prepare for, and respond, to future pandemics involving in vitro
7 diagnostic, or IVD, devices. Actual or potential emergencies for infectious diseases, in which
8 FDA exercised EUA authority to authorize IVDs, include the following: influenza in 2009,
9 avian influenza in 2013, MERS influenza in 2013, in 2014 we have an Ebola emergency, then
10 an Enterovirus D68 emergency, and finally Zika, Covid, and Mpox. The objectives today are to
11 further improve CDRH's ability to prepare for, and respond to, IVD testing needs in future
12 pandemics and emergencies or potential emergencies.

13 To cover a Covid-19 background, briefly, on January 31st, 2020, a public health
14 emergency was declared under section 319 of the Public Health Service Act. And then on
15 February 4th, 2020, HHS issues the Emergency Use Authorization declaration under section
16 564 of the Food, Drug, and Cosmetic Act. And this allowed CDRH to use EUA authorities for
17 IVDs. That same day, on February 4th, 2020, CDRH issued the first EUA authorization for a
18 Covid diagnostic test. To briefly cover the emergency use authorization authorities, these are in
19 statute, and the criteria for issuance include, there must be an agent that causes serious or life-
20 threatening disease or condition. The bars are lower than the usual full authorization bars for
21 medical products. And so, they may be effective, it is important to realize, to diagnose, prevent,
22 or treat the condition. And also, the benefits are now known, and potential benefits outweigh
23 known potential risks. And finally, there is no adequate approved, cleared or otherwise

1 available alternative. Unavailable also does include insufficient supplies of the approved
2 alternative.

3 Next, I'll cover FDA's Covid-19 test policy. It was first published on CDRH's website
4 on February 29th, 2020. This first authorization allowed laboratories who develop LDT's to
5 launch their test, once validated, and once they had notified the FDA. And then they had 15
6 business days to submit their data, all of which time, tests could remain on the market and tests
7 could be performed until FDA finished its review, and then can stay there as long as there were
8 no issues in the final decision. This guidance and test policy was updated throughout the
9 pandemic as the situation evolved. CDRH's EUA request review priorities and enforcement
10 priorities for the Covid-19 tests did change throughout the pandemic, as new needs emerged,
11 and as previous needs may have been covered well enough. By February 28, 2021, CDRH had
12 received over 730 EUA requests related to Covid-19 tests. This figure shows up to last month,
13 August 3rd, 2023, the number of EUA tests authorized.

14 Next, I wanted to cover the approaches we use during Covid-19 pandemic and
15 emergency. Early versions of the Covid-19 test policy guidance provided a policy for certain
16 developers and tests to market their tests without first obtaining EUA authorization. This was a
17 notification policy. Independent evaluation of tests to enable laboratory-based evaluation and
18 provide reasonable estimates and confidence intervals for test performance, given limited
19 sample availability. So, this was a policy where we relied on others to perform evaluations of
20 tests, independent of the developer, to ensure that the tests did function and were accurate. This
21 occurred both at NCI for serology tests and at the NIH with the RADx and ITAP program. The
22 Independent Test Assessment Program, or ITAP, was conceived and developed in order to
23 accelerate regulatory review and availability of high quality, accurate, and reliable over the
24 counter Covid-19 tests, to provide them to laboratories and to the public. This program was a

1 collaboration between NIH and FDA and resulted in a number of authorizations that were
2 highly important, provided a significant number of the over time, the tests that were available
3 to the public. Because of the close interaction between NIH and FDA, and alignment on the
4 studies performed, and the data submissions, review of this material submitted by NIH to the
5 FDA happened as rapidly as any other time during the pandemic. The FDA also pioneered the
6 use of umbrella EUAs, which allowed a streamlined approach to the authorization of tests that
7 meet specified criteria. And finally, the collaboration between UMass, NIH and FDA, on the
8 study of serial testing. It showed that antigen tests benefit from serial testing, both for
9 symptomatic and asymptomatic patients. This study, performed under FDA supervision, was of
10 high quality and allowed the regulatory decisions based on it to be applied to all antigen tests
11 without each antigen test having to perform the same step. So, these are just a small number of
12 the key advances and approaches that the CDRH used during the pandemic.

13 At this point, I want to hand the presentation over to my colleague, Kris Roth. Kris,
14 please take it from here.

15 Dr. Roth: Okay, thank you, Tim. My name is Kris Roth. I'm the Deputy Director of the
16 Division of Microbiological Devices in the Office of In Vitro Diagnostics in OPEC, CDRH,
17 FDA. Picking up where we left off, with our additional Covid-19 activities, we did have a
18 monitoring of the shortage situation, and mitigation of any shortages for certain diagnostic
19 supplies, such as swabs and VTM. We developed EUA requested templates for developers. We
20 developed external communications for SARS-CoV-2 FAQs on CDRH's website, held virtual
21 town halls, dedicated Covid-19 test inbox for questions, and developed safety communications
22 related to various topics of Covid-19. We did monitor variant impacts, in collaboration with the
23 Variant Task Force, at NIH and with Emory University. And FDA supported the collaboration

1 with the NIH RADx and ITAP programs. And you can see here on the right-hand side, just a
2 sample safety communication related to variants that was published on January 8th, 2021.

3 This slide is a summation of our various engagements with both public health
4 officials, clinicians, and the public directly. We put out 373 frequently asked questions, here
5 covering a large variety of topics. And this was not just a one-time effort. We did revisit these
6 questions as the pandemic evolved, and adjusted language as needed, and as additional
7 information became available. We issued 24 letters to health care providers and safety
8 communications. These were related to diagnostic tests, antibody tests, personal protective
9 equipment, or PPE, and ventilators. We also received and responded to 445,000 emails
10 throughout 17 mailboxes and 2 phone lines. Typical response times to this email box was 24 to
11 48 hours. And, in some cases, we had folks working in two shifts throughout the day in order to
12 handle the volume of email on any particular day. We hosted 127 webinars and virtual town
13 halls. 106 of these were related to diagnostic tests. So, these were hour-long town halls that
14 were presented on Wednesday, typically at lunchtime. And we fielded emailed-in questions
15 along with live questions from the callers that were on the line. 19 of these webinars really
16 were related to PPE and to other topics. We issued 13 templates, 10 for diagnostic tests and
17 three for other tests. These templates guided test developers in the validation of their Covid-19
18 tests, whether it be molecular, antigen, serology, home-use, or home-collection. And again,
19 these templates were updated as new information came to light and new needs were identified
20 in response to the outbreak. Finally, we participated in weekly calls with NIH's RADx and
21 ITAP programs. These were to give early feedback on proposals and regulatory strategy for
22 some of the tests that are going through these programs. We also held weekly calls with the
23 testing coordination group, the TCG group. We had weekly, sometimes bi-weekly, calls with

1 international regulatory agencies. And frequent ad hoc calls as issues arise with our other
2 government partners.

3 This slide is intended to highlight a new activity that we undertook during this
4 pandemic, where we monitored for the impact of variance on test performance. So, there are a
5 number of global databases that house genetic information. Perhaps some folks are familiar
6 with Global Initiative on Sharing All Influenza Data (GISAID). And we do monitor these
7 databases and have staff that are trained to look for genetic variation in a very large set of
8 sequences. And since we do have the proprietary information from the test developer, we can
9 kind of cross check emerging mutations for potential performance impacts on tests that have
10 EUA. However, we do require that test developers conduct their own surveillance and analysis.
11 And this is part of their condition of authorization. When we conduct our in-silico analyses, we
12 use the target sequences, for all authorized molecular tests. And again, we can query the
13 database against, you know, looking for mismatches between the target sequences and
14 emerging variants. FDA provides information on specific tests, for which FDA has identified
15 potential impacts on performance due to genetic mutations. So, we have reached out to test
16 developers, and in some cases, we have provided safety communications on the FDA website,
17 noting if there were performance issues with tests, related to mutations. This is provided as
18 recommendations to clinical lab staff and healthcare providers, which are using these tests. And
19 this is a resource that the public can use to maintain awareness of test performance in relation
20 to emerging variants. We also collaborate with NIH's RADx Variant Task Force Program. This
21 organization is studying performance of Covid tests, with variants, most recently, of course the
22 Omicron variant.

23 Participated in assessments of Covid-19 test response. These are three assessments that
24 CDRH participated in. One was from the Office of the Inspector General, titled FDA

1 Repeatedly Adapted Emergency Use Authorization Policies to Address the Need for Covid
2 tests. The U. S. Government Accountability Office, the GIO, issued a report titled FDA Took
3 Steps to Make Tests Available for Future Public Health Emergencies Needed. And also an
4 assessment from Booz Allen Hamilton titled Emergency Use Authorization Assessment Final
5 Report. And here, these links are available to you, and you can go and take a look at those
6 reports. I think CDRH's own experiences learned through Covid pandemic can be summarized
7 in kind of two bullet points. One is the value of regulatory flexibility. As the pandemic evolved
8 and the virus evolved, different approaches to regulating tests were needed. We issued a
9 number of umbrella EUAs, Immediately In Effect guidances, which were issued very, very
10 quickly. We changed policy as needed, very quickly. And participated in research programs that
11 were intended to inform regulatory decisions and then change regulatory policy based on those
12 research outcomes. These are just a couple of examples of regulatory flexibility, but it was kind
13 of a hallmark of our response, to maintain awareness of the current situation and the current
14 science, and make sure that the decisions we were making were being informed by the best
15 science possible at the time.

16 And also the power of engagement. The previous slide kind of highlights some of our
17 engagement activities through email, phone calls, issuing templates, immediately in effect
18 guidances. So, we've found a lot of value in collaborating with both partners inside the
19 government and outside the government, to maintain awareness. Of the needs, the testing
20 community, and also the clinical situation of the virus, as the pandemic went on.

21 So, here's some key lessons learned from those interactions. So, the importance of review of
22 test before clinical use, and consideration of potential alternative approaches, such as prior
23 certification of developers. But this is the kind of, you know, during the pandemic, we were
24 aware of a lot of really good tests, and some tests that were potentially lacking. And so, there

1 were quite a bit of insight and data that we needed on all tests, to make sure that we were
2 making the right decision. This potentially could be streamlined in the future, if there is a way
3 to certify certain developers, to kind of pre-qualify, I wouldn't say pre-qualify, but to kind of
4 certify that a set of developers is capable of developing a test and validating a test. The agile
5 organization, you know, we've maintained the ability to quickly respond and adapt to changes,
6 pivoting to focus on immediate needs and challenges as they rise, and this became kind of our
7 day-to-day business. The only kind of constant in this pandemic response was change, to a
8 certain degree. Again, the value of prepositioned commercial developers may be helpful in the
9 future. If we establish contracts to preposition a handful of commercial developers to be ready
10 for an outbreak response, that may lower the barrier to validation in the future. Also, de-risking
11 test development through guarantees of minimum purchases. Reimbursement and product
12 production funding support. This was evident from the large USG effort to distribute at-home
13 tests. A centralized performance validation may be helpful, if we establish a clinical validation
14 program to support test development and validation. Something that is a public private
15 partnership, such as the ITAP, where there's additional insight into test performance. When
16 folks for tests are kind of validated using kind of a master protocol approach, where everyone
17 kind of follows the same protocol for analytical and clinical validation. That can really
18 streamline the FDA review process and also help better understand test performance.

19 Sample sharing was a big issue during the pandemic. It seems that there were some
20 private sample banks and some academic institutions sharing samples, but there was no real
21 kind of coordinated effort to ensure, or help ensure, that samples were being shared
22 appropriately. So therefore, establishing more effective mechanisms for sample sharing in
23 outbreaks would facilitate test development and validation. Investment in novel technologies. A
24 continued investment in novel test development, particularly point of care at home to

1 technologies, is something that we believe was helpful. And regulatory flexibility. And really,
2 you can only have flexibility if you understand kind of what's going on with test developers, in
3 the clinical community, with patients. And so, you can only do that if you have extensive
4 engagement with developers and other folks.

5 So that leads us to the questions for the panel discussion. And I'll just read the questions
6 here. The first question is, how can test developers, including both commercial manufacturers
7 and laboratory test developers, best interact with CDRH when preparing for a future pandemic?
8 What steps can CDRH take to strengthen its communication strategies in future pandemics,
9 with test developers, laboratories performing tests, and other stakeholders such as patients and
10 clinicians? Were any methods of communication, such as town halls, telephone hotline,
11 website, FAQs, email boxes for stakeholders, or EUA templates, more advantageous than
12 others? And what might CDRH consider doing differently in future pandemics?

13 Moving on to question number two, what types of educational resources, or
14 communications, from CDRH, would be most valuable to aid test developers with respect to
15 test development in preparation for a future pandemic?

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

22 Question four. Are there certain types of tests or developers that should be prioritized
23 for review in the early stages of a future pandemic? Examples include certain test types. For

1 example, diagnostic and high throughput, test protocol development for sharing with any
2 laboratory, manufacturing capacity, or experienced test developers.

3 Question five. What are key features of tests, or are there certain test designs that would
4 be helpful in a future pandemic?

5 Question six. What other lessons from the recent Covid-19 pandemic and Mpox
6 emergencies might CDRH take into consideration in preparing for future pandemics? And with
7 that, I will thank you for your attention, and we will go on to the next step of the presentation.
8 Thank you.

9 **Clarifying Questions for FDA**

10 Dr. Van Der Pol: Thank you for those presentations. At this time, the FDA has received no
11 requests to speak during the open public hearing portion of today's meeting. Therefore, we will
12 continue with the agenda. Before I ask for clarifying questions, again, I'm going to take Chairs
13 prerogative and just say, as someone who works in a laboratory, I converted my laboratory to
14 Covid response, and we were evaluating new diagnostics. I sit on one of the RADx clinical
15 review committees, and I have to say the FDA's efforts were greatly appreciated, and
16 everybody could clearly see how much energy and how much activity was going in, to the
17 FDA, really trying to help the public health response to this situation. And you guys did a
18 fantastic job. So, I just want to take a second and throw that out there. So, with that, does
19 anyone on the panel have any clarifying questions they'd like to ask the FDA about today's
20 questions for discussion? Dr. Caliendo.

21 Dr. Caliendo: I have two. One is, how does this all end, this EUA? So that is one question. It
22 clearly didn't end when the national emergency ended. So, that's something interesting. And
23 then, are you required, or are you permitted, by regulation, to treat some companies differently

1 than others? Like, with this pre-authorization. Is that within your purview or is that considered
2 anti-competitive, or... Because that's a very interesting idea, but I don't have a sense for
3 whether, how realistic that is for you.

4 Dr. Van Der Pol: Dr. Stenzel.

5 Dr. Stenzel: Yeah, I'll start with the second question first. So, certainly, there can be within
6 the U.S. government an effort to sign up manufacturers and preposition them, you know, and,
7 and plan out response, that would likely be of course, of competitive nature. And we are
8 looking for the input from the panel today about, maybe what things to consider in looking at
9 that. What are needed in different phases of an emergency response, what is needed first, you
10 know, and so that would be welcome. Some of these lessons learned, we don't have authorities
11 for, right now. So, it would potentially take additional authorities to be able to perform this
12 function. But we do think that this type of creative, out of the box, regulatory thinking is going
13 to be important to prepare for the next response, well in advance of the next response.
14 Regarding your first question, and that is, how do the EUA authorities end? So, just to clarify,
15 there are two main statutes dealing with public health emergencies. One is the declaration of
16 the public health emergency. And the second, it has to do with FDA authorities around EUAs,
17 and those EUAs can apply to devices, to drugs, biologics, therapies. And so, they are
18 disconnected. So, the public health emergency can end, but the EUA authorities can persist. For
19 example, the EUA authorities for Mpox or Ebola, for Zika, continue. And we were very
20 grateful that we had EUA authorities that we could deploy for Ebola, because there were recent
21 occurrences worldwide, Ireland, Africa, where we needed to prepare, in case something might
22 happen. So, we continue to use EUA authorities for Covid, and are currently accepting
23 additional EUA tests. In particular, multi-analyte tests, that test not just for Covid, but also for
24 flu and RSV. And we're actively involved in those activities now, and hope to have some

1 additional authorizations prior to the peak of the respiratory season. How do these EUA
2 authorities end? They end when the secretary says they can end. It's highly dependent on any
3 continued needs. For example, Mpox, there's almost thankfully, there's almost no Mpox
4 circulating right now. There's still a very, very low level, but we still want to keep focus on
5 taking that to zero in the United States, and frankly, worldwide. But since there are almost no
6 cases, it would be very difficult to get a full authorization for any of the Mpox tests that have
7 EUAs. So, the continued availability of these Mpox tests under the EUA authorities, that
8 laboratories can use, is highly important.

9 We've also been working very closely with the CDC, both obviously, and for Covid, but
10 also for Mpox, and have given authorities to the CDC, to update and augment their Mpox
11 activities. So, it may be that the need for Mpox EUA authorities will persist for a very long
12 time. With Covid, it's perhaps a little bit different. We have so many tests authorized, and we
13 also have a number of full authorizations of tests right now. We examine that on a regular basis.
14 And, for right now, we have perhaps sufficient full authorizations for central lab tests, some for
15 point-of-care, but very few for over-the-counter. I forget, maybe just one. So, we really would
16 like to see more over-the-counter and point-of-care tests authorized. We would like to see
17 more multi-analyte tests authorized fully. But there are final guidances out, for the transition
18 from Covid EUAs to full authorization. And so, there is a pathway and a plan, carefully laid
19 out. Once it is announced that the EUA authorities will come to an end, anyone who wants to
20 have an IVD that can persist on the market after the transition period, which is 180 days, they
21 do need to come in with a full authorization submission. And as long as that's in by the
22 deadline, they can continue to market their EUA test while we review that test. And
23 presumably, hopefully, that will be a positive decision, and then they're on, you know, they'll
24 get De Novo granted, or a 510(k), you can stay in the market. So, the end of the EUA

1 authorities, in any situation, always looks at the long-term availability of tests. And so, once we
2 have enough fully authorized tests across all categories, we'll feel comfortable to be able to
3 bring an emergency authority to the end. Hopefully that answers both those questions. I see
4 there's some other questions. Thank you.

5 Dr. Van Der Pol: Dr. Petti.

6 Dr. Petti: Cathy Petti, HealthSpring Global. Another clarifying question for Dr. Stenzel.
7 As we all know, very challenging times in developing diagnostic tests during this pandemic.
8 And I think all of us on this committee also are very aware of the different purviews of where
9 EUA sits and where CLIA laboratory developed tests sit. I can't help but think that that
10 guidance in November 2021, that the FDA issued, for me, living through this and advising
11 many moderate to high complexity laboratories, as well as test manufacturers, it was sort of a
12 landmark document, because not only did it address EUAs, but it also gave great guidance for
13 those laboratories that were moderate to high complexity CLIA. And the FDA in that document
14 dipped its toes in providing some policy recommendations for those laboratories, and in
15 particular, brought clarity for the home-collection piece of this whole paradigm. So, us as a
16 committee, would the FDA like us to stay firmly rooted in the EUA guard rails, or will there be
17 some discussion and overlap with test developers of high throughput, high volume, laboratories
18 that put together LDTs.

19 Dr. Stenzel: So, I think, you know, any needs of the LDT community as well as any needs
20 perceived of any test developer, is open for discussion, today. Home-collection for Covid, and,
21 which also included some that were multi-analyzed, some that were interior narrays, some that
22 were saliva, which was very novel. We had never, prior to Covid, although we were open,
23 authorized home-collection for respiratory disease. And, I forget the exact number, but I think
24 it's over 80 authorizations of home-collection over, well over 30, home-tests, OTC tests. So,

1 this was groundbreaking in a number of ways. We had been open to home-tests for respiratory
2 diseases, and welcomed them before Covid, and now it's very clear that the FDA is wide open
3 to these tests. So, yes, you know, please bring any concerns to the FDA today. Thank you.

4 Dr. Van Der Pol: Thank you. Dr. Pereira.

5 Dr. Pereira: Hi, good morning. Marcus Pereira, Columbia University. I guess just as an
6 initial statement, you know, as a clinician in infectious diseases living through Covid, like we
7 all did, you know, I certainly am not an expert on FDA legal authorities and the legal
8 framework that sort of operated throughout, before Covid and through Covid. So, my question,
9 you know, and I listened intently to the slide presentation, which was very great, and read the
10 documents that were given to us prior to this meeting. And, you know, I guess my question is
11 sort of just understanding overall, sort of the legal framework that's going to dictate, I think,
12 some of these questions that you ask, and we'll be trying to answer together today. You know, I
13 don't fully understand sort of the nuances between, sort of, when EUA is authorized, or EUA is
14 issued, or the sort of PHE is issued, I suppose, and how that changes your authorities.
15 Obviously, I imagine that it gives you some flexibility and greater authority. But, in reading
16 your questions, it seems that, you know, there's sort of, at least a consideration to pivot the
17 agency from sort of a more passive framework and waiting for laboratories to issue or to submit
18 tests, to sort of engaging the industry and academics and sort of, you know, getting these tests
19 done more quickly and then sort of in terms of high-throughput. So, I guess my questions for
20 you would be sort of, has the legal framework already changed since, sort of, the Covid
21 pandemic, and how has it changed? And if not, I suppose, you know, where do you see some of
22 the legal framework changing around the FDA? And, yeah. And it's just understanding sort of
23 where we stand with those authorities. And also, you know, it seems also that some of what you
24 were asking is almost sort of pre any emergency declaration, right? So how are you going to

1 position yourself and attain the authority, for example, to engage industry for some of these pre,
2 sort of, you know, pandemic tests, without sort of some emergency authorization. Maybe this is
3 a broad question, but I'm just trying to understand how it would operate.

4 Dr. Stenzel: Yeah, you've touched on so many different points, so I hope I can address most
5 of them, or if not, all of them. So, the EUA authorities allow the FDA to lower the bar for test
6 developers. So, we don't have to expect, or recommend, the same amount of evidence that we
7 would for a 510(k), or a PMA. We have great flexibility to adapt to the needs of the current
8 situation. So, for example, early in the pandemic, it was in Covid, it was very clear that there
9 weren't going to be many samples, many actual patient samples, available in the U.S. And,
10 some had tried to get samples, including the FDA, from other countries. And some were
11 partially successful; others were not. So, it became very clear that asking for, you know,
12 validations with actual patient samples, was not going to allow test developers to validate and
13 submit their data to the FDA. So, we allowed contrived samples. We ask that negative patient
14 matrix be used. And that, you know, that the whole virus RNA or long sequences of vitro
15 transcribed RNA could be diluted into negative patient matrix. And ultimately arrived at, you
16 know, 30 positives and 30 negatives. And, rather than our usual recommendations and
17 expectations, that many more positives and many more negatives, and actual patient negatives
18 and positive, meaning, you know, the same thing occurred for Mpox. Mpox, while there was,
19 you know, there was an outbreak. It wasn't in anywhere near the same numbers of positives as
20 for Covid, so we allowed banked samples, from the very beginning, even contrived. The first
21 policy was going to involve completely contrived samples. It ended up that most developers
22 could access banked samples for their validation. But, you know, very few, you know, if any
23 initially, use prospective collection of patient samples to validate. As the Covid pandemic went
24 on, we switched to ask them, for actual patient samples, to be used for validation, when they

1 were relevant. So, this kind of changing authority is allowed under EUAs. And this is in statute.
2 And otherwise, it would be much longer before commercial manufacturers could develop and
3 validate and get authorized and test. So, we absolutely need those statutory authorities to have
4 that kind of flexibility. Is the FDA being more active versus passive? I would say we've
5 certainly been very active since I joined the FDA in 2018. You know, by the end of February of
6 2020, we had actively engaged with 100 test developers for Covid. These were traditional kit
7 manufacturers. These were academic labs. These were reference labs. We had a template of
8 recommendations available by mid-January. It was just an adaption of the template that we used
9 for all prior EUA emergencies. All 7 prior EUA emergencies, including Zika and Ebola. So,
10 and, we immediately made that available, not to inquiries and, you know, and engaged with
11 more than 20 developers of all types in January of 2020. So, the FDA has had our ear to the
12 ground continually. When we heard that certain laboratories didn't know that they could submit
13 an EUA, we then updated the, we made the policy decision of February 29th, 2020, to very
14 clearly state that, you know, LDT developers, go ahead. You're very welcome. And we just
15 didn't know that they were aware because we already had, you know, interacted with many
16 LDT developers prior to the end of February. But within days of realizing that we, we came out
17 with a policy that we did on February 29th. I'm not sure if I've addressed all your questions. It
18 was quite broad.

19 Dr. Pereira: No, that was very good. Thank you. It sounds like you're already engaging, even
20 before any declarations were issued in the United States, you're already engaging with the
21 industry.

22 Dr. Stenzel: Absolutely. Absolutely. That's our long-standing trend. We actively engage with
23 developers. Whenever a need's met, it doesn't always, you know, we don't announce it from the
24 mountaintop, necessarily. Many of these conversations are confidential. I would say our federal

1 partners, also were very, were engaged very early at BARDA. So, BARDA very quickly,
2 generated the list of potential companies that could assist early on. Those companies could
3 apply for money. We shared that list. We contributed the FDA to that list. And we were made
4 aware of activities around that. We're very aware with BEI's activities, trying to make virus
5 stocks available to developers. You know, FDA became engaged in being able to, you know,
6 make sure that key developers got those important samples as early as possible. So, yeah, a lot
7 of, tons of activity on a daily basis, from the very earliest days. And continued throughout.

8 Dr. Van Der Pol: Thank you. We have one more question from Dr. Wentzensen.

9 Dr. Wentzensen: Thank you. Yes, so first, I wanted to echo our chair's comments. It was
10 really amazing to see how FDA reacted to the pandemic, both on the diagnostic and the vaccine
11 side. I think that that was very impressive. So, we were engaged early on with test evaluation,
12 and we try to validate a number of the EUA tests, and some of them were really bad in the
13 beginning. So, I mean, there were a lot of tests that we would never want to use in a clinical
14 setting. But, then over time, it got very stable, very solid, I mean, and it was a great selection.
15 So, maybe can you clarify like the EUA process, does it allow for a staged approach, where you
16 can... We need a very low bar in the beginning to get tests on the market and in use, but can we
17 keep asking for additional updates to keep this EUA authorization going for specific tests? As I
18 understood, you said that the EUA rules changed over time, and so there were higher demands
19 probably later, for new tests coming along, but can the same be requested for something that
20 entered the market with a very low bar and then, I think, as the pandemic expanded and there
21 was no shortage of samples, there was a lot of real-life clinical data that could be used. So, can
22 manufacturers be asked to update these performance criteria? Is that a way that EUA could be
23 modeled?

1 Dr. Van Der Pol: And before you start answering that, can I just add, because I have a
2 question that was really just right on the same topic, but that was like, as we gather more data,
3 can we rescind? Can you, do you have the authority to rescind an EUA given to a test that was
4 fine in the beginning because we had nothing and anything was better than nothing, but now is
5 really not something people should be using. Can we get those off the market? Because I think
6 that impacts how willing we are to use those different bars, if you will. But I think that's related
7 to Nick's question. So, I thought I would just throw that in there at the same time.

8 Dr. Stenzel: Yes, that's a great question. Yes, the EUA authorities allow us to rescind
9 authorizations. Which we did, at times. And then, there's also been voluntary requests for
10 rescinding EUA authorizations, you know, those that don't want to maintain the test. And those
11 are at the request of the developer. Those were more frequent than the actual, fortunately we
12 didn't have to rescind too many. Yes, the EUA authorities allow us to shift and start with a
13 lower bar. We learned in Covid that this was very important, and we applied it to Mpox. So, in
14 the beginning of Mpox, even though we might have allowed authorization based on contrived
15 samples, we put into the conditions of authorization of the Mpox test from the very beginning
16 that they would need to repeat with actual patient samples. And that's something we can do in
17 all EUA authorizations. And we can put very specific conditions, even conditions specific for a
18 task. We can require post-market work. We required, you know, test developers to monitor
19 permutations. Kris mentioned what we did for molecular tests. We do something very, very
20 similar for antigen tests as well. And the VTF team has been very helpful to the FDA in
21 assuring that there isn't complete loss of single for antigen tests. So, yes, we can build in
22 progressive improvement or progressive additional evidence needed. It's always, though, a
23 careful balancing act, in such a situation, when everybody is working so hard. You know, how
24 much is the right amount to ask at a given time? And how much is too little? How much is just

1 right? How much is too much? So, we have lots of discussions within the FDA, but also with
2 key partners, internal and external to the government, to try to balance our approach at all
3 times, to ensure that, I'm sure the nation that the tests that are performed are accurate, and are
4 truly helpful to the situation. Hopefully I answered all those questions.

5 Dr. Van Der Pol: Thanks. Dr. Moore.

6 Dr. Moore: Thank you. Tom Moore, infectious disease at University of Kansas. So, I think
7 it's striking that we're discussing this topic actually today, which is the anniversary of the
8 removal of the handle for the broad street pump in London, that stopped the cholera epidemic.
9 Anyway, I think it's rather fortuitous. I had a couple of questions, you know, I'm thinking about
10 this from, about this problem, back relative to the anthrax attacks in 2001, when the pressure
11 that was exerted on Bayer Pharmaceuticals to provide low-cost or no-cost large samples of
12 Cipro, led to a lot of the innovation and research and drugs and treatments for biologic agents
13 sort of dried up. And so, the government's been trying to walk that back. And you know,
14 starting with, you know, BioShield and other defense authorizations in order to coax producers
15 and pharmaceutical companies back into the field of looking at, and developing, drugs and
16 other treatments for agents, which, you know, for which national emergency could be declared.
17 I guess my question, I have a couple of questions. I mean, first of all, I want to say very clearly
18 that for my perspective, in the middle of the United States, and from what we experienced, I
19 think the FDA did a tremendous job. The government itself did a tremendous job and
20 mobilizing resources and getting everyone involved and having excellent communications with
21 people in the field. Would you be able to say, specifically, what the problems with sharing the
22 data were. I mean, that to me, is one of the biggest problems. And I know that the FDA is has
23 limited authority in mandating who can share with, I mean, making people share samples, but
24 that's, I think that's an important problem. And I guess I'd like to know a little bit more about

1 what specific problems were encountered, because I suspect congressional action would be
2 required to enforce some sort of sharing of the data. But also, one other thing that I was
3 thinking about is, with the Covid pandemic, what were, and prior pandemics, that is the
4 Influenza pandemic, were there, were there offers of... I'm more interested in the, the carrots
5 that were offered to the developers. Were there discussions about extension of patents for these
6 particular pathogens in order to coax people back to the development table?

7 Dr. Stenzel: Can I ask a clarifying question? And first of all, thanks. Thanks for your kind
8 words about the FDA. Are you asking about sharing of data, and if data, what data? Versus
9 sharing of samples.

10 Dr. Moore: Well, either or. I mean, I think, some people were very open about sharing data,
11 it's my understanding. And I'm not privy to situations where they weren't sharing data, but you
12 know, really both apply. I mean, there is open sourcing of open-source publication of some
13 data. But in terms of, I guess, sharing samples, probably, I would imagine would be the more
14 restrictive part. But, if the shoe fits, whichever, whichever you think would, you could inform.

15 Dr. Stenzel: Yeah, I can discuss both. So, first of all, any data related to test validation,
16 anything, anytime a test was EUA authorized, the FDA posted our decision on the FDA
17 website. It's everything that's still authorized. It's still on the FDA website, both for Covid and
18 for Mpox. And it includes the package insert and instructions for use, it includes the
19 authorization letter with all the stipulations laid out, the requirements and authorities. And, you
20 know, essentially all the data that the FDA looked at to make their decision is in those
21 documents. And we've heard that was very viable. We've now made sure that it's all
22 information that's all available to those that have certain impediments, visual or otherwise. So,
23 everything...

1 Dr. Moore: I'm sorry, Dr. Stenzel. Perhaps I misunderstood. I meant the people that were
2 doing the research. Not FDA's communication with the public, but rather, you know,
3 collaborators, people working together to try to develop these things.

4 Dr. Stenzel: Yeah, so the FDA has, I'm not sure we have any authorities in that area, as far as
5 development goes, R&D research into Covid. We did, you know, within our authorities for
6 OTC tests, we wanted all the developers to have a method of reporting the data, so that it can
7 be used for helping public health purposes. Going to sharing samples. So, this is something we
8 began in January, when we wanted to get access to actual viral samples at the FDA to study the
9 virus, and to grow it up, and be able to produce a viral RNA. And we were very limited, and we
10 ended up only being able to get sample or samples from within the U.S. There were so few
11 samples in the beginning, there wasn't really much to share. If you're going to try to access
12 samples outside the country, there were certainly plenty of samples within some countries. But
13 some of those countries bar, legally, samples from being shared with anyone outside of that
14 country. So, not only might we need national agreements to share samples with the right
15 protections for patients, but also we would need international agreements to share samples. We
16 explored this during Covid, particularly when we saw a variant of concern of Covid, that
17 occurred in another country for which those variants hadn't yet been detected in the U.S. So,
18 Kris mentioned that we had regular conversations with our regulatory partners around the
19 world. We did, and other related governmental entities, and we very specifically asked if we
20 could get samples for certain variants, so that they could go to NIH, RADx in the variant task
21 force, to be able to make sure that they are entering tests in particular, where we couldn't use
22 just bioinformatics to predict any loss of signal once we have a signal. But for the antigen test,
23 we really needed life, actual sample, not any other independent samples, to do the testing. But
24 we were unfortunately unable to do that, at the moment. It is something that is on our list to go

1 back to and try to figure out. It's, it's, it's an important topic. It's going to take a community, I
2 don't know what authorities, or carrots or whatever will need to be used, but it is certainly
3 something that's very important. And it's just too bad that we couldn't really deploy cooperation
4 in that effort so far, on a broad scale, to be able to address the, not just in this country, but
5 worldwide. We're very happy to try to share, you know, from the U.S. to other countries, where
6 allowed, as well. So, it wasn't going to be a one-way street of somewhere else into the U.S.
7 Some have discussed, you know, we could fund activities in collaboration with other countries,
8 and have research posts that would allow tap collection and sharing, or even evaluation of tests
9 in those countries with those samples. So, there's many different paths that we can potentially
10 pursue to address the ability to share samples or share knowledge, and obviously we're very
11 supportive of those, just don't have any firm answers yet. Thank you.

12 Dr. Moore: Thank you.

13 Dr. Van Der Pol: Dr. Kelly?

14 Dr. Kelly: Angie Caliendo and Brown. Tim, one thing that's not on these questions is
15 anything related to FDA staffing. I suspect, in the beginning of this pandemic, you were totally
16 overwhelmed with volume. Should we comment or make suggestions around how to allow
17 some flexing in the staffing, for the FDA. Like, could you have pre-authorized reviewers that
18 actually aren't employed by the FDA? Is this something you want us to address? Or is this out
19 of scope?

20 Dr. Stenzel: Oh, no, that's perfectly okay to address. It was a challenge. To my knowledge,
21 our office, we had one fully funded pandemic response person prior to Covid. We are
22 dedicating more, now, and we'll dedicate more in the future, with or without specific funding
23 for that. We did receive very generous funds to staff up, and we were able to add 65 reviewers
24 with Covid funding. We are very grateful that. We use those authorities. We were able to

1 employ a third-party reviewer who has now reviewed over 100 Covid applications. That is the
2 most IVD third-party reviews that I'm aware of. So, we were able to innovate in that area. We
3 had some funds available for that, and that has been an exceedingly helpful and beneficial
4 expansion of our abilities to respond. Of course, that's dependent on additional funding. You
5 know, there was comment on vaccines and what was the carrots that can be used for tests. Well,
6 there was specific funding for, early on, for vaccine development. There wasn't such funding
7 available for test development. And obviously the lessons learned where we would like to
8 spend those monies ahead of the next, to prepare, ahead of the next pandemic. This is
9 something that South Korea did, following MERS and prior to Covid, where they invested, and
10 there's an FDA white paper on this, and Jeff Shearn and I have an opinion piece describing
11 what South Korea did, and the lessons learned, that we would like to, the overlap with what
12 works for our system that we would like to use. But they did fund specific developers to be
13 prepared, those developers met the need early on. They prepared, you know, how laboratories
14 would respond, how they would select those laboratories, who would do the test evaluations,
15 how that would be done, all those, they had priorities. And so, it wasn't an all-comers situation
16 as it was in the U.S. They selected key developers early in the pandemic that met the South
17 Korean needs. So, there were so many lessons learned as we looked at how other countries had
18 prepared and responded. But South Korea, we think is one of the best. So, yes, so, just as far as
19 staffing, just to sort of complete the response there. So, when we were at the beginning of the
20 pandemic, we had 25 virology reviewers and no more in the office or the FDA for tests. So, we
21 quickly expanded to the rest of the microbiology division, which is about a head count of about
22 50. And thereafter, we called in another 100 reviewers who were not experienced necessarily in
23 microbiology reviews. So, all in all, we were able to staff up significantly, but not immediately,
24 obviously. Still, in those early days, in the first two months, we actively engaged with 100

1 developers of Covid tests, and our response times were very short with the staffing we did
2 have. We were very good.

3 Dr. Van Der Pol: Ms. Schwartzott.

4 Ms. Schwartzott: Just another comment back to the topic of sharing. I serve with SeroNet
5 at the NIH and NCI, and, you know, they have very different groups. Throughout SeroNet, you
6 know, lab work, epidemiology data, and I serve with the data. We created a database, which is
7 now called ImmPort, that allowed sharing of data, which included slides, and I was absolutely
8 amazed at the level of sharing there. I was wondering if the FDA tried doing something similar.
9 That just seemed like a really great mechanism. And ImmPort's fairly new, but it was a great
10 mechanism to get out the data sharing information.

11 Dr. Stenzel: Yes, we are aware of it. And you do remind me that there was an example of
12 sample sharing, that was very valuable relatively early on in the pandemic, and it did involve
13 NCI. So, the NCI, I will be forever grateful to NCI volunteering to help us to evaluate the
14 serology tests that were so challenging in the beginning of the pandemic. You may remember
15 that the FDA, early on, which we then reversed the decision, and first decision was a mistake.
16 And I have admitted that publicly in writing, in the New England Journal. We allowed serology
17 test developers to market their tests under certain stipulations. We quickly saw that those
18 stipulations were not followed and that many of those tests had not been either fully validated
19 or were functioning. So, we found a ready and willing partner at NCI, and some funding for
20 them to evaluate the serology tests. The FDA, in collaboration with others, did reach out to a
21 number of academic institutions, and other institutions, to identify, and the CDC played an
22 important role here. NCI and FDA. In identifying convalescent serum, as well as pre-pandemic
23 serum and plasma, for Covid that could be used. This was an enormous effort, though, to
24 acquire those samples according to local state and federal rules and laws. To evaluate the

1 samples, we needed to pull those samples and test them at every step of the way. So, we had an
2 entire huge team, interagency, huge team, including our academic partners, to be able to stand
3 up that effort. But, sample exchange, sample sharing, was very critical to that effort. So, thank
4 you for the reminder of that. And yes, that is one program that we're aware of and that could be
5 used. Thanks.

6 Dr. Van Der Pol: Thank you. I think we've heard from most people, but just want to verify
7 that everyone has had a chance to ask any clarifying questions before we start to try to respond
8 to the FDA's questions. Okay, and seeing nothing further at this time, let's focus our discussion
9 on the FDA questions.

10

11

FDA Questions

12 Dr. Van Der Pol: Panel members, copies of the questions are in your packets. I would ask
13 that each panel member identify him or herself each time they speak, to facilitate transcription.
14 Please don't forget to use the raised hand feature in Zoom. So, with that, if we can see question
15 one on the screen.

16

Question One

17 Dr. Van Der Pol: Question one is long and has many subparts, so this can take us as long
18 as we need. We're ahead of schedule. The question is, how can test developers best interact with
19 CDRH when preparing for future pandemics, and some of the sub questions include what steps
20 can CDRH take to strengthen its communication strategies or any methods of communication
21 more advantageous than others? And then any other ideas. We will get to novel ideas for
22 communication in one of the upcoming questions, but I think if everybody wants to just throw
23 their opinions out there, I'll sort them into which question they probably go with. And when the

1 summary comes, we'll sort that out. There was a question from one of the panelists about the
2 open public hearing. I will just remind you, I read a statement a few minutes ago that no one
3 applied to make a statement during the open public hearing portion of this process. So, with
4 that, you have the question in front of you. And I'm happy to start taking comments from the
5 panelists again.

6 I think I'll take prerogative and start with saying that I think Dr. Stenzel already
7 mentioned something that's, you know, one of the critical things. And that is, there was
8 information up on the website. There is information available to people. Not everyone knows
9 that information is there. Not everyone knows where to look for it. And so, how do we make
10 sure that the information is not only posted, but actually everybody knows that it's posted, and
11 where it's posted. And I don't know if that's something that, you know, is a mechanism that,
12 while you've already got a lot of data posted on site, there needs to be easier search options. So,
13 for example, I go in and I look all the time, at the molecular 510(k) and molecular genomics
14 summaries, because I need to see what's going on in that field. But a lot of times when I'm
15 working with developers, they have no idea that those even exist, or where they exist, or how to
16 access them, until I send them a link. So, there's a lot of great data up on the FDA website, but
17 I'm not sure that everyone knows how to access it, and maybe there needs to just be a button
18 that's an accessing data tutorial. I have no idea, but you know, that's the kind of thing that I
19 think that, from my perspective, if you guys have run down such a great job of getting the data
20 online, now we just need to make sure people are A) aware that it's online, and B) have a
21 comprehension of how to find it. So, because, somebody, a web person designs things and they
22 think it's really super logical, but then for me, and I'm not a web person, it's not logical to me.
23 So, that's my two cents worth. I'm just going to throw that out there. And then, I'll call on Dr.
24 Blumberg to start us off with different opinions.

1 Dr. Blumberg: Emily Blumberg, University of Pennsylvania. First, I want to thank you for such
2 an incredible presentation and for the answers to the questions. I actually learned a lot just in
3 the past hour from everything that you've said, and I, well, you're asking partly about test
4 developers. I want to speak about the community, both the physician community and the larger
5 community. I think the FDA needs to find communication that actually is more easily
6 accessible to practitioners in the moment. I know FDA members were periodically on the IDSA
7 sponsored calls. But I think that it wasn't really a fully effective outreach for the larger
8 community and definitely for the lay public. I mean, the rapidity with which you provided
9 resources and, for us practicing, and the tremendous amount of work that went into this in such
10 a short period of time, I think is extraordinary. And I don't think was fully appreciated by
11 people. I mean, I learned so much about how things went, to actually bring testing to fruition
12 and to the public, and I think there has to be some outreach that includes lay media, lay, you
13 know, like, you need to do something that really showcases, because I think that would restore
14 public trust to a large extent. I think during Covid public trust has been hard to maintain for a
15 variety of reasons. But I think the work that really has happened is impressive and there needs
16 to be, in addition to the fact that the website's very challenging, I mean, I find it challenging.
17 There needs to be other mechanisms, social media, things that actually showcase what's going
18 on in a way that people can really learn what's been going on. And that's both accessible to
19 practitioners, whether that's every single medical professional society needs to have some sort
20 of interface as well as, you know, major media markets. But I mean, I'm really impressed at
21 what's been accomplished, and I'm sad that the public is unaware of how much and how
22 quickly it happened.

23 Dr. Van Der Pol: Thank you, Dr. Blumberg. Mr. Spring.

1 Mr. Spring: Yes, thank you. Brad Spring with Roche Diagnostics. So, I'm just going to focus
2 on the first question, but just make a statement that, because I represent all test developers,
3 manufacturers, I won't be commenting on some of the questions where you're asked who to
4 prioritize. But, having worked for my current company and prior companies dealing with the
5 pandemic, I want to echo the comments earlier, Tim, and your team, just what a great job you
6 did do, kind of plowing through a lot of the issues with pandemic and, you know, I think you
7 always did keep the public health in the forefront in the activities you did. You'll always get
8 criticism, you'll always be challenged, but I do think, in the end, I think you should be
9 congratulated on a job well done, but we'll look at some of these lessons learned and try to
10 make some improvements. I want to comment, though, on more specifics in this question. I
11 personally, and I've received comments from other manufacturers that continue the town halls, I
12 know you were doing it weekly. I think you went to what every other week and then less
13 frequent, which made sense. Those were very valuable, especially for new manufacturers, new
14 developers. I'm assuming some clinicians were involved, those developing LDTs, very
15 valuable. Telephone hotline, the website, while it might need to be redesigned and re-tweaked,
16 also very helpful. But I think as Dr. Van Der Pol said, there's a lot of information out there that
17 manufacturers just can't find. So, maybe there is kind of this, so called button you can press, or
18 if there is an FAQ that has just a listing of all the resources, that might be helpful. The EUA
19 templates are extremely helpful. I will say there's been some criticism from other manufacturers
20 on them being overly prescriptive. So, I think the advice is just to provide a little bit more
21 flexibility. But, again, very helpful. A lot of foresight went into those. And a lot of that's around
22 the communication side. As we look ahead to prepare for whatever's next, I reflect back on, and
23 I think Tim, you and I were there, and maybe other colleagues were there. There was an MDIC,
24 the medical device innovation consortium, convened a discussion during the Ebola Emergency

1 Use Authorization period, or the emergency. And we were talking about, kind of the lessons
2 learned with Ebola. How do we get specimens? So, a lot of these questions that were being
3 discussed, here, I think we were, we were having those discussions at that meeting. So, my
4 recommendation is to work with public private partnerships, other clinicians, in that planning
5 for whatever is coming next, and taking, say the lessons learned you have here with Covid,
6 trying to apply it to a future pandemic. But in that type of setting, where you get engagement
7 from everyone. So, I'll end my comments there. You know, Tim, I could probably go on about
8 this, but just wanted to give you that feedback. And I'll yield to Jennifer.

9 Dr. Van Der Pol: Dr. Stenzel, did you want to add anything? You unmuted for a second.

10 Dr. Stenzel: Oh, I was just saying thank you and you're welcome. Appreciate the input. I
11 didn't have anything specifically to say.

12 Dr. Van Der Pol: Okay. Ms. Schwartzott.

13 Ms. Schwartzott: Jennifer Schwartzott, patient representative. I wanted to follow up on
14 what Dr. Blumberg said. I mean, just the amount of information that we've learned in the past
15 hour is valuable. And I'm thinking like, just plain old informational webinars. Whether it be to
16 the test developers, whether it be to practitioners, on very specific topics, like, to the test
17 developers, you know, what's the process, that kind of thing. And to establish what the need is.
18 And then you can invite them to the town halls, show them where the information is on the
19 website, that kind of thing, but it gets them to say, oh, wait a minute, this is something different,
20 you know, and move forward. And, I mean, they're very excited. People are very excited to talk
21 about epidemic preparedness. They don't want to see what happened with Covid. So, that was
22 just my thought. That just, simple. Start simple and, you know, that's the way to get the
23 conversation moving.

24 Dr. Van Der Pol: Thank you. Dr. Petti.

1 Dr. Petti: Thank you. Cathy Petti, HealthSpring Global. As we've all learned in this world,
2 we all communicate differently. So, town halls, which is oral discourse, obviously the website.
3 Unfortunately, the FDA website has a lot of text, and I think we would benefit more from charts
4 and figures, particularly when you're trying to go through the steps of an EUA authorization.
5 Colors and boxes, I think would do very, very well. An index, I mean, I, like Dr. Van Der Pol,
6 go to that website frequently. And sometimes I forget how I got to this gem of a document, and
7 then I get frustrated. It's like, I saw this just last week. How can I not find it again? And we're
8 frequent users of your website. So, that is mission critical, because there are just amazing
9 nuggets of information there. I also would encourage the FDA, and I'm not sure if you have the
10 authority or charge to do so, but perhaps have a standing advisory committee, from, not only
11 representatives from the community, patients, different backgrounds and industry, academia. In
12 order to understand how to communicate out, you probably would benefit greatly from troops
13 on the ground. And this is what we're hearing. These are the resources and tools we need.
14 Wouldn't it be great, if Dr. Stenzel's Twitter feed would have various different ways of pushing
15 information out. So, you may already have those committees, but I would strongly encourage
16 FDA to have that, in a standing way, because we all know there's a huge vetting process to even
17 have people advise the FDA. So, perhaps do that well before pandemic hits. So, again,
18 communicating in various different channels will benefit all, because we all learn and receive
19 information differently.

20 Dr. Van Der Pol: Thank you. And I'm going to add a tag on to that, that I have an
21 organization that I work with that uses what they call digital champions. And basically, it's not
22 about creating content as much as it's just about forwarding content within their networks. And
23 so, by having, you know, about 200 digital champions, they reach millions of people. Because
24 each of those people, and again, not creating content, but just retweeting, or just, you know,

1 moving things along in whatever platform it is that you use. I'm not good with digital media,
2 but that's why I learned about this process, because I have to have help. I can't do it. But this is
3 a process that requires pretty little effort. And wouldn't require a ton of vetting necessarily,
4 because these people would not be speaking on behalf of the agency, but would just be passing
5 messages along to really improve that outreach effort. So, I think that that's something, the
6 digital champions, something to consider as well. Yes, Dr. Stenzel.

7 Dr. Stenzel: Yeah, I just wanted to make special note that this particular pandemic
8 preparedness panel, this advisory committee, under statute now, we will be meeting at least
9 annually going forward. So, this is, you know, a standing function. This is the first, of many,
10 and it's primarily, almost entirely focused on IVDs. Future ones will likely be involved in other
11 pandemic preparedness topics, other than IVDs, but IVDs are obviously the first one here and
12 we're happy to kick it off. The other thing is, you know, there's been a lot of mention of
13 communication. The FDA does social media. Facebook, Twitter, LinkedIn. We use email blasts,
14 so we, you know, you can sign up for the email blast. So, and these email blasts and these social
15 media postings, do hit tens, if not hundreds of thousands directly. And those folks can amplify
16 that as they wish. You know, we do communicate regularly with the media. We got almost daily
17 inquiries from the media recently. One of the most recent things that was picked up by the
18 media was expiration dating updates for OTC tests. That was that was picked up by many
19 media outlets and, you know, in fact, I shared that with a friend who didn't know how to
20 determine whether there, I shared one of the new stories with a friend, because that was the
21 easiest way for them to understand how the updates occurred to the expiration dating, and the
22 link to the FDA website where they could look up their specific test. Look up the lot numbers,
23 and determine if the expiration dating had been updated, and if their current tests were still
24 therefore in date, even though the printed date had passed. So, but, we always are looking to be

1 more effective. So, I do appreciate all of this input. And the other thing on the website is, we've
2 added some charts, color, and the video is a little bit harder to do potentially. But we have
3 added search functions within, on certain, so if you get to the right location where the tests are
4 listed, then you can search, there's search boxes for trying to find the test you're looking for, the
5 features of the test you're looking along. Is there a home test or is there a home collection?
6 Those features, those keywords can be searched. And we did constantly look at the website and
7 try to update it to make it the right size and as easy to access as possible. We understand there
8 are still challenges, and we appreciate the input.

9 Dr. Van Der Pol: Dr. Pereira.

10 Dr. Pereira: Hi, Marcus Pereira, Columbia University. I want to echo what Dr. Blumberg
11 said, in terms of how incredible this last hour and a half have been in terms of learning more
12 about everything that the FDA did during those initial months and thereafter. Really quite
13 impressive. You know, in terms of sort of the communication aspect, I do think that sort of, you
14 know, a greater effort in particularly having sort of communication champions within the
15 agency, who are tasked with sort of providing information to several components, right, of the
16 health care system, in terms of industry, but also to providers and to patients, I think would be
17 enormously helpful, in particular sort of people who can be very engaging and answering
18 questions. I mean, I have to say, one of the strengths of the FDA is the documents that it
19 produces. You know, and sort of when Dr. Cotton mentioned previously about the package
20 inserts, you know, for the EUAs in particular, I found myself constantly reading those
21 documents, whether it was for therapeutic agents or more importantly, actually, for the
22 therapeutic agents and sort of what they were supposed to be used for, and what they were not
23 supposed to be used for. And actually, I did use a lot of those documents for my lectures, to
24 fellow providers and even to patient groups who wanted to know more information. So those

1 documents were actually a great source of information and authoritative information, but
2 certainly they had to be distilled to the public at large, you know.
3 The serological tests documents were a little bit less helpful. We did find ourselves sort of very
4 confused by sort of, when to use all of those serology tests, as you alluded to, and there's
5 enormous debate, for example, in the transplant community in terms of, you know, how to use
6 them, whether to assess whether someone had responded to the vaccine or not, people were
7 becoming very creative with sort of new tests that were coming. And there was sort of, I felt at
8 that moment there was a little bit of lack of information from the FDA in terms of whether you
9 should or should not, or under what circumstances those tests could be used, and could have led
10 to a little bit less confusion. And that's where I think sort of, some communication officers
11 would have been helpful. The last point I wanted to make, in answering your question,
12 obviously, I'm not a developer, not a person from the lab. But one of the things to think about,
13 in preparing for future pandemics, because obviously, they're never going to be like what the
14 past pandemics. And I think that we can obviously learn a lot from Mpox and Covid-19 and
15 everything, but sort of maintaining a certain sense of creativity, so to speak, and what may
16 come next. I think it's obviously paramount here, right? You want to sort of figure out what
17 could have been done better and what went well with these past ones, but also prepare for the
18 things that you cannot even imagine at this point. So, to that effect, I don't, this might be a
19 question. Is there, does the FDA, or sort of the public health sort of authorities, ever, sort of,
20 undergo simulation games? Like, you know, preparing sort of a certain type of pandemic that
21 comes, and are the agencies prepared, and are they, sort of, have the communications and
22 relations with industry prepared?

23 Dr. Stenzel: Yes, yes, we do prepare. In fact, prior to Covid, we had assigned an interagency,
24 MOU, a tri-agency, CMS, CDC, and FDA, and had met, started to meet, on a regular basis to

1 prepare prior to the pandemic. When the pandemic hit, we met weekly with that group. And we
2 addressed anything of need. And we still meet regularly with that group. Now we're more
3 focused on preparations for the next potential pandemic. We also have expanded a lab group led
4 by the CDC, as well. So, the FDA is now an active member of that. And yes, I also wanted to
5 comment that the FDA did what it could as far as how to use tests, and for, you know, which
6 depended on the validation of the test and how well it worked for certain groups. And then
7 provided that information in the instructions for use package insert, in the intended use
8 statements. We also try to do some additional things, but it was always in collaboration with the
9 CDC, which is the entity that does take lead for communicating to clinicians, laboratories, and
10 public about how to use, in this case, how to use tests, whether they be diagnostic or serology.
11 So, the CDC does take the lead on providing that kind of input and recommendations and
12 information. And we collaborate and coordinate very closely with the CDC. And most of the
13 time, anything critical is, you know, the FDA puts out, is that involves CDC, also gets to review
14 and vice versa. So, lots of communication there and collaboration and alignment on our
15 messaging. Thank you.

16 Dr. Van Der Pol: Thank you. Dr. Walker?

17 Dr. Walker: Hi, Dr. Walker, a consumer representative. And I echo the sentiments expressed,
18 and I want to say, you know, excellent job on what has already been done and communicated
19 thus far. However, I would be remiss if I don't say something from the consumer side. And the
20 world we live in now is a digital world. I don't know about you, but I take my cell phone with
21 me everywhere I go, from the restroom to the grocery store, so when I'm outside walking. And
22 when we're talking about communicating and reaching other stakeholders, such as patients,
23 such as individuals who look like me, there has to be, and I think somebody said it, a creative
24 way. I went and looked on Instagram at the FDA's page, and there was nothing that attracted

1 me, to want to, you know, browse through the communications that are put there. I went on the
2 website, and so, I'm saying all this to say that all of the communication that has already been
3 put out, we understand it. We understand it because we work, and we live and we breathe in
4 this field. But when we're trying to really execute and communicate to individuals who may not
5 understand, there has to be other methods that we can employ that will be creative, creating
6 reels on the Instagram page. If you want to, get something out quickly, post it on social media,
7 and it will spread like wildfire, but it's all in how it's presented. I have individuals in my
8 community who may hear something on the news that the FDA said, and they may not quite
9 understand it. So, they call me because they trust me. to interpret it, but then to break it down
10 so they understand it, in a language in which they get. So, hopefully I'm making sense of what
11 I'm trying to communicate, as it relates to the consumer side of things, and being very creative
12 to make sure that, you know, whatever measures and critiques are put out there, that
13 individuals, especially low-income individuals, African Americans, Hispanics, and Latinos,
14 fully understand and can take action to protect themselves and their community. Thank you.

15 Dr. Van Der Pol: And while I understand Dr. Stenzel's perspective that the CDC does a lot
16 of the communication for, you know, patients as well as health care providers, but I think that,
17 the world changed, and I think that the lay public actually has more of an interest in what the
18 FDA does than they ever did before. And so, even though CDC is the primary communication
19 mechanism for these things, people now, you know, it's so funny for me as a laboratorian to
20 hear somebody saying, oh did you use the antigen test or the PCR test? It just slays me because,
21 you know, two years ago I could have said, oh I'm going to use an antigen test for you, and they
22 would have gone, what are you talking about? So, the world has changed, but that means that
23 we need to keep that in the back of our minds. So, I think Dr. Walker's perspective is exactly
24 right. Even though that's not your primary focus, and even in this question where we're really

1 supposed to be focusing on how the FDA interacts with developers and manufacturers, I still
2 think that that lay user piece, especially once things are approved and people, as you just said,
3 you know, you were helping a friend understand what the extension and expiration date mean.
4 It's things like that, that people would like information, not from the CDC. But actually from
5 the FDA. And so, I do think it's worth reinforcing that how important it is to communicate with
6 all sectors, even though it's quite difficult. And I recognize that. I'm not good at it myself. So,
7 Dr. Stenzel, did you have some feedback for Dr. Walker?

8 Dr. Stenzel: I did, just a little bit, and thanks for the input. It's all very valuable to us, and I
9 would love to be able to do more, more quickly and, no excuses, and just to add, though, that,
10 the clearance process for any communication and the official communication is quite thorough
11 within the FDA, and within the government. So, it's very you know, we try to do that as quickly
12 as possible, and we have timelines dependent on the need. But we have our process, so, thank
13 you.

14 Dr. Van Der Pol: Dr. Caliendo.

15 Dr. Caliendo: Angie Caliendo, Brown. I just want to say that what Dr. Walker is saying is very
16 important, in trying to fight misinformation, right? And if you can get information to lay public
17 in a way that they can understand, that could be extraordinarily helpful. I just want to comment
18 on, coordinating with the CDC with your communications. I'm sure you were doing it; it just
19 didn't look like you were doing it. And I just think it would have been so helpful to physicians,
20 other providers, the public, if there was just more alignment. With, because you do have
21 different roles, I very much appreciate that, but to find a way to coordinate, I think would have
22 been helpful. I'm really glad you guys are now involved with their laboratory system, because I
23 think we'll get to that later. About things you could have done to help get us some information
24 across tests, that the CDC could have helped with. So that's just one thing, is that that the

1 messages were so scattered at times, that better coordination, I think, would have helped
2 everybody.

3 Dr. Van Der Pol: Thank you, Dr. Caliendo. And Dr. Honein.

4 Dr. Honein: Yeah, Peggy Honein, from CDC. Thank you. And I really wanted to congratulate
5 FDA on this extraordinary communication and really setting up all these town halls, the volume
6 of email that went through, keeping response times really short is incredibly impressive. I
7 would recommend, in addition to all those things, which I think are great to keep doing, is to
8 consider communication channels to reach people who aren't part of that community already
9 going to those town halls. So, thinking about, national scientific meetings that may be relevant
10 where something from FDA could help highlight it to people who aren't already plugged in to
11 the FDA system. You know, building on the comment by the last person, I think there are some
12 opportunities for coordinating with CDC, such as the clinician outreach communication calls,
13 or the COCA calls that go on, could be a good time for CDC and FDA to co-present and reach
14 the clinician community. There's a lot of existing calls with public health officials that go on
15 every week, which could be another audience to reach state and local public health officials
16 who can then amplify those messages in their communities. So, just encourage adding channels
17 to the extent it's feasible, so that you broaden the audience, and more people have the
18 opportunity to then directly access some of the ongoing things like the town hall meetings.
19 Thank you.

20 Dr. Van Der Pol: Thank you. Dr. Stenzel, your hand's up. I don't know if you want to
21 respond to that or if your hand's still up.

22 Dr. Stenzel: I just wanted to comment, you know, basically on the communication with CDC
23 and others, and the coordination, it can always be better, we know. But the testing coordination
24 group, which Kris mentioned in his talk, is ongoing. We meet approximately every other week,

1 and the CDC is represented there, high levels of CDC, I'm not sure if I should mention names,
2 but often the White House is on the call, and then many agencies, including BARDA, and
3 ASPR, CMS, FDA, of course, and NIH. And we're, you know, and this has been going on for a
4 very long time. It's in addition to the tri-agency calls that I mentioned between the CDC, CMS,
5 and FDA. And then in addition, I do meet with significant and publicly known leaders at the
6 CDC. It's a meeting between me and my office, and key laboratory personnel at the CDC, and
7 that is on a monthly basis. That started prior to the pandemic, and stepped up, and has included
8 visits to the FDA as well, by the CDC. So, we can always do more. We need to do more. Thank
9 you for the input. And oh, the other thing was, I was a frequent, if not weekly visitor on the
10 CDC lab calls, and addressed open questions as well as pre-submitted questions there. And on
11 the American Public Health Lab weekly calls, then moved to bi-weekly and then monthly. And
12 still, I'm invited back to those meetings on occasion. Also, the state epidemiologists' calls, I
13 was a key visitor and speaker there, and addressing questions. And have accepted numerous
14 invites to various meetings. I can't accept all of them, but if it's an important meeting, I have
15 somebody else on our team participate in those calls. So, but always can do more. So, thank
16 you.

17 Dr. Van Der Pol: Dr. Ng.

18 Dr. Ng: Thank you. I'd like to present the perspective from the clinical laboratory. I want
19 to commend the FDA. Your website, constantly updated with the EUAs, was the beacon of
20 truth and the lighthouse for us, to identify tests that we wanted to bring in, at a time when there
21 was no way to actually verify the performance outside of the submitted data. So, for me, your
22 website was perfect. You can push me all the stuff you want, but I want to go pull it when I
23 have time to pull it, and your website worked well. I want to add on to the communication to
24 the laboratory network. The CDC brought up that lacks laboratory outreach communication

1 system early on. We met weekly, the chat line was a pure tsunami of comments, questions from
2 anyone. It was overwhelming. I want to also comment about, when I think about
3 communication from a laboratory perspective, the key stakeholders for me are my users, which
4 are the providers, the epidemiologists, which is public health, and then underlying that is the
5 community, where the demand is. CLIAC happens to be a committee that brings together the 3
6 governmental entities, CDC, CMS, and FDA. We met through this pandemic. The agencies
7 were well informed of what was happening at the ground level. I do recall early on, one of
8 these meetings, our public representatives were Jennifer and Roblena, very passionately argued
9 for free home-testing. And this was early in the epidemic, and shortly thereafter it became
10 available. So, the role of the public consumer is critical and key in these committees, in case we
11 all are running down some rabbit hole that is not aligned with what the demand is. And then
12 finally, I would challenge this group. What is your role in the communication? My role is
13 everybody comes to me and says, what test are you offering, and why are you offering it? And
14 how does it perform? And you all know we're offering a test. We're basically flying the airplane
15 while we are building it. But more importantly, as part of a public health system, I work with
16 my county public health department, through the community organizations that stood up all the
17 pop-up testing sites, and through all the faith-based organizations that are intimately engaged
18 with our public health department to bring the message in an intelligible, clear to understand
19 and factual message to our community members. That's not something I can do. It's very clear. I
20 don't speak anybody's language. But it's through these partnerships that we can make that
21 message heard, and I would encourage everyone on this list to figure out what your
22 partnerships are and take ownership of that. That's what we have to do, sitting at the
23 intersection of science, and providing a service that everyone needs. Thank you.

1 Dr. Van Der Pol: Thank you Dr. Ng. Are there any other comments? I'm going to just
2 remind you exactly what the components of question one are: How can test developers best
3 interact with CDRH when preparing for a future pandemic? So, I think we've focused a lot on
4 users of product, and once products have an EUA, so if there's any comments that people want
5 to take a step back, before that. If you're a test developer and thinking about how to get
6 information about what information you need to provide to the FDA, is there a mechanism that
7 would be helpful? What communication strategies should be strengthened, and how do we
8 include other stakeholders such as patients and clinicians? That is part of it. And were any
9 methods of communication particularly useful, or are there things that you have novel ideas
10 about how the agency should approach communication? And I think we've got things in each of
11 those categories, but I just wanted to throw those reminders back out there in case anybody had
12 an epiphany and they wanted to share yet one more idea with us before I summarize.
13 Okay, seeing none, I'm going to give it my best shot. It is a complicated question. And I tried to
14 sort of sort the different responses people had. So, the interaction mechanism, particularly as it
15 applies to developers, I think, is really to think about how to improve the mapping of the
16 website, so that people can find those documents, those guidance documents, those other
17 people's already approved documents, so that people can model after what has been successful
18 for other developers. So, I think that that interaction mechanism could be improved on the
19 website. In terms of strategies for strengthening communication overall, make sure that you're
20 including data specific for providers, healthcare providers, but also make sure that you're
21 including methods of providing data to the public. And make sure that you're working with the
22 lay media whenever possible, and also including digital outreach strategies. So those are some
23 things that you have going on, but that could potentially be strengthened. One of the other
24 things in the communication strategy that came up, was using more graphics and alternate

1 learning mechanisms as opposed to text. Infographics are something like, for example, CDC
2 has really gone to. I would urge you not to lose the text. For example, CDC's STD annual
3 surveillance reports are now all infographics, and there's no text. So, for those of us who want
4 to read the details, that's a disadvantage. So, don't throw out the baby with the bath water, but
5 again, try to make sure that you're offering a variety of different ways to present those data.
6 Also, in the communication strengthening process, consider standing advisory committees,
7 which I think maybe you've just indicated. This is one of those standard advisory committees,
8 for pandemic preparedness. One of the things that we've heard sort of repeatedly in terms of
9 mechanisms that are really useful, is the town halls were very well received. Webinars,
10 providing basic information, exactly like the information that was presented to this committee,
11 to this panel today, about the activities that are ongoing and how much it requires in terms of
12 resources to present those activities. The telephone hotline was also very useful, particularly
13 mentioned by our industry representative as well. And the EUA templates were also very
14 useful, although it was suggested that maybe they be a little less prescriptive and a little bit
15 more broad in their content. Also, in terms of mechanisms that were most useful, do include
16 things like the basic information about how people should be accessing more information, or
17 how people should be going to start their process of developing studies and documentations.
18 But do start simple and include processes. I think that goes for not only manufacturers, but also
19 the lay public.

20 My husband asks me all the time, why does it take so long? This has already been
21 approved by the panel, but it's not approved yet. Because my husband's watching this Covid
22 stuff with a fascination that for a lawyer, I find odd, but he wants his vaccine booster and the
23 vaccine booster has been reviewed by the panel, but it's not approved yet. What's the holdup?
24 I'm like, I don't know. But apparently it's a burning question for some people. So, people like to

1 understand process and that transparency and process is helpful, just to say, oh I get it now, and
2 I'll just wait until, you know, it's available.

3 And then the novel ideas were, I think, probably the most important one, but
4 communicating clearly with all the public through a variety of different digital mechanisms, as
5 well as the email burst that you're already using, as well as, as the public. But also broadening
6 your reach by working more with national scientific meetings, and not to say that you're not
7 already doing that, but just continue that. That sort of outreach effort in places where people
8 may be not looking for the FDA, but the FDA is there, and they're usually very... Those
9 sessions, where the FDA is at meetings that are national society meetings, are always so well
10 attended. People really are so eager to hear what's behind the curtain. So, working with those
11 societies. And then that leads us in the novel interaction idea, and it's not novel per se, but
12 working with these public-private collaborations and building these networks. And it may
13 require multiple networks because when anything gets too big it's non-functional but maybe
14 task force or, you know, networks that include societies, academic institutions, a ton of public
15 health agencies, obviously. Many of them were mentioned today, including CDC, NIH,
16 BARDA, DOD wasn't mentioned, but probably should be included. CMS, APHL. So, these
17 public health agencies, academic institutions, large commercial laboratories, and
18 manufacturers. And so, if there are subsets of those groups of people that could be in a task
19 force to talk about emergency preparedness and strategies going forward that could perhaps
20 meet quarterly or on some basis, just to build those relationships, so that when something hits,
21 everybody is quick to mobilize and you start having weekly meetings instead of quarterly
22 meetings, something along those lines. Cathy Petti has a comment at this.

23 Dr. Petti: Yeah, I apologize. This is just a very quick comment, circling back to that very
24 first question. Since promoting development of new technologies is cornerstone in responding

1 to a pandemic, Mr. Spring, would you be able to speak to, when the EUA templates may not
2 have been sufficient for small startup test manufacturer, did you find that there are sufficient
3 resources, a hotline, where they could immediately engage with the FDA, such that they could
4 start the test development process?

5 Mr. Spring: Yeah, thank you. Brad Spring with Roche Diagnostics. And I think Tim, you'll
6 probably have some comments here too. So, the answer is yes. I mean, very early on the
7 pandemic I think we were all scrambling for answers on how to validate such tests and bring
8 them through the EUA process. And I know, from my experience, now, I don't work for a small
9 company, but FDA did make themselves available to, you know, they're rushing to get the right
10 resources on this. So, I don't know if a hotline existed early on. But, you know, you just have to
11 know who to call. I think that's probably the first challenge, who to call about this. Sometimes
12 you're calling Tim himself, or you're calling one of the reviewers, or Uwe or someone on the
13 staff there, but they did make themselves available. But I think too, the challenge with that is
14 getting inundated with multiple manufacturers all at once, and the ability to provide consistent
15 information is a challenge. So that first call comes in, you know, you're trying to give some
16 advice. Then the tenth call comes in. Are you giving the same advice? And that's why the
17 templates, I think, and other advice were very helpful, along with the town halls. And Tim,
18 maybe you can comment on when those town halls came into play, because I thought those
19 were helpful as well.

20 Dr. Stenzel: Sure. Tim Stenzel, FDA. So, the email was available very early, may have been
21 January, that you could request Covid template recommendations. And that was staffed, as Kris
22 mentioned, from early days, and we even went to two shifts. And we received submissions of
23 pre-EUAs, which was asking us questions, and we also received the EUA submissions, via that
24 email, and any inquiries about, you know, we got inquiries from labs about, you know, I can't

1 get this item. I can't get the swab. Could we substitute? Those email questions often, based on
2 frequency, would show up then as frequently asked questions on the FDA website.

3 Dr. Van Der Pol: And the town halls started when?

4 Dr. Stenzel: Yeah. The webinar town halls started in early March. First Monday in March
5 was the first, of 2020, was the first webinar. And we provided the access to the components of
6 the commercial access to components of the CDC test, on that first webinar, with lot numbers
7 that had been QC-ed by the CDC. And then, obviously we discussed the February 29th policy
8 on that on webinar, and then webinars and town halls were regular from then on. We also, in
9 addition to emails through the hotline, we also had calls. Everybody in the office that was
10 handling Covid inquiries would be on calls, including me. I mean, I noted the peak day, when I
11 had 22 scheduled meetings, during the pandemic. I don't know how I made it through that day.
12 And we took calls from test developers, labs, states, cities, Congress, and so, it was all hands on
13 deck 24/7 sometimes. So, much of this, obviously not visible to the public.

14 Dr. Van Der Pol: And I think that, one of the comments from the panel is that maybe it
15 should be made visible to the public, because we all many, of us worked with the FDA very
16 closely through this period. But also, many people did not. And so, I think you heard
17 consistently and with really high levels of appreciation, for the volume of effort put in by the
18 FDA and the rapidity of the response. I mean, if you think about January of 2020 already
19 having EUA templates. I mean, that's really incredible because not everybody in the public
20 health community was even taking Covid seriously at that point. They were thinking about
21 whether they should take it seriously, but you guys had already taken action, you know, with a
22 work product that was useful to the community. And I think that that response on the part of the
23 FDA cannot be overstated. And I don't really think the agency always, and it's not that you're
24 seeking glory, as much as, I think it would be really useful for the public to understand that

1 their tax dollars went into this, and that there was just this absolutely enormous, rapid, and
2 really high-quality response. And so, I think that the panel, I'm seeing a lot of nodding, and I
3 think the panel in general agrees with the statement, and it needs to be part of the record. And I
4 think that, when you think about novel mechanisms for interacting, I think getting this out into
5 the lay media is just another way to make sure that we rebuild that public trust, not only in
6 science in general, but in medical technologies as well. Because, you know, we kind of
7 constantly fight with that.

8 Dr. Stenzel: Sorry.

9 Dr. Van Der Pol: Oh, go ahead.

10 Dr. Stenzel: I was going to say that some of those conversations, many of those
11 conversations, were treated by the FDA as strictly confidential.

12 Dr. Van Der Pol: Sure.

13 Dr. Stenzel: Needed to be. But, you know, and we can always improve, but when repetitive
14 information or repetitive queries came in, we put out frequently asked questions on the FDA
15 website. We mentioned the town halls. We do safety communications. So, we would take that
16 information and those interactions and try to do something. But I hear your point that,
17 committee panel's points here, and we will redouble our efforts to make it more transparent.

18 Thank you.

19 Dr. Van Der Pol: Dr. Wentzensen.

20 Dr. Wentzensen: Yeah, thank you. I just wanted to just ask, and I'm not sure if you can
21 address that, but I, so, Covid-19 was an extraordinary event that hopefully happens very
22 infrequently. But for each of these, there are things rising somewhere and we read about them
23 in the news, and there is... That's probably like, things being initiated that prepare a response,
24 but then it's not needed. So, I wonder if you could comment on like, how many, and like, how

1 early these alerts happen, and when do you get engaged? Or is it at the stage when we're all
2 aware and is it kind of like when we are deep in this already, or how early can you react, and
3 how often does that happen?

4 Dr. Stenzel: So, the FDA typically, if not always, engages very early with CDC and other
5 public health authorities and other agencies. So, for Mpox it was the earliest days. For the
6 recent Ebola outbreak in Africa, the earliest days. And, you know, things pop up that don't ever
7 make it public, that the U.S. government agencies prepare for, and hope that we don't have to
8 do anything. You know, I would say that avian influenza is something that's been, you know,
9 top of mind for a very long time, for those not aware. You know, avian influenza has been very
10 problematic for, at least among birds, in the United States and around the world. And we have
11 been monitoring it very closely. We, we've looked at available flu tests, and whether or not they
12 can detect avian influenza, and have reassured within US government agencies that yes, we
13 have the needed tests, if and when it might be needed, to respond to a flu pandemic involving
14 avian influenza. But, you know, that's an ongoing, all the time activity, but when we don't need
15 to broadcast that, we realize that, you know, when we say something, even if it's to say don't
16 worry, it can you know, raise attention that isn't necessarily helpful. So, it's a balance. Always a
17 balancing act, you know, when and how to communicate on something.

18 I wish there were more ways to show how much, and how effective, both the FDA and
19 the U.S. government working together, is. I mean, this role that I play and within the FDA, this
20 is the most professional organization of any that I've been in, and I've been in academics, I've
21 been in industry, now the FDA. And it's really, you know, truly amazing how the U.S.
22 government works together, most of the time, behind the scenes, to anticipate and prepare and
23 to respond. And a lot of it goes unsung. We're not looking for kudos. It's just, it's our job, you
24 know.

1 Dr. Wentzensen: And I think it's an important message to put out, even if you can do it at a
2 very high level, and maybe you have it somewhere, but it's like buried in layers of FDA
3 homepages. But I think like, just a general statement about that there is an alert system, that
4 functions all the time and that's the reason why the response was so fast. Because otherwise, if
5 you had started in March, when everybody now was aware, I mean, this would have been much
6 later. So, I think I think that's a very important message, and people now actually understand
7 after having gone through one, how important that is. Because before you get all these scares
8 left and right, and it never comes here, and so it's yet another of those. But I think that that's an
9 important, like, positive message to put out there.

10 Dr. Stenzel: Thank you.

11 Dr. Van Der Pol: Dr. Moore?

12 Dr. Moore: Yeah, just to echo that, I, you know, having worked in the government myself
13 when I was at the NIH, and, you know, the government is in fact staffed with many, many
14 professionals who take their jobs seriously and, and functionary, despite what you see on the
15 headlines with the politicians and political yin yang, but, it's very clear that it, you know, that it
16 works well when, especially when it needs to. My question is, yesterday it was announced that
17 the Biden administration stopped, had to stop funding for the deep VZN, the research into
18 zoonotic viruses. I'm not sure the reasons behind that. But the reason I bring this up, because in
19 terms of anticipating the next pandemic, do program changes like that require the FDA, or is
20 that something the FDA is involved with the CDC in terms of, as you mentioned, looking at,
21 something may not be public, that is looking at emerging viruses early on. And you mentioned
22 that you were doing that, that the FDA was involved, the CDC, and obviously avian influenza
23 and Ebola. But I don't know if there are other viruses, or other pathogens of interest, with which
24 you're engaging with, outside international authorities.

1 Dr. Stenzel: So, our surveillance system you know, for looking at potential threats, I don't
2 think is affected by that. But you know, I really can't speak to that. It's above my pay grade, on
3 all of that. But we're going to stay vigilant at potential threats. This focus today is primarily on
4 IVDs, and our authorities and systems are in place. Fortunately, you know, in today's world, test
5 developers may only need a sequence of a new virus to develop the test. That's typically all
6 they need. They need a good sequence. The more sequence they have, the better they can
7 design the test. And so, the world is very open in many ways. Some places are not so open, you
8 know. But even those not so open places, we got an early sequence out of, that was used for the
9 Covid response, and that was incredibly valuable and needed, and helped us get a start, before
10 even, you know, spread to potentially other countries. So, all I can say is that we're doing the
11 best we can with the tools we have, and we'll continue to work on, every day.

12 Dr. Van Der Pol: Thank you, Dr. Stenzel. I think that people have raised their concerns, as
13 well as the things that they think are going well and right. Do you feel, Dr. Stenzel, that you've
14 gotten everything that you need related to this first question?

15 Dr. Stenzel: Yes. Sorry, I was on mute. Yes, I think this was a lot of input, a lot of very
16 valuable input, and we'll be examining this and redoubling our efforts, so thank you.

17 Dr. Van Der Pol: I was going to say, this is one of the ones where you're going to have to
18 go back through the transcripts and really, really read it and take some time with it.

19 Dr. Stenzel: And we have talented communication experts within the FDA, and they will be
20 with us looking through these transcripts and seeing what they can do. It's not members. I
21 mean, certainly content-wise, members of our office provide content for the FDA website, but
22 we're not website designers. We're not we're not coders for the website, but we work with them
23 closely and communicate with them on a daily basis.

24 Dr. Van Der Pol: Dr. Kotton.

1 Dr. Kotton: Thanks, Camille Kotton, Mass General. So, for the past three years, I've been a
2 member of the CDC Advisory Committee on Immunization Practice, and one thing I've learned
3 is just how easy it is, as an ACIP, member to access so much at the CDC, and then for my
4 institution and for colleagues, including many colleagues on this call, I've been a point of
5 access. And I feel like I'm sort of an ambassador between the CDC and then the largely
6 academic, medical world. But I guess I would think about whether, you know, even a call like
7 this, I think many of us on this call we've said great things about the talk this morning, and the
8 work that's been done, and the amazing work by the FDA. I think that we could almost serve as
9 ambassadors to the FDA, in that, if you had more people like us in the community saying like,
10 oh yeah, you know, there's a great FDA website on that, or let me show you how to answer that
11 question, or actually I know someone at the FDA who would be interested in talking to you
12 about that. I do think that we can serve an important role, kind of as ambassadors or liaisons, or
13 it whatever it might be. And for many of us, we felt, at least the way I was brought up, is sort of
14 the FDA and CDC were like federal agencies that were hard to penetrate and might even be
15 unfriendly or not interested in what we have to say. And it turns out it's actually quite the
16 opposite. And, I mean, I had amazing conversations with different, largely vaccine people at the
17 FDA, when things were especially challenging. But I will remember the nighttime calls, like,
18 being available anytime, just to basically save lives during this horrible time. So, I would just
19 think about us as ambassadors.

20 And then, I keep thinking about this as well, but both the CDC and FDA could probably
21 use a little bit more marketing, which is something that we don't really think about much in
22 academic medical circles. But now we are being encouraged to do so. And I mean, honestly, the
23 FDA is amazing. Amazing. Amazing. Amazing. So is the CDC, right? And it's been horrible to
24 watch, especially the CDC, kind of get beaten up during this time. And so maybe just, I don't

1 know what marketing looks like there, but if I were in charge, I guess I'd try to do a little bit
2 more positive public information. Not that I know how to do that, and not that I know anything
3 about marketing, but I think we all probably know what I'm talking about, because really the
4 work you do is the best in the world. So many countries follow what you do, what the FDA
5 does. And so, I would think, both about more ambassadors and more marketing. Thanks.

6 Dr. Van Der Pol: And I think, I would add on to that, if you feel that your role can be to be
7 an ambassador for the FDA, and if you're involved with a society that has annual meetings
8 and/or you see, when they say, do you want to submit an idea for a symposium? Speak with the
9 person at the FDA that would be related to that topic. Speak to the person at CDC, whatever,
10 but invite them. I have found that to be a super successful strategy for making it really clear. I
11 think there was a perception, in my particular field, that the FDA was just the stumbling block
12 we all had to get over, right? And I think that making people have a better understanding of the
13 process, the rationale, and the willingness, as you said, of the FDA to actively work with
14 industry to really meet common goals and needs. I think it's on those of us who are involved in
15 those national meetings to make sure that the FDA is invited. They can't invite themselves to
16 give a talk, you know? We have to actively reach out and say, is this something about which
17 you can talk? And then are you interested in doing that? So, I think that all of us on this panel,
18 you know, probably have access to people that plan meetings. And we should just be thoughtful
19 about that. That's a novel strategy as well for getting information out there. And I think that we
20 can be involved in that. Dr. Stenzel.

21 Dr. Stenzel: Yeah, CRH has a speaker liaison, and our office gets daily invites to speak at all
22 levels of our staff, and we want to meet those needs whenever we can. And we do have travel
23 funds. We can't accept outside funding to travel, but we do have sufficient travel funds to go to

1 meetings. And sometimes our staff are incredibly busy, so, virtual participation is always
2 greatly appreciated when schedules are tight. Thank you.

3 **Question Two**

4 Dr. Van Der Pol: So, I think I'm going to wrap up question one, unless there's anything
5 else that people, I think we're going to move to question two, because we have time still before
6 lunch is scheduled. So, if we could see question two up on the monitors. I'm wondering if we've
7 already answered some of these, the components in here, with what types of educational
8 resources or communications from CDRH would be most valuable, again, from the perspective
9 of aiding test developers. So, we're trying to think about what can the agency do to make it
10 easier for test developers to get data and products onto the market, so that in the future when it
11 comes to pandemic preparedness, we're moving quickly. Are there items that people would like
12 to discuss that we didn't discuss during that first question, because they are somewhat
13 interrelated? But any educational resources or communication strategies that would be part of
14 reaching out to developers. I see Dr. Ng has her hand up.

15 Dr. Ng: Thank you. I am curious. I kind of view this as a pyramid. The ground level is
16 there's many, many, many people who are interested in developing a test, but sort of getting
17 from that and having it available, that middle section, is how adequately can they scale up and
18 what is the plan for scaling? And are they aware of what are they planning for? Whatever type
19 of demand there might be.

20 Dr. Van Der Pol: Can we drop the slide presentation?

21 Dr. Ng: And perhaps question number three might relate, might be the bridge to talk to
22 the developer, and then which manufacturers they can work with, who can scale up, right?

23 Dr. Van Der Pol: I think that that's going to be the key in three. So right now, but
24 educational materials about, or just documents about, what scaling might be useful.

1 Dr. Ng: Yeah, the FDA to say this might be a possibility, right? And then how would you
2 respond?

3 Dr. Stenzel: We were making inquiries of test developers early on in the pandemic about,
4 you know, throughput manufacturing, and was monitoring that, early on a daily, weekly, if not
5 daily, basis. A test availability, volume of tests that were produced, and providing that
6 information within the U.S. government. And then as we moved ahead with prioritization, we
7 were asking for the volume numbers and for kit manufacturers that we wanted high-throughput,
8 high-volume test manufacturers when we had plenty of manual low-volume tests already. We
9 were prioritizing those. Some of the lessons learned, part of, you know, and I think we'll get to
10 this in other questions. How do I identify which manufacturers, what types of tests, what kinds
11 of manufacturers to identify, to work most closely, perhaps, with them, to make sure that they're
12 ready. Then, within the U.S. government, there did become financial resources available to
13 invest in scaling up, so that, in the RADx program or one, ASPR also, BARDA. So, there were
14 eventually funds to help with scale up. If the manufacturers that had tests that we needed, didn't
15 yet have the manufacturing scale to meet the needs. And those efforts were really amazingly
16 successful. So, those are clear lessons learned.

17 Dr. Van Der Pol: I think we'll come back to that as well. So, keep that in the back of your
18 mind, and be thinking about different types and priorities. But I'm going to... Dr. Petti.

19 Dr. Petti: Cathy Petti, HealthSpring Global. I think, in addition to those EUA templates
20 that we could issue to emerging test developers, about, if there were a pandemic, this is what it
21 would look like. I think importantly though, it is an important communication to relay. And
22 should you develop a test, these could be prioritization strategies the FDA will use to accelerate
23 EUA review. And obviously it's a fluid process, but I feel like many, particularly startups were
24 caught off guard when the prioritization strategies were released, and especially as we all know,

1 in this world, people have very short-term memories. Will people remember? Oh yeah, I either
2 have to be a high-throughput, high-volume test, or really cost-effective, easy to use home-based
3 test, where I could also scale up a supply chain. And even if we were to foreshadow that, I think
4 that would be important communication pre-pandemic. I also think an important
5 communication would be, a potential expectation is, a proficiency panel with an artificial
6 matrix that you may be expected to use, to see how you perform against other potential
7 manufacturers. Because I think some manufacturers were caught off guard when those kinds of,
8 I won't say roadblocks, but...

9 Dr. Van Der Pol: Requests.

10 Dr. Petti: There were expectations that were placed on new test developers. And I think
11 they're important, but those new in the business, as we all know, analytical validation is not a
12 simple process. And matrices are very different for different kinds of tests and different sample
13 collections. So, almost educating new test developers. This is what we might expect.

14 Dr. Van Der Pol: Dr. Stenzel.

15 Dr. Stenzel: Yeah, we engaged with over 1000 test developers during the Covid test. And
16 many of them were new. And the town halls and the webinars and the templates were all in the
17 frequently asked questions. Were all efforts to assist and educate. We do, if there is new
18 guidance, we have rules against making foreshadowing, that public before it's issued. The many
19 new test developers were really not familiar with how the U.S. FDA operates. They gained an
20 education. I think there's a need to think about ways to educate all the, you know, so these, a lot
21 of these new developers got EUAs. Now, they're probably thinking about how do they convert
22 to a full authorization because, it is different. So, I will say we've been having that discussion.
23 And we have the q-sub/pre-sub process, which I don't even think most, you know, new
24 developers know about that process. It's a free submission to ask questions of the FDA. The

1 other thing to keep in mind is, even though there are EUA authorities during the pandemic,
2 there is also the full authorization pathway that's always open, even when the prioritization
3 happens, and by necessity, and in need, we needed to focus on the need of the day, and it
4 switched from central lab tests that weren't necessarily high-throughput or high-volume, to
5 point-of-care and over-the-counter. And now it's switched to multi-analyte. So, I understand
6 that lots of people are interested and have plans. I would also say that the pre-EUA process... If
7 we agree to something, just like through the pre-sub and the q-sub process, if we agree to
8 review something, or if we state something, we'd like to hold to that. We reserve the right to
9 change, you know, certain things if new information comes to light, but developers can always
10 use pre-EUAs. In fact, it may not be known. We're open to receiving pre-EUAs about any
11 potential outbreak at any time. It doesn't, you know, you're concerned about, X disease that
12 might come to the U.S., and you're thinking about developing a test. You can come in through
13 either the q-sub/pre-sub process or the pre-EUA process. Both are free. Both are always open,
14 and an avenue to explore. So, but I understand that it's really challenging, especially as a new
15 developer, and wanting to help out, and not knowing all the ins and outs that so many other
16 developers who've have FDA experience know, and aren't necessarily in neon lights out there
17 about how to do this or how to do that. But we were very open to helping everyone, in the
18 beginning, and we did open it up to everyone, which, you know, it'd be nice to get the panel's
19 input on whether that was the best decision to open up to everyone, because we ended up
20 having the opportunity to help a lot of new developers, and say about learning, and it, you
21 know... Is that the most efficient, effective way to respond in an emergency situation? So, but
22 we're looking to panel input on that.

23 Dr. Van Der Pol: Cathy did you have a follow-up?

1 Dr. Petti: I did. So, I hear loud and clear how the FDA may not be able to foreshadow,
2 then perhaps we can have a little button on the FDA website. This is your how to Covid-19
3 packet, that test developers could, it could be their guide for when we have our next pandemic.
4 And in that how to Covid test development packet, it would say, this is the evolution of
5 prioritization. First, it was the high-throughput, and then all the way to the multi-analyte, just to
6 get their wheels turning, because I believe knowledge is best when it's distributed, not
7 centralized, as does the FDA. I don't want to lose these precious lessons that we learned, and
8 wouldn't it be great if it could just be in a little button on the FDA website, because as we all
9 know, the FDA sometimes can't issue things as quickly as they would like. There's a process.
10 But perhaps manufacturers can then look to well, this is what was working with Covid. It may
11 not be the same, but at least I can get an idea.

12 Dr. Stenzel: Yes, thank you for that recommendation. I will point out that in the three reports,
13 following investigations or inquiries and other activities around the FDA response on IVDs,
14 that Kris noted in his presentation. There are recommendations around preparation, and we take
15 those recommendations seriously, and they do include the recommendations that you just made.
16 So, and we would be, you know, not doing our duty, if we weren't working on those things. I'll
17 just say that.

18 Dr. Van Der Pol: And, I have a comment. I'm not sure if it belongs really on this question,
19 or maybe on the next one or two, but I'm going to throw it out here when we're talking about
20 education. And one of the things that I learned during Covid and, you know, it used to be that
21 diagnostic assays for infectious diseases were developed by microbiologists, and they had an
22 understanding of the bug, or they were developed by, you know, closely working with
23 clinicians who had a good understanding of the disease. That's not the case anymore. We're
24 really working more with engineers, you know, bioengineers and people who do biosensing and

1 all kinds of people come up with this really fantastic technology for us, but don't have nearly as
2 much understanding of the pathogens, of the realities of clinical outcomes. I don't know if it's
3 quite within the FDA's purview, but when we're thinking about educating manufacturers, if
4 there could be some sort of document that teaches people something about use case scenarios,
5 because I think that in different use cases, we have different requirements for sensitivity and
6 specificity, for example. I mean, I know we'd always like them all to be as high as they can be,
7 but you know that there's a tradeoff. And the thing that kept coming, and I'm not exaggerating
8 this, I kept getting calls about how are we going to get people into Alabama football games? We
9 need to screen 100,000 people very quickly because the game must go on. And I mean, this is, I
10 am not making this up. This is my reality.

11 But so, when people were talking about a volatile organic compound detection method
12 that had terrible specificity, but excellent sensitivity, so they could just block people from
13 coming into the game, whether or not they had Covid, they had anything going on. Versus,
14 really trying to say, okay you have Covid so you can't come in for this elective procedure,
15 which is a very different use case. But these manufacturers had no concept of that at all, and so
16 they don't think, oh maybe I can get an approval for this because it will fit that one use case.
17 But that means that they need to think about that when they're creating an intended use, right?
18 Because those intended use statements drive, and the limitations of with whom or for whom
19 these products can be useful. I think that that lack of understanding of use case was one of the
20 most stark lessons that I learned during this whole developmental process. And I think that
21 anything the FDA could do to say, okay, during the early stages, our use cases, we need some
22 sensitivity and we're not going to care about specificity because we just have to find people
23 who are infected, until we get down to the next stage. And then we get to the next stage, and we
24 get to the next stage. And I think that that would be a really helpful, useful educational tool for

1 developers. And that's my two cents worth. But again, it may be outside the FDA's purview
2 because it may be something that people have to figure out on their own. I don't know.

3 Dr. Stenzel: No. No, no, that's well within, you know, the guardrails of this, of this panel and
4 the recommendations to make, you know, that we consider all those different use cases and
5 prepare for it and be ready to help develop.

6 Dr. Van Der Pol: Make sure we don't interrupt Alabama football.

7 Dr. Stenzel: Well, you know, but, you know, the same technologies that could screen 100,
8 000 people quickly can be used to screen visitors to the hospital.

9 Dr. Van Der Pol: Or airports.

10 Dr. Stenzel: Or airports, or other borders. So, you know, there are lots of connections to other
11 things as well. And we authorized the first breath test for respiratory virus, you know. Quite
12 novel. So, in support of those, and help, with developers of those novel tests are, you know, or
13 any device, is important. We have our breakthrough program at CDRH. The office I am
14 fortunate to lead leads the way in the number of breakthrough requests, and the number so far
15 of granted breakthroughs, for the center. So, lots of innovation in the test development field.
16 And that program allows some more attention to those novel developers, through our normal
17 processes.

18 Dr. Van Der Pol: Brad?

19 Mr. Spring: Yes, thank you. Brad Spring with Roche Diagnostics. Just a follow up to your
20 comment, Dr. Van Der Pol, is, first of all, I agree. I think it's not just in this environment of the
21 EUA and Covid. I think diagnostic manufacturers and developers have this challenge just
22 almost every day, as we think of developing new tests and what are the use cases, and what
23 would an intended use look like, but also what are the clinical guidelines that are currently
24 used? So, I think an educational resource that would be developed, and Tim may be already

1 thinking about this, not just with the FDA, but FDA outreach to experts in certain fields. Not
2 just the microbiologist, virologist, whoever we're working with, but maybe also experts in
3 certain technologies. So, obviously, you may not find that if the technology is brand new, and I
4 think that's some of the challenge too, that we face is, how do you even validate a new
5 technology when no one's ever seen that before? But I think convening kind of these, like,
6 maybe small expert panels, that would help. It would certainly help us as manufacturers
7 because we get a lot of the upfront challenges out of the way, and not learn the hard way after
8 we submit to you, what we should have thought of. And I think that's just a general comment
9 overall, but that would be a helpful approach.

10 Dr. Stenzel: Yeah, thank you, Brad. Not that we can't improve, but I do want to note some of
11 the activities around education that we already do. So, twice a year, the FDA hosts the IVD
12 round table for manufacturers, and I think that's open to all manufacturers. It's very well
13 attended. There's a didactic portion and then there's open question portion, and we have
14 restarted that. There was a little bit of a pause during the pandemic as we were having so much
15 focus on Covid test development. We interact with the medical device innovation consortium,
16 which is also open to manufacturers. We have, it's at least once a year, it might be twice a year,
17 with AMDM manufacturer association, a two-day didactic meeting that the FDA are the
18 educators, are the lecturers, to reach out to manufacturers. And then there is the collaborative
19 community program, where the FDA can recognize collaborative communities and participate
20 in those that the FDA recognizes. And there are at least four that are IVD related. One, for
21 example, you know, is a very hot topic these days, is on liquid biopsies. And so, these are just,
22 you know, as we're discussing, and there's just so many activities that we're already involved
23 with that are known to those communities, but aren't necessarily widely known. So I'd like to
24 mention them here. Thank you.

1 Dr. Van Der Pol: And maybe that speaks to, you know, increased diffusion of that
2 information, just so that people are more aware that those are out there. Whether or not it's
3 appropriate for them to all participate is a different question. So, do people have other
4 comments on this particular question, which was types of educational resources or
5 communications from CDRH that would be valuable for test developers responding to
6 pandemics?

7 Seeing none, I'm going to try to summarize. In general, I think that the panel has
8 expressed appreciation for the fact that there are templates like the EUA templates. And we find
9 that it would probably be useful to make sure that examples from the Covid process are made
10 available to people. And there was some mention that it would be useful to describe processes
11 for prioritization, so that it's transparent and so that developers know in advance what those
12 prioritizations, or as soon as they're available, let's put it that way. What those prioritizations
13 are going to be, so that they can know if they fit into that scheme. And I know that later in this
14 panel meeting, we'll start talking more about how to prioritize, and which types of tests and et
15 cetera. The other thing is that documents describing the requirements for scaling, and
16 requirements for proving LoD or LoQ against pre-created panels of pathogens would probably
17 be useful for developers to have in the back of their heads. And finally, some educational
18 materials around how to think about use case scenarios, so that people have a little bit better
19 understanding of that before they come to the FDA. And they would understand where their
20 assay might fit in a prioritization scale because of those use case options. Have I, is the panel in
21 agreement that I've captured most of what we've discussed? Okay, Dr. Stenzel, were there other
22 topics that you would like the panel to discuss on this particular question?
23 Dr. Stenzel: No, and really appreciate the abundance of feedback. We can always use it.

1 Dr. Van Der Pol: Great. So we're about 10 minutes early, but I think we'll go ahead and
2 break for lunch, and let everybody catch up on their emails and do other things, but we'll come
3 back one hour from now. So, it will be 20 minutes after the hour, depending on your time zone.
4 You should be able to work that out. Okay. Thanks.

5 **Question Three**

6 Dr. Van Der Pol: Welcome back, everybody. We're going to start up with question number
7 three that's in your packet. We have four remaining questions to review, and I would like to
8 remind you to please identify yourself each time you speak to facilitate transcription. So,
9 question number three is related to types of instrument manufacturers or test component
10 manufacturers with whom CDRH should collaborate in preparation for a future pandemic
11 response. Please remember that this is types of instruments and types of manufacturers, not
12 specific brand names per se. For an example, would earlier engagement from CDRH to work
13 with manufacturers high-throughput systems help ensure that well designed high-throughput
14 tests can meet be made available at an appropriate volume to meet the needs of any future
15 outbreaks?

16 And I think I might start just by saying that I think from my perspective, the types of
17 instrument manufacturers and test components that are likely to be critical since most of these
18 outbreaks are infectious diseases, we are likely going to always need collection devices, whether
19 that's for blood collection, or whether it's swab collection, and probably some sort of universal
20 transport media. And I think I bring this up because the stock outs on those supplies actually
21 were a bottleneck, even once we started having testing reagents available. So that's sort of my
22 two cents worth about test components. But types of instruments become then a sort of different
23 question. So, I'll open the floor up to get others' opinions on these topics and we can take the
24 slide down. Dr Caliendo?

1 Dr. Caliendo: Angie Caliendo, Brown. You know, when I thought about this question, what kind
2 of came to mind is the diversity of types of tests that we needed and that prioritizing one type of
3 instrument, or one type of platform is probably not a good idea. We talked a little bit about it this
4 morning about the ebb and flow of the needs of during the pandemic. And so, I guess my thought
5 is a broader range of manufacturers or different types of platforms that we could use. The other
6 thing that I have to say is I was still thinking, how is it possible that the FDA interacted with a
7 thousand different companies? And was that actually good use of their resources? How many of
8 those tests actually were used in any significant volume? And should there be different types of
9 systems? But do you really need a thousand companies coming to you with a test? So, I don't
10 know. But I'm afraid if we just prioritize one certain type of platform that you'll leave people
11 behind because one thing we really understood was the value of being able to test in our own
12 institution and not send it out, as far as turnaround time and the impact on care. And so, I think
13 we're going to need diversity. I don't think people would have predicted the supply chain. I don't
14 think any of us would have could have predicted that.

15 So, that's a whole other thing that Bobby just brought up that I think we really have to be
16 prepared for and that's in some ways easier to prepare for than you having to make a new test
17 because, as you said, Bobby, we're all going to need collection devices and we shouldn't be going
18 through that again. So, just some thoughts.

19 Dr. Van Der Pol: Dr. Stenzel.

20 Dr. Stenzel: Sort a follow up question for Angie or anybody else, Dr. Caliendo or anybody
21 else. Does it matter when in the pandemic, if you look at its phases, early, middle, late and you
22 look at the technologies and the lead time to develop them and manufacture them, for example,
23 molecular tests are probably the easiest to develop and deploy, what do we need early on from
24 molecular tests? And then, serology tests, what role do serology tests play and how much

1 importance should there be on them? And then antigen tests, obviously, can play a role, but they
2 take longer to develop, typically, if you don't already have antibodies. And in the beginning,
3 some developers used antibodies developed to SARS, the emergency that happened in early
4 2000s and it worked. It worked pretty well. It was amazing. But if you don't have antibodies,
5 you've got to develop antibodies and not just ones that that weekly bind, but ones that bind to the
6 right location and tightly. That can take a lot longer than we would wish to do so. And so, I just
7 would add that there could be different need for different kinds of tests at different points. And
8 then, are there any that are less important at certain points than others? So, just to sort of build
9 out some of the past.

10 Dr. Caliendo: So, it's interesting because if you look at Zika, for instance, the antigen test really
11 never came into practice. So, I do think you're right, molecular will often be the first out of the
12 gate. I do think we have to step back and ask the interesting question of what value did serologic
13 test ultimately bring to the table? And particularly early on. I remember when the first serology
14 tests came, people thought it was going to be a game changer. And I was confused by that.
15 Because how is this really going to help us decide who to immunize, who to treat, who to do
16 anything with? So, I think we have to be prepared to do molecular up front. Particularly, if you
17 look at the pathogens that you're worried about, I suspect molecular fits the bill for all of them
18 and whether they should be preparing now for unusual flus. Because I agree with you about
19 avian flu. So, it's interesting, but you're right, I do think you need molecular upfront for most of
20 these things.

21 Dr. Van Der Pol: And I think if you want to talk about what instrumentation, as Dr.
22 Caliendo mentioned, you need a broad coverage because it's not clear if you're going to do
23 serology or if you're going to do some sort of antigen detection, even if it's an ELISA, not a
24 point-of-care. But, if you're thinking about instrumentation that you might want to focus on,

1 having a preparedness plan, so not those that you necessarily do, because it will depend on the
2 outbreak. But I wonder if, in a broad way, it makes sense to say those instruments or those
3 manufacturers that make instruments that cover the spectrum, because there are large systems
4 that will do molecular and will do serology, and not necessarily in the same instrument, but those
5 instruments can communicate with one another. And I think that you will also want to make sure
6 that you put a focus on those instruments that have a user-defined capacity because that's going
7 to be supporting your lab developed tests, which is often your very first response to a pandemic,
8 is the large reference and/or research labs that can quickly turn out a lab developed test. And if
9 they can develop it on a standardized instrument, then it might quickly be applicable in many,
10 many lab settings. Sorry, took panel or chair's prerogative. Cathy Petti was next.

11 Dr. Stenzel: Well, I would like to riff off that. You're absolutely right. So open systems that,
12 any developer, whether it be an LDT developer, another developer, we know what those types of
13 common open systems are, might be the very first wave of tests, whether it's LDTs and/or kits.
14 But if the need for high-throughput, as we saw with COVID, that labs that were doing manual
15 setups on these open systems, they were limited in the number of tests that could perform per
16 day. And we inquired of them on a regular basis. And then, clearly, when high-throughput
17 systems became available and you could get the reagents, those were the workhorse. Those are
18 the workhorses of the lab, but that might take a little bit longer to develop tests for those systems
19 unless you pre-prepare for them, you sign up. The lessons we learned, especially from South
20 Korea, and as we thought about this, is if you can pre-prepare certain types of manufacturers.
21 You want those, common open systems that a lot of labs have to be used, perhaps very early on,
22 but you don't want to delay getting really high-throughput automated systems deployed to fight
23 the emergency is as well. So that's the kind of input that we really look forward to getting today.
24 Thank you.

1 Dr. Van Der Pol: But I think what I'm thinking of is not exactly what you're thinking of.

2 And that takes us back to definitions probably. But when I think about open systems, I'm not

3 talking about me having a thermal cycler. I'm talking about me having a Roche Cobas or an

4 Abbott Alinity or a Hologic Fusion that I can put my own primers and probes on, but that system

5 as a whole is a high-throughput system. So, if I get my system to work, then I can put the high-

6 throughput on that. So, I'm not talking about these small, with manual DNA extractions. I'm

7 talking about the automated systems, but that have an open channel, because I think that's going

8 to be one of our first wave responses.

9 Dr. Stenzel: That's excellent feedback.

10 Dr. Van Der Pol: And I'm not calling up those companies per se. I was trying to distribute

11 that over a lot of different manufacturing.

12 Dr. Stenzel: Those are and perhaps others are very high-throughput systems and to focus on

13 those that also have the so-called open channel or open modules that you can put your own tests

14 on. And they can be high-throughput early on. Um, but then when you get. When you get out of

15 the reagent business yourself, you can go to commercial reagents. So that makes sense. And it's

16 still a high-throughput. Okay, thank you for that clarification.

17 Dr. Van Der Pol: Yeah. All right. Cathy, sorry, I'd left you out for a long time.

18 Dr. Petti: Cathy Petti, HealthSpring Global. I think there are two questions within that first

19 question. Uh, first question is, which I think Dr. Caliendo and Van Der Pol articulated extremely

20 well is with what we know. And with what we know with these high-throughput systems, such as

21 the manufacturers that Dr Van Per Pol mentioned, very appropriate to have early guidance from

22 the FDA, where we could rapidly deploy an LDT on an instrument that is very well known by

23 the FDA and following that process all the way through on the supply chain from soup collection

24 to nuts, which is result reporting. But I think what's embedded in that question is, well, where

1 were our failure points and one of the greatest failure points wasn't just lack of supplies and
2 reagents all the way through, it was our technologists and the inability to have enough staff to
3 process specimens to keep up with demand, and that's in a large reference laboratory. So, I'm
4 going to speak from a very, very, very small community-based hospital where we did not have
5 that luxury and early in any pandemic response, we're not going to necessarily have those closer-
6 to-the-point-of-need instruments. So, I think I would charge the FDA to start having pandemic
7 planning with BARDA on what would be the more novel instrument requirements that would
8 help distribute, as Dr. Caliendo said, for having results tested on-site, no matter where you are.

9 I mean, there are technologies that use NMR. Could we use MRI instruments that exist in
10 almost every hospital in the United States? Like, I think we need to start exploring, if we're
11 trying to scale up a true pandemic response, let's not always focus on where the high-complexity
12 laboratories are for the early phase of the pandemic, but how could we distribute high-throughput
13 with instrumentation that truly already exists for technologies or platforms that aren't necessarily
14 even the laboratory setting? They could be in the radiology suite. And that starts very early on
15 with RFAs, RFPs, with BARDA now.

16 Dr. Van Der Pol: Mr. Spring.

17 Mr. Spring: Yeah, thank you. A couple of comments here, and obviously I won't comment on
18 the types because I represent all types out here, but maybe follow on what you were saying, Dr.
19 Van Der Pol, I think we have to do a landscape analysis first off and just saying what is out there.
20 You won't know specifically because it is business-confidential information, who has what, but at
21 least a landscape of all the systems out there, what are their capabilities and so forth. But I do
22 think allowing manufacturers, developers who put out these open systems, right now, we are
23 restricted from working directly with laboratories to develop tests. I think in an EUA

1 environment, we should be able to open up that and maybe address that challenge just because of
2 the urgency, and maybe carve out an opportunity there. That's one suggestion.

3 Maybe it's more of a question of the panel is, I don't think you can answer the question
4 today about a future pandemic, around who to work with first, where you should prioritize first,
5 but if you were to look back at, let's say, December, January, that time frame when we first
6 started to see it here, at least the United States, or maybe even earlier in other countries, would
7 we have been able to foresee? Because Dr. Caliendo, right, you're questioning the value of
8 serology, although serology seemed to have a bit of a prioritization at one point. Would we know
9 that high-volume tests would be a priority, in-home tests would be a priority, point-of-care and so
10 forth? Or is it something where you convene, and maybe the recommendation is, you convene
11 these expert groups, representatives of the public health sector, maybe reference laboratories, the
12 community hospitals, I think the moderately complex labs, around what are the needs there and
13 where should the focus be? And then we, as developers, or even up-and-coming developers can
14 prioritize our funding towards those initiatives. And maybe there is a type of scenario analysis
15 that can be conducted that would look at what a future pandemic could look like. Just some
16 suggestions there.

17 Dr. Van Der Pol: Thank you. Dr. Honein.

18 Dr. Honein: Yes, Peggy Honein from CDC. Just want to mention that early on in a response,
19 the public health laboratories are an important network to utilize. So, in thinking about which
20 instruments should be prioritized for preparedness, it would be good to look at what the public
21 health laboratories have and make sure that that selection of repertoire, which is not a single
22 thing, but which ones are the most common are also being prioritized early on and for
23 preparedness, so that the public health laboratories are able to play that initial role and really
24 make sure that testing is facilitated, can be expedited, can be prioritized for the greatest need and

1 can be a bit of a safety net system. Also, to emphasize, while I agree with a previous commenter
2 that it's probably not efficient to think of thousands of different devices, but it is important to
3 have some redundancies and not rely on too small a number of devices that are going to be more
4 impacted by supply chain issues so that having enough of a repertoire that when one is knocked
5 out from being a key player, there are others that we can turn to. And I know that the Laboratory
6 Response Network has collected a lot of that information on public health laboratories. Of
7 course, it's always changing, but that's something that CDC could make sure FDA has access to
8 so that that can help with their planning. Thank you.

9 Dr. Van Der Pol: Dr Stenzel.

10 Dr. Stenzel: Yeah, thanks for those comments as well. And the CDC works closely with the
11 laboratory research network to make sure that their needs are met. We have heard from those
12 groups and others that we certainly don't want to put all our eggs in one basket and have options.
13 We know that a virus like COVID mutates, every single base virus seems to have mutated.
14 Fortunately, tests have been relative. The ones that are authorized at least have been relatively
15 well designed, targeting conservation, we have encouraged two or more targets, for COVID,
16 especially being that it's an RNA virus. So, the redundancy, yes, is something that makes a lot of
17 sense, but I did want to say that public health labs, they're one of the first lines of defense and
18 preparation. It's definitely on the minds of FDA and we're interacting with them more than ever
19 before on an ongoing basis. And they're initiating efforts and they engage with us, too. So, we
20 appreciate that. Thank you.

21 Dr. Van Der Pol: Dr. Caliendo.

22 Dr. Caliendo: Dr. Angie Caliendo, Brown. Tim, one of the things that you brought up in your
23 presentation was this pre-authorization of labs, which I think is a really good idea. It could be a
24 broad spectrum that covers different platforms. And what Peggy said is really important. If now's

1 the time to do the inventory and what platforms are in our public health labs and our LRN labs,
2 and then if there's common themes, preauthorize some of those companies so that you can get
3 them out of the blocks. And again, it's not just one type, right? It wouldn't just be high-
4 throughput companies. You want a diverse array of platforms. But I think your idea for pre-
5 authorization is really, really smart because they will then be prepared, just like our LRNs are
6 prepared, right? These companies would be prepared to quickly shift and hopefully they'll be
7 doing internally what they would need to rapidly create a test. So, this is the way to link what the
8 LRN labs need and getting them to them quickly. And I was on a working group to advise the
9 CDC and one of the pieces of advice that we gave them was to make sure that the CDC tests that
10 come out that are usually the first tests out are on more than one extraction platform or more than
11 one amplification instrument so that they can be more widely deployed. But I do think there's
12 real value to that pre-authorization idea.

13 Dr. Van Der Pol: And I'm just going to jump on that bandwagon by saying the pre-
14 authorization kind of ties back into what I had brought up earlier with the open channel and what
15 Angie finished with, CDC, if they develop primers and probes and amplifying conditions that are
16 optimized. If I have an open channel on any of my high-throughput instruments, I can instantly
17 put that assay on all of my instruments, right? And so, if you're thinking about pre-authorizing,
18 I'm not even sure whether it's sort of a company or it's more to say it's the instrument because
19 you know that this instrument A) can do high-throughput, B) has an open channel, but maybe C)
20 has multiple components or modules. And so maybe it does molecular, but it also does serology,
21 or it also does whatever else we can think of that might be a requirement. Part of what we're
22 doing with this is where we might be doing like some sort of liver toxicities as an indicator that
23 this particular thing is really causing disease in certain people. And so maybe we need to hook in
24 with chemistry or maybe we need to hook in with hematology. And I'm not saying that we have

1 to have only platforms that have all of those components, but maybe those are somewhat
2 prioritized, but at the same time trying to recognize that we don't want to close the door to people
3 who have more point-of-care options instead of these huge monster options, but more point-of-
4 care options, but they still have quick flexibility because they internally have an open channel
5 thing. A great example of that is Cepheid with the cartridges, but they have a generic mix that
6 you can put primers and probes into that cartridge. So, if I just needed something at a point-of-
7 care and I got the primers and probes from CDC, I might be able to put it on the Cepheid, even
8 though that's not a high-throughput thing, my need might not be high-throughput.

9 And again, I'm not endorsing any particular company. I'm just trying to provide examples
10 of some of these different platforms and their structure so that we can think about maybe what
11 makes sense in terms of, especially if we're thinking about preauthorizing. But I think we need to
12 focus probably on the instrumentation. Dr. Ng.

13 Dr. Ng: Thank you. Valerie Ng, Alameda Health System. When we talk about high-
14 throughput, I like to split the hair into centralized versus distributed models of how testing is
15 performed. So, I'll start with centralized, and I'll focus on the large reference labs that have miles
16 of automated instruments that are put together. So, they can scale up pretty quickly if there's
17 something that's out there, but the blocks we uncovered were the front end, getting a sample
18 from an individual lab to the reference labs, that's FedEx, that's couriers, and then in the central
19 lab, the front-end accession, not the specimen prep, but just moving a sheer number through. And
20 then finally on the back end, how to get the result back to the submitting lab. This all points to
21 the need for an informatics backbone. So that's the central lab.

22 We've talked about if there could be a landscape of how moderate small community
23 laboratories, what their instrumentation is. And could we deploy in a distributed fashion of
24 preauthorized test? I can tell you, I would be very loath to use an open system and use a

1 preauthorized method, mainly because I don't have the intellectual expertise in my staff or
2 myself to verify or even validate that that thing is working the way it should be working. So,
3 what I would want is a preauthorized thing, maybe you have a whole row of primer bottles on
4 the wall, you send me a primer bottle and you send me an IFU for an EUA and I will implement
5 that. I would need the informatics underlay to in the instrument. How to program it. What are the
6 tolerance limits? You know, auto verification, all that other business. And then finally, I want to
7 comment around our beloved, truly beloved public health laboratory system. But what we
8 encountered in this pandemic, they have the same severe staffing shortage we do, ours works
9 Monday through Friday, no weekends, no holidays. They work one shift. At one point when we
10 were pushing through our COVID testing, we learned the critical point was to move the 96-well
11 plate manually from the sample processor to the thermal cycling. That happened at 11p.m. at
12 night. There's no one there to do that. My results would not come out until noon the next day
13 when the staff came in at 8a.m. in the morning to move that plate.

14 So, I asked, can I have permission to come into your lab and move the plate and I just ran
15 into a lot of bureaucratic stuff. Because that particular public health lab is housed in the same
16 building as the share. And so, there's all kinds of security restrictions and it took us forever. So,
17 what we ultimately had to do is ask our public health department to authorize overtime and
18 hiring additional staff, and that's what we went through. So, I just wanted to bring those points
19 out and to emphasize the importance of courier's transfer system transport, especially the
20 informatics backbone that is so critical to getting to the results. And as we also learn, we could
21 do the testing, but our state epidemiology systems could not receive this deluge of reporting. So,
22 we have to fix that on the back end.

23 Dr. Van Der Pol: Yeah, and I think that like in my lab, we would have told you no, because
24 from a CLIA perspective, you're not a qualified technician to move a plate from hither to yon,

1 and so do I turn a blind eye? Not in front of the FDA, no, of course I don't, wink wink, but you're
2 right. It ends up being a staffing issue, ultimately, and I think I agree with you about the
3 informatics support and lots of things.

4 Dr. Ng: The moving the plate is not a technical thing.

5 Dr. Van Der Pol: But it is.

6 Dr. Ng: So that's trained incompetency.

7 Dr. Van Der Pol: But it is. From a CLIA perspective, it is. It is part of running the test. Yes.

8 Dr. Ng: So, we can sidebar on that.

9 Dr. Van Der Pol: Well, regardless, I think maybe that's part of the other thing is that when
10 the FDA is working with other agencies and when they're communicating strategies for
11 preparedness, maybe they need to communicate where we can turn a blind eye from a CLIA
12 perspective, right? So not patient safety or quality of results, but little things like this that really
13 are meaningless, but under normal circumstances, we would be restricted from doing. Dr.
14 Stenzel.

15 Dr. Stenzel: Yeah, I just wanted to comment that, yeah, always can improve, but we did have a
16 great working relationship with CMS and there were definitely allowances by CMS to help deal
17 with the pandemic. Remote sign out, was one obviously, but also when we needed to start testing
18 folks who were without symptom, and there wasn't necessarily validation and authorization for
19 asymptomatic people. So, expanding the sites that could do testing. So, CMS was a great partner
20 during the pandemic, but obviously, from the FDA perspective, we can always get— (cuts out
21 due to muting).

22 Dr. Van Der Pol: Dr. Caliendo.

23 Dr. Caliendo: Angie Caliendo Brown. I think Valerie's point is really interesting for LDT
24 wouldn't have helped her or an open channel. There were many other labs that would clamor for

1 the same thing. Would have absolutely wanted that and couldn't get it fast enough. And I just
2 want to reiterate the diversity of what has to be out there to meet everybody's needs. And to
3 prepare for that ahead of time, I think, and, you know, the CDC probably should be part of this
4 conversation because most people that do LDTs that are not their own commercial companies are
5 going to use the primer pairs and the package that the CDC puts out. So, knowing that, what
6 platform should we tell the CDC this would be really good if you validated on these three
7 extraction instruments and four amplification instruments or something like that? Just thinking of
8 that stuff ahead of time, I think would allow people to burst out a little faster.

9 Dr. Van Der Pol: Thank you. Dr. Pereira?

10 Dr. Pereira: Marcus Pereira, Columbia University. I know that we're in the middle of a very
11 lab technical discussion here, and obviously I'm not part of that, but just a sort of a statement,
12 just to step back a little bit. I know we're talking a lot about molecular testing, but there's nothing
13 to say that in different pandemics, other forms of tests, and I know that we've talked about
14 serologies and antigen testing, but certainly those might prove to be more useful, not necessarily
15 from a diagnostic perspective, understanding that antigen test can be more complicated, but
16 certainly understanding which populations might be immune and non-immune, which may have
17 huge repercussions in how these pandemics are handled. So, as you sort of plan on pre-
18 authorization of certain labs, certainly focusing on the ability to rapidly develop those tests as
19 well might be important.

20 Dr. Van Der Pol: Great. Dr Kotton

21 Dr. Kotton: Camille Kotton, Mass General. In considering various test types, I guess I would
22 just request a somewhat of a focus on testing equity, in that some of the testing we do is very
23 expensive. Some of it necessitates expensive platforms, transport, all kinds of things. And, the
24 kind of work I do, I do transplant infectious disease. So, I take care of many people very far

1 away from academic institutions, northern Maine, northern Vermont, rural populations. And
2 especially during the pandemic, the access to diagnostics was often really highlighted where if
3 you lived close to Mass, generally, just pop by for a CR test and it was all good. But for many
4 people who live far away, there really was testing inequity. There were a lot of inequities
5 highlighted during the pandemic, but I would just argue for, testing equity and also financial,
6 looking at the cost of testing and thinking about equity there. Thank you.

7 Dr. Van Der Pol: Dr. Stenzel?

8 Dr. Stenzel: Thank you, Dr. Kotton. I wanted to respond. Equity is very important and equity
9 across sites and populations and locations and geography, whether it be at-home or in-clinic, and
10 cost is, is a big driver of that. And there isn't anything less expensive to the end user than a rapid
11 antigen test, although there's potentially tradeoffs, obviously on sensitivity. Though, specificity
12 can remain very hard. And it's probably important as well. So, part of, say, readiness or
13 preparedness can be focused on having this one form of preauthorized is a fully authorized test
14 that are say, pan disease. So, pan influenza and SARS. If we had such tests right now, authorized
15 as such, they could be stockpiled, or they could be ready to be produced in large numbers and
16 distributed very widely. And the other thing is there are technologies that could allow even today,
17 and distributed tests today, that are sort of universal pathogen on tests. And the ability to have
18 those in place or ready to be deployed to any site that needs to be testing, it could certainly
19 address some of the issues that we discussed and others we've discussed. Thank you.

20 Dr. Van Der Pol: Thank you. Ms. Schwartzott.

21 Ms. Schwartzott: Jennifer Schwartzott, Patient Representative. When I'm thinking about the
22 components of the tests, I'm also thinking about the packaging, the labeling, the instructions that
23 go with it. A lot of the problems that I encountered when I had Covid and with all the at-home
24 test kits and everything, that was one of the biggest problems. When I first got it in March of

1 2020, of course that's early on, but I went to the local urgent care, very, very, very sick. And the
2 young girl doing the test had absolutely no clue how to use it and she brought the other people in,
3 and they didn't either. And there was nothing to show them what to do. And Advent Health, I'm
4 sure some of you have heard about this, ended up throwing away tens of thousands of their
5 results because they were not properly done or whatever the other issues were with them. And
6 also, just like the at-home test kits. I mean, the ones I have here in my house that came from the
7 post office were wonderful. I did one at my brother's house and he and I both have master's
8 degrees, and we were confused. So, that's a big issue. So maybe, coming out with suggested
9 guidelines for how to use, like bring in a layperson on how to make these labeling decisions. And
10 it should be done ahead of time because if you wait till then they're so worried about getting the
11 actual specific disease covered, they're not thinking as much about those labeling issues.

12 Dr. Van Der Pol: Dr. Stenzel, I see you want to respond.

13 Dr. Stenzel: Those comments are really well received and important, and we've done our best.
14 We can always improve. So, when we put out the recommendations for home-tests in the
15 summer of 2020, one of those recommendations to developers was they needed usability testing
16 of their over-the-counter test their home-tests, which means they take inexperienced users, give
17 them simply the instructions and can the users follow them? So, that worked to a large degree,
18 but we learned later on, and this gets back to equity as well, that there were certain subgroup who
19 were, say, visually impaired or physically impaired, dexterity potential issues, comprehension
20 issues and we partnered again with NIH ITAP to address some of those needs. One such test, it's
21 the pen test. If you're familiar with it, was very, very easy to use, the simplest of all the tests. But
22 we did ask developers and reviewed it in our UA reviews. How did novice users in the home,
23 through usability studies, how were they able to do it? And then we also evaluated prospectively,
24 the accuracy of those users of performing the test.

1 But again, we didn't state this, but for an EUA authorization, whether it's an over-the-
2 counter test, the point-of-care test or a central lab test, we only asked for 30 positives and 30
3 negatives, so we're not collecting a lot of information. The numbers, the end, as we've decided
4 yesterday, we discussed the end or the number of patients in the study, is very small. And so, we
5 certainly didn't have the luxury of making sure that all sorts of types of users could do this. We
6 were focused on quick development of invalidation to a certain level of tasks that could assure
7 reasonable accuracy and expectations of accuracy. Thank you.

8 Dr. Van Der Pol: I think one of the issues that comes up with this, because I think Ms.
9 Schwartzott is completely correct that these things have to be evaluated by end users, because
10 what happens is when we do usability studies, often we do that in a clinical setting, but at a
11 research institution where our patients are not naive because they have participated in other
12 research projects, or they've done this, or they've done that. But then, even if it's their first
13 research project, they did self-select to be a research project. And so, they are at a level of
14 understanding that may be different from the average user. And so, I wonder if you know what
15 Ms. Schwartzott has sort of suggested was that if you had a panel of people recruited off the
16 street, as it were, we can do a Jay Leno session of interviews on the street. Can you use this
17 COVID test? But I think that it would actually be relatively informative. I don't know how we
18 would continue to recruit people because after a while people become educated. And so, you
19 can't have the same people giving you feedback all the time. But I think her point is really spot
20 on. And I would really encourage the FDA to think through a process where they could maybe
21 independently get a review of those instructions.

22 Dr. Stenzel: Right, and when we focused on folks who had certain physical impairments, we
23 reached out to those communities, it was primarily NIH, and had listening sessions. They already
24 had what was available at the time, so they could say what was good about these tests and what

1 was not good about these tests and what we really need. So, that was that was very helpful in
2 designing the next types of tests that could be more widely, more easily used. But the point is
3 excellent. Thank you.

4 Dr. Van Der Pol: Dr. Hoz.

5 Dr. La Hoz: Yes. Hi, Ricardo La Hoz from UT Southwestern, with a big caveat that my
6 expertise is not in laboratory medicine. But as I think through the last outbreaks and pandemics, I
7 think I've always been humbled on how all these pathogens may wreak havoc. But there's been
8 the respiratory infections that we've had, but at the same time, we've also had outbreaks with
9 diarrheal illnesses like cholera. And I wonder if we need to start thinking, they may all be
10 diagnosed in different ways. And for example, what are the nuances of testing on a respiratory
11 sample with a molecular assay, versus testing in stool, versus testing in tissue where a biopsy
12 needs to be taken from the skin and run molecular testing. And again, I am not a laboratory
13 person, but I think we may have to be prepared to test in different types of samples on what are
14 the nuances to testing stool versus respiratory versus tissue and so forth. And also, it brings us to
15 the idea of this diversity of testing for certain diseases. Maybe serology may be the test to go
16 because there's no compartment where molecular tests can be done, like a respiratory sample.
17 But also want to think about who were the most affected by the COVID pandemic and certainly,
18 those with comorbid illness, but currently a fair amount of the patients that we have in our
19 hospital with COVID are those immunocompromised, in which either a natural or vaccine-
20 induced immunity is waning. So, if the only diagnostic tests that we have is serology, we need to
21 be mindful that that may underperform in the immunocompromised patients, and we have to
22 keep that in mind that test may have to be developed for those at risk for complications that may
23 not mount a serologic response.

24 Dr. Van Der Pol: Thank you. Dr. Ng?

1 Dr. Ng: Valerie Ng, Alameda Health System. I wanted to respond to Ricardo, Marcus and
2 Jennifer because you triggered some things for me. Antibody testing, right? The antibody tests do
3 not inform on immunity, right? That was an assumption that was made. There are neutralization
4 tests out there, but what's the correlation of the *in-vitro* result to *in-vivo*, right? We don't know
5 that answer. So, in terms of antibody testing, there is some magical thinking about the value of it
6 and that magical thinking carried over into blood banking, that whole thing around convalescent
7 plasma. Right? Which was ultimately not shown to be effective, and it was rationed so that
8 created a lot of anxiety.

9 And then the second thing, there was a brief period, I think it was a companion drug? It
10 was either a companion drug monoclonal antibody, or it was a drug that was out there, but was so
11 heavily rationed that we were asked to bring up an antibody test overnight to identify who would
12 be eligible for that treatment. They had to be antibody negative. And so, some of those things just
13 rolling around about the antibody. For Jennifer, I wanted to tell you, my colleague of 20 years did
14 one of those home tests and couldn't figure out how to interpret it. He FaceTimed me and said,
15 what does this mean? So, I will say, the only thing I can follow is if it's in pictures. And the test
16 ID, which I got through the postal service, the back of the box says one, two and three and I can
17 follow one, two and three.

18 And then my final comment is around both social and structural determinants of health.
19 The communities that COVID disproportionately impacted, the unhoused, the undocumented
20 residents, they can't access any of this. So, I mean, they don't have smartphones, they don't have
21 phones, etc. So, it's really us engaging with our community outreach to try to take care of that
22 population. I want to highlight one population in particular, the Hmong. We have a large group of
23 them in the Central Valley. They have no written language. So, it's got to be pictures, or it's got to
24 be people talking to me. Thank you.

1 Dr. Van Der Pol: Great points. Dr. Pereira?

2 Dr. Pereira: Sorry. Yeah, Marcus Pereira, just point of clarification. I didn't mean sort of
3 serology testing for SARS-CoV-2. I think we all lived through that period of uncertainty and me
4 and my colleagues certainly fought very hard against that understanding that an antibody meant
5 immunity and so forth. But, you know, this is more about future pathogens that it may play a
6 role, right? I think we need to keep our mind open for what may come next and not necessarily
7 look back at the models that we've seen before. And I think this is where we need to sort of have
8 an open mind for the future pandemics.

9 Dr. Van Der Pol: Dr. Blumberg.

10 Dr. Blumberg: Emily Blumberg, University of Pennsylvania. I just wanted to say that I think
11 COVID really taught us the importance of bringing testing to the community in a real diverse set
12 of ways. And as sort of thinking forward about what kinds of tests and how to hazard resources, I
13 think we've unleashed something very powerful in offering the community the ability to perform
14 tests that would be helpful to maintain their health and protect their own local communities. And
15 so, the whole community outreach piece and the equity piece, I think, are especially important to
16 emphasize because we sort of made the laboratory outside of the actual clinical laboratory now.
17 And I just think we have to be cognizant of this is going to expand the diversity of the type
18 testing we're going to need to bring on.

19 Dr. Van Der Pol: Yeah, I think that's a really strong point. And one of the things that you
20 could take away from that is that when you're prioritizing the types of instruments, or the
21 components that support that instrument. The component may be those platforms that already
22 have a self-collected device approved for a different assay that they could roll that device for
23 self-collected samples over to a new assay. That's not always going to work, but if you're talking
24 about prioritization, that may be a scheme for helping to do that. Dr. Kotton.

1 Dr. Kotton: I have a question that kind of relates to this general topic, but does the FDA ever
2 give, I think the answer is no, but who gives guidance on pricing? Because I think Valerie's point
3 is really well taken about access. And you know, when I, in CVS, I'll sometimes see two test kits
4 for 25 bucks. And even I think, I'm not spending 25 bucks on that. So, I'm just wondering who
5 sets pricing and I've increasingly felt that there's kind of predatory behaviors out there. Is there
6 any, because that, that to me has an impact on overall ability to test people and whatnot. Does the
7 FDA ever give commentary there?

8 Dr. Van Der Pol: Dr. Stenzel.

9 Dr. Stenzel: Tim Stenzel, FDA. So, certainly it's not our role to have anything to do with
10 pricing or reimbursement. Those are not in our guidance. But what we can do is make sure that
11 we prioritize technologies that are lower cost and include them and in our in our plans, like
12 antigen tests. So, yes, even though antigen tests are probably the least expensive of something
13 that can be deployed, many, such as yourself, didn't think that they were inexpensive enough. We
14 hear in other countries, in Europe, where the test is one euro or two euros. It should be pointed
15 out that it's our understanding that those tests were heavily subsidized, that those governments in
16 those countries spent money to make it really cheap and that if it was left up to the free market as
17 sometimes it was in the United States, the pricing would be very similar to the U. S. But there
18 was funding for the home test from the federal government, which was free, it wasn't free to the
19 government, or to taxpayers in the country, but that was an effort and I recognize that those that
20 don't have homes or live in homes couldn't get those tests. But there were other programs that
21 would reach out and provide tests to those other at-risk populations that wouldn't necessarily be
22 able to have an address to receive tests. So, it's front of mind at the FDA to make sure that if the
23 technology is good enough to be authorized, even though it might be less expensive, that we give
24 priority to them as well, which we obviously did.

1 Dr. Van Der Pol: Thank you. Mr. Spring.

2 Mr. Spring: I think just some of the conversations, too, around equity, and by the way, I can't
3 comment on pricing, I represent a number of manufacturers and I don't know how everyone
4 comes up with the pricing, but I thought Tim provided a good answer. But I think just about
5 equity and again, it's more advice that as you look at capabilities out there and the fact that some
6 technologies might require certain platforms, cell phones, what have you, as long as you're also
7 looking at that equity question where you might need simpler, lower cost tests that are easy to
8 use without any sort of technologies. I think that's appropriate. When you look at prioritizing and
9 who to work with is they may come up with the same result, but they may use two different
10 approaches to get there at different cost points and just consider that. I think one thing on the
11 sample collection devices, an example I want to raise to the panel that I thought would work very
12 well with FDA is there are some products that are available outside of the country. And I think
13 there's an example I can think of, there may be more, where you had a similar collection device
14 outside the United States, didn't have FDA clearance, but it went through the EUA process just to
15 get it into the United States to help fill that gap. And I think as long as you can continue to follow
16 that type of approach, encourage manufacturers that have similar products out there to take those
17 through the EUA process, especially when it comes to specimen collection, I think that'll help fill
18 the gap in the future.

19 Dr. Van Der Pol: Thank you. Dr. Pereira.

20 Dr. Pereira: Yes, Marcus Pereira. Sorry. The gears are turning now. You know, I realized that
21 we haven't had any talk about pediatrics and children sort in terms of vulnerable populations. But
22 one thing to keep in mind as you sort of pre-authorize tests for these platforms that can take in
23 consideration sort of neonates and children, particularly when you think about molecular testing

1 and how much blood it requires and so forth. So, just sort of thinking about the populations that
2 you would be particularly wanting to test.

3 Dr. Van Der Pol: Other comments people might have? Again, the specific question as
4 written is, are there certain types of instrument manufacturers or test component manufacturers
5 with whom CDRH should be collaborating? I think we've gone a bit far afield from that specific
6 question, but that's okay. Because they're the questions that come up next anyway. Dr. Roth?

7 Dr. Roth: Yeah, thanks. Yeah, I'm going to go stick with the far afield kind of topic. I heard
8 a little bit of feedback about usability and some of these home-tests, and I'm just wondering if
9 there's any more kind of feedback. Like what part of the instructions were unclear? Was it the
10 interpretation of the test? Was it the execution?

11 Dr. Van Der Pol: Can I tell you that my experience, I'm big into the equity and outreach
12 things. So, we're working all over rural Alabama. We're working with community health
13 workers. So, they're not necessarily trained and certainly not laboratory-trained, and we just send
14 them the test. And as we get the test, because of supply issues, sometimes it's this test. And
15 sometimes it's that test. And every time we change a test, we have to go through, even though
16 there's a quick instruction reference sheet, we have to go through and create something with
17 pictures. Not drawings and cartoons in our case, we have to take a picture of the device, we take
18 a picture of the tube and the swab if it has a buffer, and we take a picture of results. And still for
19 the first week, I will get questions from all over the state. Well, but this one didn't quite, or, well,
20 this one did that, or what does it mean when this, so, Dr. Kotton needs to teach them a lesson in
21 how to read the IFU because they have the IFUs, but they also have these laminated sheets that
22 we send out in advance, and sometimes I still have to do a webinar, and these are all for CLIA
23 waved tests, so, it seems like the instructions should be obvious, it looked okay to us, it didn't
24 pass the sniff test of the average person and so these are people that have been testing. It's just

1 every time they change the platform and I'm talking about using, for example, of Visby test that
2 you just squirt the stuff in, and it gives you a lateral flow sort of output versus something that
3 gives you a plus or a minus versus something that says COVID positive doesn't matter. That
4 every single time, it's new, it's starting from zero. Thank you.

5 And other people can chime in on your experiences with that, but my experience is not
6 how to run the test. It's not really how to extract it as much as there's so much on that quick
7 information sheet. It's very tech-text dense. They don't want to read it. So that's why they want
8 pictures, and they want to call somebody. So, they want Dr. Ng's step one, two, three, because
9 they can do step one, two, three, and so if we give them that in picture format, they're fine, but
10 you have to cut out all the verbiage, right? There's just a lot of extra words, and you have to say,
11 stick the swab in the nose, spin it three times, stick it in the tube, break it off, squirt it in the
12 machine, wait for the timer. I mean, you have to just use bullet points, no full sentences. So
13 anyway, other people that have had experience with that, maybe Jennifer, you could weigh in on
14 your experience.

15 Ms. Schwartzott: Yeah, the ones that come in the post office are wonderful, but this other
16 one that my brother and I had, I think it was missing total directions. It made absolutely no sense,
17 and it kept saying to look at the app and you had to download an app, which we couldn't get to
18 work, and we finally just ended up going and getting another one, a totally different kind. But it's
19 not just the people though, the layperson doing the tests on themselves. I mean, this was an
20 urgent care place with staff that didn't know what they were doing. And yes, it was at the
21 beginning, but with that shipment should have come directions on what they were supposed to
22 do. And they didn't seem to have that; an error on their part for sure, because I'm sure that there
23 was at some point, but the fact that the nurse didn't know that was the to-the-brain one. I mean,
24 she didn't know how far to put it in, how many times, how long, I mean, that was a huge issue

1 and all the tests that they did, you can go back and look it up March of 2020, Advent Health in
2 Florida, they were all thrown out. All of them. So, all those people got false positives, false
3 negatives, who knows what from all those tests. And what damage did that do? And again, it was
4 at the beginning, but this is what we need to prepare for if there's another pandemic, that this
5 doesn't happen again, because it wasn't just one or two, it was a huge amount. And when I read
6 that article I said, I know exactly why, it was unbelievable how they were not prepared. And I'm
7 sitting there with a 105°F fever, and they don't know how to treat you, how to even test. So that
8 was a big issue.

9 Also, for people with disabilities, I'm visually impaired, but I have good acuity, but there
10 are a lot of people in my community that don't. And others that have learning disabilities and
11 autism and that's why the pictures are important. Bigger font size is important and clarity. And
12 then why you're doing this, there was so much misinformation out there, and it got to the point
13 where nobody knew what to believe, and why should we do this, this isn't worth it, it's
14 government control, whatever, all those different things. It's important to have it simplified to
15 where they get it and understand why, because they'll gripe to me about, oh, we don't need this.
16 And I'll say, no, you do. You really, really do. And then they start listening, because they're
17 hearing it from somebody that they trust, that's at their level and not from a pamphlet or
18 whatever. So, my suggestion is work with the big organizations that serve the people, serve
19 people with disabilities, serve the communities with disparities and find out what is needed. And
20 then have those recommendations, those guidelines to the companies so they can act on what
21 you've learned. That's my two cents.

22 Dr. Van Der Pol: Thank you, Dr. Stenzel.

1 Dr. Stenzel: I wanted to make sure before I speak that Kris got some of the feedback that he
2 wanted. What I was Pictorials, or even actual pictures, really simplified visual instructions
3 without needing to read.

4 Dr. Van Der Pol: Angry birds.

5 Dr. Stenzel: I'm sure there's branding that has to be licensed. Kris, did you get what you
6 needed there?

7 Dr. Roth: Yeah, I heard one key piece was I think some of the directions do have kind of a
8 stylized look to them, right? It's not the picture of the actual swab or the picture of the actual test.
9 It's more of a drawing or a rendering or something like that. So, maybe that's something that we
10 can consider actually having realistic images of gosh, here's what's in the package and here's
11 what to do with him.

12 Dr. Stenzel: Yeah, thanks. That was a lot of really great input. I want to give a shout out to
13 NIH RADx funded an effort to try to create universal videos for how to do a home-test and they
14 involved the FDA. And one of the challenges was every test seemed to be just a little bit
15 different. You know, there were some tests where you put the swab in the card, and then you
16 added the drops to it and you had to have not two, not four, but three drops. And other tests, the
17 liquid that the swab would go in was not pre-aliquoted into the vial. And so, the users had to pre-
18 aliquot. Part of it was all comers. It was, we didn't want to delay the access to the test just
19 because the workflow wasn't optimized. But one of the things, if you preset who the types of
20 technologies you're going to use, and the specific manufacturers you're going to use of, say, rapid
21 antigen tests. If you have those contracts in place, as South Korea did prior to Covid, you can
22 specify, it needs to be this workflow, which is made easy for visually impaired or autistic
23 individuals, folks with learning disabilities, or physical dexterity issues. We can make those in
24 positions onto the designs in the workflow. But if we're on our heels and not fully prepared as a

1 country, then it's a little bit more challenging to make sure that at least some of them are really
2 easy to use. The other thing that we potentially could do, although manufacturers wouldn't like
3 this, is there could be some independent usability measurement, you know, this test gets an A,
4 this one gets an F. I would hate for the FDA to have to decide on this, but certainly independent
5 organizations can do what they want and can make these assessments and make
6 recommendations to certain groups. You can use this test, because it's super simple, works great.
7 So, the FDA by law has to play fair with all developers, of course.

8 Dr. Van Der Pol: But one of the things that I know is that you do some types of research at
9 the FDA, and maybe one of the things that would be super useful is you take all of the over-the-
10 counter assays and even all of the point-of-care assays because I find that point-of-care people
11 are not trained laboratorians either. And so, there's still some problems there. So, if you take
12 anything that has a CLIA waiver or an over-the-counter claim, collect all of those instructions for
13 use, the quick reference guide, the one pager, and get together a panel of like a hundred people
14 that agree to do this and you just send it out to them and have them rank. This was the easiest for
15 me to use, one through a hundred. And it's not that you're going to do that so that you can give
16 feedback to manufacturers as much as so that you could say, okay, the common elements in the
17 ones that were liked are these five features and the things that seemed universally disliked were
18 those components. And then maybe you could put together guidance that would say: "For over-
19 the-counter or point-of-care tests, this is the way your quick instruction sheet needs to look."
20 Right? I mean, so I think you could do that with what we have from Covid right now and make a
21 really great study out of it at fairly little cost. Brad, hang on one minute while I go to Jennifer.

22 Dr. Stenzel: Yeah, a good suggestion. I like that suggestion. We'll see if we can actually do it.

23 Dr. Van Der Pol: Let me cut the line and go to Jennifer.

1 Ms. Schwartzott: I just want to comment on what you're speaking of. You have the whole
2 patient representative program right there for your testers. We all have disabilities and illnesses
3 and represent communities. And there's an entire program of people that would be perfectly
4 willing to do that kind of thing. Any kind of testing.

5 Dr. Van Der Pol: Great. Dr. Wentzensen, sorry.

6 Dr. Wentzensen: Yeah. (unintelligible) I agree with you. It would be great to use that
7 experience to really to have some user testing and give some guidance. At the same time, I think
8 it would be again important to consider doing this in a staged approach. In the beginning of a
9 response, you have virtually no barriers, like a test should work somehow, but you want to get it
10 on the market. And then over time, you raise the stakes and say, okay, now, please make this
11 more uniform. I mean, there were some tests that even differed by a lot, whether it was pre-
12 aliquot or not. And then sometimes you realize, oh, it's in a separate tube. So, I think that there's
13 a lot that could be improved over time. But in the beginning, you don't want to hold anybody
14 back, putting their test out. And so, I think it could go in parallel with more performance metrics.
15 There could also be more usability assessment, but in a staged way.

16 Dr. Van Der Pol: Brad.

17 Mr. Spring: Brad spring, Roche diagnostics, lots of good discussion. I don't disagree with the
18 fact that, I mean, we want our tests to be used appropriately. We want to have accurate results,
19 and no result is an inaccurate result, delays treatment potentially. So, anything we can do as an
20 industry to improve that, we're willing to do. I know FDA does have human factors programs, so
21 there is a capability there to at least look at what kind of human factor studies were done. But I
22 think Dr. Wentzensen's point, we were in a mode where we had to just so rapidly develop these
23 tests. I think his point is correct that we probably had to then say, we're going to make it this way
24 for now, but commit to improve it over time. And all these suggestions are very good

1 suggestions. The one other thing we do, I know this is a U.S. focused conversation though, but
2 we do make these tests for global use too, which actually lends itself to a more, you know,
3 image-based approach. And I think a lot of us try to do that to avoid worrying about translations,
4 but, but a small comment here is, remember, some countries also read right to left versus left to
5 right. So, we have to consider, we've seen these faux pas, as we call them, where countries will
6 look at a picture, but they're starting where we might start at the end and go backwards. So, we
7 have to take all those things into account. Because we don't want to just make one test for one
8 country, then we're making 100 different types of tests. So, just things to consider, but definitely
9 would align with the comments here that we got to make these tests as easy as possible. For all
10 types of patients, if we're talking to the home-use, point-of-care use, all types of users and
11 patients that will use that test.

12 Dr. Van Der Pol: Are there any other points? And again, I think we've strayed a bit, but it's
13 fine. Are there any other points that you want to bring up about types of instruments or types of
14 test components that the agency should be prioritizing, building relationships with in advance?
15 Okay, I'm going to try to sum this one up, but it was a very robust conversation, which was a
16 good thing, I think. Let's see what I hit. Okay. So, I think the first point that we need to remind
17 you, the agency, of is that the panel all agreed that we would hope that you can find some
18 mechanism for prioritizing so that you are not having to deal with reviewing a thousand
19 applications for new tests. And then, not all of them actually being super useful on the market,
20 but we do need redundancy so that nobody's depending on any one specific manufacturer or even
21 any one specific type of test. So, we need broad coverage and diversity in the types of
22 mechanisms.

23 There was mentioned that it would be nice to utilize high-throughput systems that had an
24 open channel so that LDTs, because LDTs are often the first responders, if you will. So, it would

1 be nice to be able to use those. And so, if you were going to prioritize types of manufacture or
2 types of instruments, those instruments that have high-throughput, but also have open channel
3 access, you may need to consider during an emergency situation, relaxing some of the
4 restrictions on manufacturers, helping individual labs develop or optimize those tests on that
5 system so that everybody can be optimized as quickly as possible. And consider taking CDC into
6 this conversation so that CDC is validating or optimizing their first line of primers and probes on
7 a variety of platforms, and especially focusing on those platforms that public health laboratories
8 have in their settings, since public health laboratories are also going to be first responders. So, if
9 they can put these lab developed assays onto those systems, that will help the whole country at
10 once.

11 Also think about, those systems that are commonly widely used in commercial or large
12 reference labs and central labs, but think also beyond just instruments, but think about those
13 manufacturers that could help you with the informatics to ease up the problems with
14 accessioning, but also with resulting so that we're not bottlenecked. And that running the test is
15 the part that takes the time, but not receiving the test or getting results back out. But then also
16 remember that fast followers to lab developed tests have to be things that have full and complete
17 instructions because smaller laboratories don't have the capacity to do the validation and
18 verification work that's required of LDTs. That may be that some of those LDTs could come
19 under one of those umbrella approvals that you were mentioning earlier, so that public health
20 labs in particular, or large reference labs weren't having to do a lot of independent validation. If
21 it's already been shown to work on this instrument with these primers and probes, then each lab
22 shouldn't be having to redo that validation. They should only be doing verification, which is
23 much less expensive and time consuming.

1 Don't forget the equity concerns. So, when you're prioritizing manufacturers or platforms,
2 you need to prioritize at least some that are going to be in that more affordable range and/or have
3 more stable transport conditions that allow specimens to come in from further afield if that's
4 what's happening. But we do need solutions that can be closer to the point of care. So, we don't
5 want everything to be focused on reference labs. That may be the first responder, but then the
6 second responder needs to be things that can get out into smaller settings. There was mentioned
7 that it might be useful to try and prioritize work with someone who manufactures something that
8 has a more broad target. Like the pan-SARS example was a good example, whether that's a
9 molecular target or whether it's an antibody target, you could envision that going multiple ways.
10 And you'd have to see where that would fit best. You also do need to consider a diversity of
11 sample types. So, if you're looking at platforms, especially platforms that are molecular
12 platforms, maybe you should prioritize those platforms that can use things like stool and tissue
13 and respiratory samples, and so on and so forth.

14 So, you do need to consider solutions for immunocompromised people, particularly if
15 you're working with antibody-based testing or immunological markers. It wasn't said exactly this
16 way, but I think one of the things that came out was you need to keep biological plausibility in
17 mind. And so, if somebody comes up with some scheme that this is the next best thing, make
18 sure you think that through and then really decide "maybe it is the next best thing", or "maybe
19 we've got some concerns about it." And so, in your prioritization, you take biological plausibility
20 into consideration. I think that it's important to prioritize those components of testing. If
21 somebody already has claims for a self-collection device and/or for a self-testing device, those
22 people are most likely to be able to roll over and put new pathogens on those same types of
23 devices and maybe the safety of the device or the safety of the transport buffer has already been

1 assessed and we don't have to start at ground zero, we can start somewhere further down the
2 road.

3 And then finally, and I left it for last because I think it's actually quite important and I
4 want to make sure it's on top of our mind. I think for anything that's at the point-of-care or that's
5 over-the-counter, we need to really work to create user-friendly instructions. There should be a
6 review process that includes actual end users. Possibly you should consider analyzing current
7 Covid instructions for use and making sure that you find the commonalities that end users find
8 useful and those commonalities of things that they did not find useful and you have to take
9 equity and diversity and inclusion considerations into account when thinking about those
10 instructions and if you could create some sort of template, to say: describe how to collect the
11 sample, describe in one sentence how to handle the sample, show a picture of what the result
12 looks like. Something like that that you give people a template that's not specific to any pathogen
13 that would help them in their developmental process once something new emerges and we're
14 trying to respond to it. Does anybody have anything to add that I forgot to cover? Dr. Caliendo.
15 Dr. Caliendo: Angie Caliendo, Brown. I just didn't quite hear it, Bobby, but the whole pre-
16 authorization idea. Right?

17 Dr. Van Der Pol: I kind of thought this was all going into a pre-authorization idea.

18 Dr. Caliendo: You just didn't use those words and I just wanted to make sure that that they
19 understand that we think that's a great idea.

20 Dr. Van Der Pol: Yeah. And so that was mentioned, and I'll make sure that I say it in a full
21 sentence, but that the agency should consider pre-authorizing certain manufacturers or certain
22 types of tests by working with those manufacturers to understand how they can quickly mobilize
23 to meet the needs of what's out there. But again, in the context, probably of those systems that

1 are already in use in large reference labs and in public health labs, I think. Anything else that I
2 forgot or didn't explain well? Okay, Dr. Stenzel, anything else that you needed on this topic?

3 Dr. Stenzel: Well, first of all, wow, that was a long list and excellent job. Another very robust
4 discussion and many things to the panel. A couple of things to mention. One is there was mention
5 of sort of an umbrella authorization that we hadn't discussed, the saliva direct test. We've been
6 staying away from specific tests, but they weren't the only one that got, I think University of
7 Illinois also got an authorization, that we authorize their protocol. There are protocols specified,
8 order these primers, use these reagents, use these instruments, and Yale SalivaDirect was very
9 active in working with the FDA and getting updates to that and scores of labs asked to be signed
10 up and we authorized Yale SalivaDirect to actually select the lab, so there would be a checklist,
11 "Are you going to follow the instructions? Are you going to use the components that are
12 authorized? Okay, then you can use this test," but it was a very effective way to get essentially a
13 lab developed test out and used. And really, it seemed appreciated by many, many, many users. I
14 don't know if all labs can necessarily do that as we heard today, but for those labs who have
15 certain capabilities, that certainly leveraged, with one central, original application, the ability to
16 distribute a test protocol that was EUA authorized by the FDA, and that was great. There are
17 certain things we can we can do in advance but there's others that we don't yet have authorities
18 for, and there's discussions about how to obtain those authorities that the FDA can, through text
19 or sort of programs and things like that, being able to give authorization to labs to develop tests
20 and there are different ways of doing that. But some of that we don't clearly don't currently have
21 authorization to do. It's not in our authorities to be able to do that. So, by and large, for the time
22 being we're restricted to sometimes using enforcement discretion which we have done quite
23 liberally, but we've also been criticized for that because some of the tests launched were not
24 necessarily prior to FDA review or were not necessarily the best test, so we said. So, we'll do as

1 much as we can under our current authority, so that's my promise. But no other comments or
2 questions and thanks again to this distinguished panel, appreciate all of it.

3 Dr. Van Der Pol: And I want to say, thank you for reminding us about that, for anybody who
4 doesn't know, because it is kind of a lab-y thing. Yale had created a process for testing saliva for
5 Covid, and they sent it to the agency for review. But then it was a protocol. And so, any
6 laboratory that that met their criteria could apply that protocol. So, it was the same as, -ish, not
7 legally necessarily, but similar to having a lab developed test, but without each lab having to go
8 through the whole validation process, even though each lab would source their own primers and
9 probes, but they would source them through these companies that Yale had already sort of
10 evaluated and so it was a great mechanism that a lot of people were able to adopt this that might
11 not otherwise have been able to go through the validation process. I wonder and I, again, don't
12 understand the authorities at all and so I wonder if this is something that when a situation like
13 Covid emerges, does the agency have the capacity to solicit someone to submit something like
14 that or are you not allowed to ask for submissions?

15 Dr. Stenzel: I think we can encourage it. It was a creative solution.

16 Dr. Van Der Pol: It worked really well.

17 Dr. Stenzel: One that we were very open to. And there was comment about how proactive or
18 active versus passive the agency has been. And, you know, when we heard it, we said, "Yes, let's
19 do this." And I was pleasantly surprised at how well received it was. And I think it's in our
20 toolbox going forward.

21 Dr. Van Der Pol: Great.

22 Dr Stenzel: And there's, there's no reason, I'm sure there's other FDA people on the line, but I
23 see no reasons why we can't fully authorize. Not just EUA authorize some of these kinds of
24 concepts. So, we look forward to potentially doing that.

Question Four

Dr. Van Der Pol: Great. All right. So, with that, we're going to move on to question four. So, we have four, five, and six to go, but before you all take a heavy sigh, I'd like to put four up on the screen and see if we've actually answered it already because I don't think we restricted ourselves to instruments in the last hour of our conversation. So, the question is, are there certain types of tests or types of developers that should be prioritized for review in the early stages of the pandemic? I think that we covered that. I don't think we restricted ourselves to instruments, but does anybody on the panel have anything that they'd like to specifically say about types of tests and types of developers? Mr. Spring?

Mr. Spring: Yeah, I'm not going to comment on the types necessarily, but I know there were, and Brad Spring, Roche Diagnostics, there were comments around the agency and having to deal with a thousand manufacturers and that there were challenges with the quality of the documentation that was coming in, the data that was coming in. So, is there a way to address because you want to be fair, right? So, there's this kind of first in first out, so to speak approach, which is fair, but is it really the best use of your time? And maybe I'm saying something here that you're already doing. But this refused-to-file type of approach that we have with current submissions, I think you were doing some of that, but is there a way to be much more efficient and focus on those submissions that are coming in that A) meet your priority list, but also give you that early sense that this is a quality submission upon first review, and that we're not going to be spending a lot of time haggling and whatever else you need to do there. So just a statement or comment on that. And I guess maybe Tim, I think I see your hand up to respond to that.

Dr. Van Der Pol: Dr. Stenzel.

Dr. Stenzel: Yes, Tim Stenzel. Okay, so we have tremendous authority and flexibility to tailor the EUA process for a particular need. And, with Covid, that changed with updated guidance.

1 That went through review and was very targeted and specific in what we were trying to do with
2 that. So, we did move, when we were continuing to get a lot of me-too tests that weren't
3 immediately going to really add to the response in a meaningful way when we really wanted to
4 focus on, say, high-throughput tests or over-the-counter tests, or point-of-care test. Also, we had
5 realized that that there were, at some point, and I don't remember the exact dates where this
6 happened, where we really wanted to focus on well-experienced manufacturers, and we define
7 that experience rather broadly. Basically, if you had gotten an EUA for Covid already, or you had
8 a full authorization saying, for a respiratory virus, those were the kind of companies then we
9 began to gain more priority to. And then we applied that all at the beginning of Mpox with our
10 first and still to date the only guidance we've done on Mpox, where we really more closely
11 imitated what was done in South Korea, where they had an open solicitation for developers and
12 we use the pre-EUA process to come in and there was a window of time, I think it was around 30
13 days, he said, if you're really interested in developing an Mpox test, let us know through the pre-
14 EUA process. We'll review your EUA, and we'll make selections and we outline the priorities
15 and the guidance which said we were going to give preference to test developers that had
16 demonstrated success with the FDA that included, say, an EUA for Covid or full authorization
17 for something applicable to Mpox. So, we got those requests, and we made selections and we let
18 the developers know who had been selected and that was an incredibly efficient process. So, we
19 kind of want to know from the panel, is that supported by this panel? Is that something that we
20 should be doing? Is that a good thing to do? It certainly allowed us more quickly to get to the test
21 for Mpox and focus our attention on Mpox. And it vastly reduced the need for head count for
22 Mpox at the time when we were still, this is more than a year ago that Mpox hit, we were still
23 very busy with many Covid EUA applications. So, our busy team was further divided, but
24 because of those mechanisms we use through the authorities, we're able to more limit the head

1 count within our office that was needed to properly and adequately respond to Mpox. And I think
2 the feedback in Mpox to-date is good, but we're always open to hearing feedback that helps us to
3 improve. So, thank you.

4 Dr. Van Der Pol: Dr. Petti?

5 Dr. Petti: Kathy Petti, HealthSpring Global. I think we've all witnessed the tremendous gap
6 with home-based testing and the lack of chain of custody of data and reporting back to either
7 agencies or to health care providers. There are some test manufacturers that have developed
8 some solutions, be it external apps or use of QR codes, so perhaps in the prioritization list, those
9 manufacturers that have made a commitment to closing that gap with home-based tests and
10 having those results somehow reported back to the health care system or to the public health at
11 large is pretty much mission-critical for us. As we respond to a pandemic, we've been shooting
12 blind, not really knowing the numbers.

13 Dr. Van Der Pol: That's a really great point. To go along with that point, I would also
14 suggest that the agency really work with CDC. One of our problems with older diseases that we
15 report is that each jurisdiction has its own reporting mechanism. Their variables are not in the
16 same structures and it's not consistent. So, from a manufacturer's perspective, it's quite hard to
17 make a product that can seamlessly upload into something that can be communicated to local and
18 national health agencies. With Covid, CDC developed a new reporting process for Covid that
19 was the same across all jurisdictions, which supported development of connectivity solutions.
20 So, I would strongly encourage CDC to also be part of this sort of emergency-preparedness-
21 thinking process about making sure that future reportability is more streamlined so that that
22 supports manufacturers who want to help us. Help them help us, I guess. So, other thoughts
23 about the types of tests?

1 Dr. Stenzel: I could add some thoughts about Dr. Petti's comments on data. The FDA did ask
2 and require, not necessarily pre-market, but post-market for over-the-counter tests, which were
3 not required under certain Covid bills to be reported. So, home-tests didn't have the same
4 requirement that labs did to report data. We did put into the conditions of authorization of every
5 over-the-counter test to develop a data reporting system. And many did and some of them are
6 now, or were connected, I assume they're still connected. I haven't gotten a recent update on that,
7 but certainly not across the board. And NIH, we've been in discussion with the CDC, obviously,
8 and NIH played a large role and also making a reporting option available and others as well as
9 the FDA. One of the challenges that some have expressed with collection of home-based testing
10 data is the reliability of that data and of those results. I think others are very open to the idea and
11 if you start collecting it and recording it, you can get geolocation data, not to a neighborhood, but
12 to a zip code, and you could be reporting back to that zip code. And so, everybody in that zip
13 code can go to an online chart that says, "Well, you know what, Covid is very low right now. So,
14 the risks are lower, not that they're zero." But in other times, the risk may be very high in a
15 certain community, and people can take that into account as they go about their lives.

16 But then there is an open question of the reliability of the data, especially if the reporting
17 isn't automated. We've been talking about low-cost tests. So, to have an automated upload of a
18 home-based result, there has to be some sort of instrumentation, whether it's even just a
19 smartphone or other device versus manually an app, even, or manually going to a website and
20 putting in your lot number, your test and reporting your result, whether positive or negative, and
21 it's their bias. Are people more likely to report positive results rather than negative results? So,
22 these are all great open questions, but I still believe that you could at least monitor trends, and
23 even monitor performance in a zip code, say, between different home-tests is suddenly one of
24 those tests is yielding a lot more positives, or maybe a lot fewer positives than the rest of the tests

1 in a geography. You might discover that there might be a test that's out of spec, that's not
2 performing well, but if they're all performing about the same, which we might expect, and they're
3 trending up, that tells you one thing, or they're trending down on positivity, that tells you another
4 thing. So, can you have the same granularity and assurance of quality that you have with, say, a
5 central lab test performed by high-complexity personnel and reported through existing reporting
6 systems? No, probably, unless you have these automated systems that report every result, but
7 then those are more expensive and harder to deploy and have equity issues, et cetera. But an
8 excellent point that obviously we've been putting a lot of thought to. There are also some funded
9 efforts at the FDA and other agencies to address the reporting issue and many grants have
10 already been awarded in this area to develop and seek ways, not just for reporting, but the use of
11 real-world evidence or data for regulatory purposes, whether pre-market or post-market. So,
12 thank you.

13 Dr. Van Der Pol: So, question number four is: Are there types of tests or types of developers
14 that the agency should be prioritizing in their approach to planning? I think that we've covered
15 that mostly, again through the previous conversation. And then if there's any other things people
16 want to say on this topic? Okay. So, what we've heard from the things that were added to the
17 previous conversation are that some of the ways to prioritize may be based on the type of test.
18 Once it's clear what that type of test is, that's ideal. But again, based on our previous
19 conversation, we haven't picked a specific type of test that we know we can focus exclusively on
20 to consider the quality of the submission, which is part of what Dr Stenzel said was an evaluation
21 component in prioritizing during Covid or during Mpox on those manufacturers who already had
22 experience in submitting a successful product for the EUA process for Covid or for something
23 similar to Mpox. And then the last thing was to consider as a prioritization criterion, whether or
24 not the assay has connectivity, but, as Dr. Stenzel mentioned, that's going to have to be taken into

1 the context of the other factors that you're considering when prioritizing. So, I think that the
2 general summation is that the panel doesn't feel like there's any one type of test or any one type
3 of developer that we could say you would be better off to focus on because the future is too
4 uncertain for that, but based on past track records and the things we talked about previously
5 about public lab support and central and reference lab support, I think that you sort of have your
6 answer there that we want it all. And we want you to be ready to supply it all. It's an easy answer.
7 Isn't it? Dr. Stenzel, do you have any more things that you'd like us to dig into more deeply on
8 this particular topic?

9 Dr. Stenzel: No, thanks again for the input. We'll continue to do our best.

10 **Question Five**

11 Dr. Van Der Pol: Okay, so question five. Question five is: what are the key features of tests
12 or certain test designs that would be helpful in a future pandemic? Again, we discussed a great
13 deal of this when we discussed the earlier questions. And some of those features that we've
14 already mentioned include things that can be high-throughput. There are things that can be run in
15 laboratories that already have existing instrumentation, things that are very user-friendly, and that
16 can address equity concerns and inclusivity and diversity concerns. And perhaps getting
17 feedback from people about the usability, both in the laboratory and in the home of different
18 Covid options that came out. Some of the options that came out were adopted by labs because we
19 were in a hurry, and we would take anything. And then as soon as the next thing came, we
20 dropped them. Might be worth the FDA's time to ask why we dropped the ones we dropped.
21 What were the features that ultimately, like my lab right now is only running one Covid test. So,
22 why was I running five Covid tests a year ago and now I'm only running one. So, there are things
23 out there that laboratorians might be able to tell you if there was a survey process or something
24 to ask that would help you learn a little bit more about the features that really made a difference.

1 I will tell you, one feature that I think is important that we've not talked about today that I
2 recall is either using a dry sample or an unadulterated sample and say if it's a urine or a stool. So,
3 something not in transport buffer is what I'm getting at, or using something that's in a universal
4 transport buffer, because then that allows me what I did, during the beginning days of code was I
5 took every platform that I have. I have five in my lab. I was able to use all of them. And so,
6 anytime I had a supply out, I could move everything over to a different instrument. Or if I got so
7 many samples, I couldn't run them on one instrument, I had multiple instruments, but that was
8 because I was running everything mostly out of UTM. And so, it was very easy for me then to
9 aliquot that into the manufacturer's tube and run it on the system. And I'm not saying I want to
10 spend my days aliquoting, because that's not ideal. But then when it got to the point where
11 people had, "Okay, that's fine, you can put the tube in UTM directly on the instrument." Well,
12 then it becomes easier for me, right? But in the early days, something that I can run on anything
13 because it's in a universal process, or it's unadulterated, if you will, really helps early response.
14 So that's something that manufacturers that have those options available for other types of tests,
15 may be those manufacturers that you want to focus on for sort of that prioritization. I see Dr.
16 Caliendo has her hand up.

17 Dr. Caliendo: Angie Caliendo, Brown. I think one opportunity that was lost during all this was
18 to assess agreement across different tests. By December of '20, there was an international
19 standard for Covid. For SARS too. And while the FDA tried earlier in the pandemic to send out
20 material that manufacturers would run in their tests, it was a lost opportunity to require
21 everybody who had an EUA to get that material and report back to the FDA in the same units.
22 What, in those international units, what their LoD was because you were looking at TCID₅₀s, you
23 were looking at molecules, you were looking at copies, you were looking at who knows what.
24 And when we did have a choice, we didn't know, really, how these tests performed. And I mean,

1 people were desperate. We were running anything we could, no idea how they compared to one
2 another. And that standard sat out there and was never required, and that could have been a “You
3 want your EUA to stay on the market, give us your LoD and then publish it, put it out on your
4 website.” This is what everybody's international units. And like I said, I know you tried to do
5 that, but the material you sent out wasn't compatible with the last season. So, it was somewhat
6 uninterpretable. But, moving forward, that's an opportunity we don't want to miss. I was so
7 impressed that the WHO had a standard out that fast.

8 Van Der Pol: Great point. Brad?

9 Dr. Stenzel: If I could comment on the international standards. So, we did interact early and
10 often with the WHO and the group, and they simply didn't have the ability to distribute that
11 material to any lab it wanted in the U. S. So, secondary standard would need to be made. We
12 would love to hear more feedback on the reference material that the FDA did send out and what
13 was good about that or what it was not so good about that. We did link the FDA reference
14 material to the international standard. So, we have the linkage between the primary standard and
15 in our reference material. And we're going to take another run for Covid with reference material.
16 So hopefully this one is successful. We've done this to some degree for flu for many years now,
17 where the antigen test developers are required to obtain annual material and make sure that they
18 have reactivity. Most of the molecular, not all molecular manufacturers, voluntarily also test that
19 material. We needed to switch producers of that material. So, we didn't skip, I think we might
20 have skipped one year, but it's coming back. So, this kind of effort for reference material and to
21 be able to look at reactivity and potentially go further and determine comparable LoDs is
22 something that the FDA does feel strongly about and feels like is important. But feedback on
23 what we did for Covid here or other places would be greatly appreciated.

1 Dr. Caliendo: So, the feedback you're going to have to get from the companies. The feedback I
2 got was from talking to manufacturers saying, why does your test look so bad? And so, we
3 weren't the ones testing with that material, they were. So, I think the companies are where you're
4 going to have to get that feedback for and then reaching out to a company that makes secondary
5 standards and engaging them ahead of time so that the next pandemic, you have material that can
6 be made. I mean, the manufacturers could go to WHO and get it. It's what they do now, right?
7 And then make their own secondary standards. So, there's a way. This is another proactive
8 engage ahead of time because, you know you're going to need it. H-5, H-7, whatever, people
9 should be thinking about this already, to have a secondary standard somewhere so that the CDC
10 or you could send out this panel.

11 Dr. Stenzel: Thank you for that input. Uwe may have some additional information to add.

12 Dr. Scherf: Yes, that's fine. Uwe Scherf, FDA. So, Angie, we totally agree with what you said,
13 but I think one nuance that might not be known by everybody that the standard from WHO was
14 not available in the amount they needed to be obtained to really do the LoD studies and for the
15 assessment of the performance. Of course, they could have developed a secondary standard, but
16 also it took a lot of resources and time, and this really didn't fit the purpose. And the material
17 that we made available early on, which was, not perfect either, but that gave a certain assessment
18 early on. Really was used to come up with these numbers. But as you said, there is space for
19 improvement. But I have to say, from our perspective, we were head on, early on we provided
20 material that allows us to make a good assessment that actually helped us later on to establish
21 evaluation criteria and approaches for the antigen tests that otherwise wouldn't had allowed us to
22 make the antigen tests available so quickly with the appropriate information about their
23 performance.

1 Dr. Caliendo: And, Uwe, moving forward when you do that, requiring that to be in the package
2 insert will be very helpful. Right?

3 Dr. Scherf: It is. Yeah, I mean, what is in there, you might have seen it, is in the authorization
4 letter, it is proactively included as a condition of authorization. If we find the material that people
5 believe helps to make this assessment, the sponsor need to test it. That's one of the conditions
6 that they have to fulfill.

7 Dr. Stenzel: But Angie, I think you brought up one of the challenges that the FDA faced that
8 some didn't like how we did it. And we are a responsive agency, and we have the opportunity to
9 work with a lot of different people. So, you, you alluded to some challenges and that existed.
10 Thanks.

11 Dr. Van Der Pol: Dr. Pereira.

12 Dr. Pereira: Marcus Pereira, Columbia University. So, thinking about sort of test features that
13 I think will be important as you begin to understand whatever pandemic may come your way,
14 obviously good diagnostic sort of sensitivity and specificity, not only among the general
15 population, but also in particular populations. Again, I'm going to mention pediatric population
16 that may have sort of different testing characteristics. And you do want to from the very early
17 onset be able to characterize that. But I'm also thinking about immunocompromised patients who
18 generally might have a different burden of disease and perhaps either lower or different testing
19 sensitivities and specificity. So, it would be important from the get-go to include some of these
20 important vulnerable populations that in some ways may actually be sentinel populations, right,
21 in terms of sort of the beginning of a pandemic and so forth. That's one important point, I think,
22 in terms of diagnostic component, we've been talking a lot about that particular component, but
23 also monitoring of disease. We haven't talked a little about that in terms of developing tests that
24 could give us some sense, is this patient, is their infection resolving or is it progressing and are

1 they still infectious or not? I mean, one of the things that I think we struggled with during Covid
2 was when could patients come off isolation, whether they were still contagious or not, and trying
3 to characterize or develop tests that could give those answers from the get-go would also be an
4 important feature as well.

5 Dr. Van Der Pol: So, before Dr. Stenzel comes in, I'm just going to respond to you quickly
6 to add to your list of populations that need to be included in research is pregnant women. And I
7 understand why we don't, but we really just must. And we need to do that in a safe way, but
8 pregnant women are at risk, and they need to understand how different things work and pregnant
9 women are somewhat immunocompromised as well, so they have different needs depending on
10 what type of test it is. I will add very quickly is that I think one of the features that Dr. Pereira
11 maybe doesn't necessarily know is out there but is maybe a feature we want to think about is if
12 we're doing molecular tests, maybe we need viability assays. And so, people that have a viability
13 assay as part of their molecular diagnostics, maybe they should be prioritized because they
14 already know how to make that process work. Sorry, Marcus, if you want to go again.

15 Dr. Pereira: No, that's exactly it, sort of link those tests. So at least they have sort of surrogate
16 markers, right? A certain, we use a lot of CT values, right? In terms of nasal pharyngeal PCRs,
17 obviously completely off-label. And I think it's sort of described how we needed that data for
18 clinical practice.

19 Dr. Van Der Pol: And I will remark that some companies who shall not go named, Mr.
20 Spring, are stopping us from allowing having access to CT values in the future from their
21 instruments because they don't have claims for a quantitative test. So, you had access to that
22 during the EUA process, but you're not likely to have access to it going forward. So, recognize
23 that's a barrier as well. Dr. Stenzel.

1 Mr. Spring: I was going to say on that, Dr. Van Der Pol, my experience was we were told we
2 were no longer allowed to.

3 Dr. Van Der Pol: Oh no, I'm sure that's where it came from. But just as an FYI, I mean, I use
4 those all the time for a variety of different tests and analytes. So, I was just warning Dr. Pereira
5 that things that you've used in the past, you may not have access to in the future. And that's
6 something maybe for the agency to consider as well. All right, Dr. Stenzel, you've been waiting
7 patiently.

8 Dr. Stenzel: No, I didn't want to respond. There's a number of topics that Dr. Pereira brought
9 up. But first, I want to know, hopefully, Brad, it wasn't the FDA that said you couldn't report out
10 CTs because that's not our policy. And we, in fact, had a frequently asked question that didn't
11 object to reporting out on CTs even if we didn't necessarily, after reviewing the literature and
12 reviewing professional guidelines this area, which almost universally said that CT views are not
13 comparable between labs, in fact, we only authorize one truly quantitative Covid tests. But given
14 the nature of the sample type, typically of a swap, it's not the same sort of thing as I was involved
15 in earlier in my career, in quantitative HIV from blood samples or HCV or HPV from those same
16 samples on one of the commonly used or older commonly used by platforms now, because I'm
17 not as young as I used to be, but, with respiratory samples, and we're open to these ideas as long
18 as science and data backs it up. But delving into infectiousness is challenging. Some of the
19 literature we've seen says that even very high-CTs people can transmit Covid.

20 The various at-risk populations are very important to us. We talked yesterday about
21 certain populations for those tests, and we take that into account here as well. I think the serology
22 authorizations, probably for EUAs, my team can confirm this perhaps, stated that you had to take
23 to account, the immune status of the patient when you're reviewing the serology results. But the
24 immunocompromised, this is an important group. I don't know that enough research has been

1 done on them for how they express infection to respiratory diseases or Covid and you know are
2 they as easy or as hard sometimes to detect with antigen tests versus molecular tests? How do we
3 optimize testing for those groups, whether it be an immunocompromised or pregnant patients.

4 As far as the pediatric population goes, I did want to comment that if the developer
5 wanted to have a pediatric claim and that we wanted to see data, even though the numbers are
6 small in the positives, and then the FDA was involved with another Emory, NIH, FDA scientific
7 study that, in a back to school effort, looked at the ability of kids at school, down to age five, to
8 self-collect and enter nasal swab. A video, a short video was developed in that process. They
9 watched that then they collected. They had observers in the study. That study was published, I
10 forget where, and we were pleasantly surprised to see that even five-year-olds at school could
11 adequately swab their interior areas and get a good result. Actually, some of the older kids
12 showed a slightly decreased performance. Teenagers were a problem, I think. But anyways, these
13 are all important points. And the last point to make is that you talked about monitoring disease
14 and resolving and prognosis. The FDA is open to all of these types of test submissions, always.
15 We're always open and always available through if it's an EOA type test through the pre-EUA
16 process is the best way to talk to us about novel technologies or applications and figure out what
17 would be the best way to validate that? And what is the best pathway to submit to the FDA or the
18 q-sub/pre-sub process that we talked about yesterday? Thank you.

19 Dr. Van Der Pol: Dr. La Hoz

20 Dr. La Hoz: Hi, this is Ricardo La Hoz from UT Southwestern. Thank you, Dr. Stenzel. I think
21 you've addressed the comment that I was going to make already. So, I don't want to go as deeper
22 as I was thinking, but the immunocompromised host tends to be lumped in a in a single group
23 when, in fact, is quite the heterogenous in in in itself. Some of the patients that are on monthly
24 reduction map had very unusual presentations where they have persistent infections. Some of

1 them, although the vast majority of the population fall within the bell curve off of infectivity, and
2 we can institute isolation practices based on that, I think there is a need to determine the
3 effectivity for isolation, for example, in a bone marrow unit. That could be quite helpful, no
4 matter what the pathogen may be during the pandemic. But in transplantation, a question that
5 became quite relevant was when to proceed with transplantation after infection, and I think we
6 had to balance the tangible risk of dying on the wait list for the solid organ transplant candidate
7 versus relapse of the malignancy in the bone marrow transplant patients. A well-known fact that
8 at least some respiratory infections have been associated with worse outcomes after
9 transplantation. So that's another area where infectivity assays may be helpful. And last but not
10 least, there was a point in the pandemic where a large proportion of donors were testing positive
11 for Covid it at the time of donation. And although some ventured to use those donors, there was
12 an understandable concern to use the organs from those donors. Eventually the non-lungs were
13 used with some degree of safety, but there was a large drop in the number of lung transplants
14 performed and as much as we've recovered it was still a challenging situation. So, the infectivity
15 assays may serve multiple roles with the big caveat, like I said, that the immunocompromised
16 host is really multiple different populations and they're not all the same.

17 Dr. Van Der Pol: Thank you for that. Well, are there other comments on the key features or
18 test designs that people think are important to consider in preparedness? Seeing no hands raised,
19 I'm going to summarize this. I will remind the people that read the transcript that we also
20 discussed many key features and types of test designs in previous question responses, but the
21 ones that came out of this particular conversation include the potential to consider universal
22 transport or samples that were transported without any buffer to look at agreement across
23 platforms, particularly using, well-standardized panels so that we can see LoDs and understand
24 LoDs across platforms using assays that have good performance regarding sensitivity and

1 specificity that included in their study designs: pediatrics, immunocompromised people from a
2 variety of different backgrounds because the variety and types of immunosuppression is large,
3 and so they need to be taken into account, including pregnant women as well. It might be useful
4 to have those tests that have potential for quantification or viability assessment so that we can
5 monitor disease status as well as infection status. I think that pretty much sums up the features
6 that the group thinks might be very useful in terms of assays for future pandemic response. Dr.
7 Stenzel, did you need anything more on this topic?

8 Dr. Stenzel: No, and thanks again to you and the panel. Appreciate you guys.

9 **Question Six**

10 Dr. Van Der Pol: All right. This is our last question, question number six in your packet. I
11 think we've covered some of these, but we may be able to discuss more in-depth this question
12 about other lessons learned from the recent COVID-19 pandemic and Mpox emergencies that
13 might help the agency to take into consideration when planning for future pandemics. We discussed
14 several of these features in previous sessions. One thing that I'll reiterate is that we thought it was
15 important to review the clarity of the quick information sheets for people who are running tests at
16 the point-of-care or buying over-the-counter tests. We thought it would be important to use packets
17 from the COVID EUA and the full approval process since we've gone into that phase as a template
18 for future submissions. And we thought it would be important to remind people that they need to
19 use the pre-EUA process to help get feedback very early on in their developmental and design
20 process. I see hands up from people who want to tell us about other lessons learned from COVID.
21 Let's start with Dr. Honein.

22 Dr. Honein: Yes, Peggy Honein from CDC. One lesson learned that is completely
23 understandable, but with the great ramping up that Dr. Stenzel described of adding a lot of new
24 reviewers to the process, there was a lot of variation and the familiarity of some of those reviewers

1 with the FDA processes. Some of the feedback we received was that it was a little more challenging
2 than we would typically expect. I also had a similar issue at CDC, when trying to onboard and
3 train people during a pandemic. It was a huge challenge for all of us and I'm highlighting it as this
4 is something we may want to give some consideration to as we're preparing moving forward.
5 Thank you.

6 Dr. Van Der Pol: I would say that when inclusive, extensive guidelines are very helpful
7 because they help the reviewers stay consistent as well. Next was Dr. Blumberg.

8 Dr. Blumberg: Hi, Emily Blumberg, University of Pennsylvania. We've talked about this before. I
9 think it is especially important, when you think about pandemic preparedness, to make sure that
10 the testing access, so the test platforms are created with access to those most vulnerable
11 populations, as they may be the ones most likely to sustain or perpetuate ongoing infection.
12 Platforms have to be available to people who will be lower resource charter, to reach things that
13 are going to be simple, not something that will require a lot of effort on the part of the individual
14 or a cost.

15 Dr. Van Der Pol: Agreed. Dr. Petti.

16 Dr. Petti: Yes. I'm following up on something that Dr. Caliendo had said earlier and also
17 following up on Dr. Honein's comments. Could there be legislation where the FDA, at the time of
18 a pandemic, could be a resource to hire an "X" percent increase, to respond to a pandemic where
19 that legislation would be preexisting in anticipation of the next pandemic? Then, you would not
20 necessarily have to ask for a resource increase. Another thing is that in the military, we have the
21 reserves in the physician world. We actually have our medical boards that know who's retired but
22 still holds a medical license. During the pandemic, a lot of those resources were actually activated
23 to help with the human capital. I don't know if the FDA has a repository of retired reviewers or
24 people with experience that you could call upon when you have so many submissions to review. I

1 wouldn't say any of us truly had the full capacity, but many of us are here to serve if called upon
2 to review a submission or two. I think there are just more resources than full hires that you could
3 draw from.

4 Dr. Van Der Pol: I will add my two cents to that and wonder if there would be a possibility
5 of considering an NIH study session situation where you had pre-vetted people and you knew what
6 their conflicts were in advance. Obviously, you wouldn't assign them to something that they were
7 conflicted on, and you might only be able to assign one to a person, but if you had 100 people in
8 the country, then it might not work. They wouldn't be your exclusive reviewers and obviously, they
9 wouldn't be as familiar with the statutory requirements, but they could certainly look at the data,
10 at the science of the performance, at the instructions, and the usability questions. They wouldn't
11 give you everything you need, but they might be able to help.

12 Dr. Petti: And often you're blinded on who the manufacturer is.

13 Dr. Van Der Pol: Dr. Ng.

14 Dr. Ng: From the left field, for the future, please do not require any dry ice transport. I
15 cannot get dry ice.

16 Dr. Stenzel: I know what you're referring to and the FDA never made that requirement.

17 Dr. Van Der Pol: Dr. Caliendo?

18 Dr. Caliendo: Angie Caliendo, Brown. I'm going to bring it back to center field and it is related
19 to what Kathy said. You said that you contracted out to a group that did 100 reviews for you.
20 Having that in place ahead of time would also be helpful. Again, it's the same concept: you're
21 screening people ahead of time, whether they're individual experts or a company, and you're ready
22 to roll, if you need them.

23 Dr. Stenzel: The group we used had many former FDA years. But it required funding that's not
24 in our...

1 Dr. Caliendo: And you can get us poor souls, for free.

2 Dr. Van Der Pol: I was going to say, they pay you.

3 Dr. Caliendo: Lunch would probably be all we would really need.

4 Dr. Van Der Pol: Yes, we're pretty, cheap, I must say!

5 Dr. Stenzel: We're open to that, but when we call after you've already been working 24/7, just
6 remember that you volunteered to help.

7 Dr. Van Der Pol: It is really an interesting thing that people in the healthcare field do things
8 because we feel it's our expectation; it's our job to respond. I'm not saying that it's easy for people,
9 but people will find a way to make time to help because I think that we're all on the same team and
10 we all want the same outcomes. If there's a little bit of suffering, we're willing to deal with it. I
11 think that's just life. We're saying that we're there for you, so find a way to use us.

12 Dr. Caliendo: Tim, I'll just add that during the peak, many of us were writing guidelines and
13 volunteering our time for various organizations. I want to reiterate with Bobby just said. I think
14 people appreciate that they have expertise, and they want to help.

15 Dr. Stanzel: I think it's a great idea.

16 Dr. Van Der Pol: Both Kathy and Angie said it and that is really the key. Do it now! Create
17 now a cadre of people that you have on your list and send them once a year, so that they stay in
18 practice. When something like this comes up, they have the skill set. Just as with anything else, if
19 you've ever sat in a study section or just done this panel, it's formulaic. I have a script that I'm
20 reading. If you sit in the study section, there's a process and everybody knows exactly what it will
21 be. So, if you get external reviewers, you can get them in the loop, so that they're doing it once or
22 twice a year. They will understand the process and they will be ready for you if and when you need
23 that level of support. I know that you can't legally say, "We'll do it for you for no charge.", but the

1 reality is that we'll come as close to that as you can statutorily let us because that's what we do. So,
2 keep that in mind.

3 Dr. Stenzel: Yes, I do. Thank you. I do want to reiterate that we will take seriously every bit of
4 input from yesterday and today and consider it. Thank you.

5 Dr. Spring: Yes, Brad Spring with Roche Diagnostics. I want to comment on what you just said,
6 Bobby. Tim, I know that sometimes your FDA hands are tied with the third-party review program,
7 as far as what can be reviewed. But I think there is a good point here of having that pool available
8 and maybe even sending them 510(k)s or EUAs that have already been through a review, as a bit
9 of a test and a refresher. Then you can coordinate back on what the FDA looked for in the
10 submission, what kind of comments came up, and maybe use that as a check. Just as a suggestion.

11 Dr. Van Der Pol: That's a really great idea. Also, going forward in the future, maybe you end
12 up deciding that this becomes a process that the FDA wants to use for everything. You have people
13 who are experts in the field, helping you in the same way that NIH has people helping them. Maybe
14 it's an affordable way for you not to have staff when you don't need them, or have those staff freed
15 up to do the things that are legal, restricted, and confidential that we can't look at. I think there's a
16 lot of possibility in that.

17 Dr. Stenzel: I think it's a great idea. We'll take that. Thank you.

18 Dr. Van Der Pol: Are there other thoughts? We're still on lessons learned. If there are other
19 things that we should be recommending to the agency to really pay attention to based on what we
20 learned during the response to COVID, now's your chance to share. It's Friday afternoon. Dr.
21 Kotton.

22 Dr. Kotton: Camille Kotton, Massachusetts General. I was just curious to know if there are
23 SOPs in place. If this happens again, is the wheel or the pathways greased? Do we know what will
24 happen next time?

1 Dr. Stenzel: Yes, we can respond as needed and when needed. The Mpox responses are proof.
2 Mpox is our 9th emergency response under the EUA authorities. So, we have more than a decade
3 of experience in doing this. The scale impacts things tremendously. Fortunately, Mpox scale was
4 small. I was worried it would get into other populations, early on and it didn't, although a lot of
5 harm was done, and it impacted the populations. I don't mean to minimize that at all, but it was
6 neither at the same scale as COVID nor was any of the prior emergencies. We have to be prepared,
7 not just for anything that might come our way, but also for something that's very big and that
8 requires all hands on deck. The reports that were done on our response, contained a lot of good
9 recommendations, including, making sure that we're ready for the next one in various ways. We're
10 working on it. It will always be a work in progress. When requested, we interact with entities inside
11 and outside the U.S. government, all the time, in preparing for the next time.

12 Dr. Van Der Pol: Are there any other thoughts on lessons learned before I start to sum it up?
13 As I mentioned with some of the previous questions, there will be responses that apply to this
14 question, in other sections of today's conversation, which you'll be able to get from the transcript.
15 Here are our additional thoughts that apply to this question. There should be SOPs and templates,
16 in place, based on what was successful, what worked well with COVID applications related to this
17 response, and the Mpox response, so that you can continue to build on those activities that were
18 successful. There was some concern about the variability in the review process because new people
19 had to be brought on board and trained remotely since nobody was working together. That was
20 another aspect that probably made a difference. But, again, templates, SOPs, and guidance will
21 help reduce that variation in the review process. We must consider assays and products to be
22 prioritized that provide access to the populations that are the hardest hit by whatever the pandemic
23 may be. But that often is going to mean people who are in lower socioeconomic classes and people
24 who, for other reasons, are disadvantaged or marginalized. We need to consider whether or not

1 there could be legislation in advance that when a public health emergency is declared, triggers a
2 funding mechanism to allow FDA to quickly hire more people with the anticipation that you might
3 need additional staff. We also suggested that the agency consider a pool or a cadre of retired FDA
4 employees who might be reactivated, to quickly help and need less training or people in other
5 settings that have served as reviewers for the agency in the past. We also suggested that the agency
6 consider an expert review process, somewhat similar to the NIH study sessions. To end our day on
7 a happy note, I'll add that there was a request for nothing that involves dry ice.

8 And with that, you see everybody on the screen is smiling, so that's just a perfect way to
9 end this. I would like to have an opportunity to speak to some of the people who are representatives
10 from other sectors. We have Dr. Walker, who's our Consumer Representative, Mr. Spring, who is
11 our Industry Representative, and Ms. Schwartzott, who is our Patient Representative. Dr. Walker,
12 we'll start with you, if you have any extra comments that you'd like to add at closing.

13 Closing Comments

14 Dr. Walker: Hi, Dr. Walker, Consumer Representative. In all, I think the last two days have been
15 well spent. Today has been the most exciting for me, just really understanding exactly what the
16 FDA has done to ensure communication strategies. We've all engaged in that dialogue. I'm excited
17 to see what will come from this meeting. Thank you for everything that you've done to support our
18 communities. I don't have anything further to add.

19 Dr. Van Der Pol: Thank you. Mr. Spring.

20 Dr. Spring: Yes. Thank you. Brad Spring, Roche Diagnostics. I don't have anything else to add.
21 This was a pretty intensive two days, but as always very informative. I've been through a few of
22 these, and not to belittle what was done before, this was by far, one of the more rewarding

1 conversations because there were a lot of “what ifs?” and I appreciated that. There is nothing else
2 to add from my end. Thank you.

3 Dr. Van Der Pol: Thank you. Ms. Schwartzott?

4 Ms. Schwartzott: It was a very interesting discussion. We learned a lot from COVID. It was a
5 terrible thing but some good has come out of that. Thank you for considering people from different
6 disparities, and comorbidities, and thank you for all your hard work. I wish everybody knew what
7 went on behind closed doors because they'd be a lot more grateful. Transparency goes a long way.
8 I try to tell people how great the FDA and these panels are because there is a large amount of work
9 that nobody knows about. Thank you all very much.

10 Dr. Van Der Pol: Thank you. At this time, the panel will hear summations, comments, or
11 clarifications from the FDA. Dr. Stenzel, you have 10 minutes.

12 Dr. Stenzel: I won't need that much. This has been a really wonderful and helpful two days.
13 Every part of yesterday and today has been very valuable to the FDA. I also want to thank all those
14 members of the public who have attended this meeting online for their kind attention yesterday
15 and today. I want to thank you, Dr. Van Der Pol for your expert and excellent chairing yesterday
16 and today. I want to thank all of our panel members, including the Patient, Consumer, and Industry
17 Representatives, and all those at the FDA, who made this day happen. The input, comments, and
18 recommendations are all welcomed, appreciated, and valued. It was a great day and the FDA
19 received important input on questions of today. Thank you one and all. Thanks.

20 Dr. Van Der Pol: Thank you. At this time, the panel members are actually allowed 10
21 minutes. If we have any extra items that have not been covered. Dr. Moore?

22 Dr. Moore: Yes. The biggest unmet need in these types of situations is really not in the FDA's
23 purview, it's really the CDC and the rest of the government. That's the messaging from the FDA
24 we talk about, post-marketing or marketing, and trying to get information out. It's not really the

1 FDA's responsibility, but I think the single greatest unmet need is to convey information about the
2 problem to various populations. I'm just stating the obvious.

3 **Adjournment**

4 Dr. Can Der Pol: Any other comments? I'm not seeing any hands raised. I'd like to thank the
5 panel, the FDA, and the open public hearing speakers for their contributions to today's panel
6 meeting. This meeting of the microbiology devices panel is now adjourned and we're only two
7 minutes late.

8