Over-the-Counter Diagnostics: Advancing Home as a Health Care Hub

March 25, 2026 | 1–4:30pm ET
Hybrid Public Meeting

Transcript

Welcome

Moderator: Susan C. Winckler, RPh, Esq, Reagan-Udall Foundation for the FDA

Susan Winckler (00:00:34):

So hello and welcome. One of the things about our foundation meetings is that we try to start right on time. So we're going to get going. I am Susan Winckler and I serve as Chief Executive Officer at the Reagan-Udall Foundation for the FDA. And we are pleased to convene today's public meeting on Over-the-Counter Diagnostics: Advancing the Home as a Healthcare hub.

(00:00:56):

For those of you who are new to the foundation's work, we are the nonprofit, non-government organization created by government, so created by the Congress to help the FDA do more to protect, promotes the public's health. And we do that by convening meetings such as today.

(00:01:13):

Today, we aspire to bring together experts from across sectors to explore a critical area in consumer-driven healthcare, which is OTC diagnostics. It's a meeting about shared learning, which we hope then would inform the agency's work, as well as what the broader ecosystem is pursuing. It is not a meeting about regulatory decision making. The foundation does not engage on regulatory decisions.

(00:01:40):

Now, I do have a few housekeeping notes, both for those of us who are in the room and the folks who are joining us online. So thank you to all of those who are in the room and attending virtually. Because of the size of the meeting, virtual attendee cameras and microphones will remain off throughout the event. If you have a question and are joining virtually, please submit it through the Zoom Q&A and we will address those as possible.

(00:02:08):

For those of you who are in person, you should have received note card with your agenda. If you have a question, write it on that, hold it up, and one of our staff members will bring that to me. We promise that I will see it. We don't promise that I will say it. We have a very packed agenda today and will aspire to address all of the questions that we have, but that simply is a caveat that we must provide.

(00:02:35):

We are recording this event and we'll post the recording and the transcript on the foundation website next week. For those of you in the room, that means you may be caught on the camera, particularly if you walk towards the stage versus on the side of the room.

(00:02:50):

The slides for today's event are already available on the event page at reganudall.org, and we have paper copies available in the room for those of you who are present. There may be a slight difference between the paper copy slides and what's posted online because speakers adjust their slides. But you should get the most recent copy on our website.

(00:03:11):

And then finally, for those of you who are present in person, we ask that you do not join the virtual meeting. It just creates the potential for AV chaos.

(00:03:22):

So before we dive into the agenda for the day, I thank each of our speakers for investing in the time to prepare for our discussion. And we also thank Apple, Checkable, the Consumer Health Products Association, Hims & Hers, and the National Association of Chain Drug Stores for sponsoring today's event.

(00:03:40):

So let's review our agenda, which will be the next slide that comes up. We will begin with a grounding on the snapshot of the landscape for OTC diagnostics. Then we're going to talk about the regulatory environment and what we might learn in real world data. And also then think about how these products are used in the current healthcare system. And then finally, we'll close out with talking about potential next-generation OTC products and emerging innovations and opportunities to expand their impact on public health.

(00:04:15):

So to help us with all of that, the front of this room is populated with representatives from regulators, health professionals, manufacturers, researchers, and users of OTC diagnostics. That last category might capture all of us at some point in our day. Well, maybe not daily, but at least capture us at some point in our consumer experience. And our goal today is to surface practical insights and opportunities to advance OTC diagnostics as part of a more connected, accessible healthcare ecosystem.

Snapshot of OTC Diagnostics

Elizabeth Richardson, MSc, Canal Row Advisors

(00:04:52):

So with that, I'm going to invite our first speaker up to the stage, and then we will hear from Liz Richardson, who is Vice President at Canal Row Advisors. Liz, take it away.

Elizabeth Richardson (00:05:05):

Thank you so much for that introduction, Susan. Good afternoon, everyone. So my job in the next 15 to 20 minutes is essentially to set the table and try to make sure we're all grounded in a shared context and a set of definitions. So let's jump right into it. Let's see. Uh-oh. Do I know how to do this? I do, okay.

(00:05:24):

So I want to start by discussing the broader shift that's underway in how Americans engage in their own healthcare. It will probably not surprise anyone here that a majority of Americans, 58% by one calculation, have reported using telehealth at some point. 72% have reported using an at-home test at some point. More than half of Americans own at least one wearable or connected device. These numbers are pulled from Rock Health Consumer Adoption surveys. These would have been pretty much unrecognizable a decade ago, basically.

(00:05:53):

And I think what this underscores is that care is increasingly something that happens, or at least is initiated outside of a clinic or a lab. The home has become a genuine site of healthcare. The home, it's including testing, monitoring, receiving treatment, talking to a clinician, and OTC diagnostics are really integral to that shift. And this shift creates enormous opportunities, but it also creates new responsibilities and new risks for regulators, for payors, for developers, for the clinicians who have patients that are showing up to talk to them with data that they've gotten from tests they ran themselves.

(00:06:29):

Before we wade into that ... Okay. I want to spend a moment on the broader technology landscape just to make sure we're all clear on what we're actually talking about when we discuss diagnostics as a category. The term OTC diagnostics includes several distinct technology categories that are converging in many cases. So it's not as neat as this slide would lay out. And they all have different regulatory pathways, different consumer use patterns, and I think importantly, different stages of maturity.

(00:06:58):

So obviously in vitro diagnostics, the classic OTC test category, involve biochemical analysis of a specimen like blood, saliva, urine measured outside the body or analyzed outside the body. So pregnancy tests, glucose meters, COVID antigen tests, these are the most familiar to consumers and the most established regulatory category.

(00:07:16):

Your sensor-based diagnostics, wearables, biosensors, collect continuous or episodic physiological data directly from the body. The growth here has been pretty remarkable. By one calculation, I found the global market for AI powered wearables is projected to grow to $39 billion this year. And roughly 44% of American adults reported using at least one wearable health tracker in the years following the pandemic.

(00:07:39):

Regulatory clearance in this category is much more variable. While some wearable features are cleared by FDA and subject to all the associated regulatory requirements, others sit in a wellness category with more limited validation requirements. And the line between a diagnostic device and a wellness tool is, shall we say, contested. And the landscape here continues to evolve.

(00:08:02):

And then smartphone integrated imaging, this is the newer category, uses mobile cameras and AI to capture and visually analyze data. This is earlier stage, but advancing quickly, and has a broad range of potential use cases, including body composition assessment, fitness assessments, AI powered dermatology applications, among many, many others I'm sure we'll hear more about later today. It's also worth reiterating, actually, before I jump into this, that the boundaries between these three categories, again, are increasingly blurry. A CGM paired with a smartphone app and an AI coaching layer is leveraging multiple technologies at once. So that conversions is part of what makes this policy discussion really interesting, but also more complicated.

(00:08:46):

And before, again, we go further, I want to just dive in a little bit on the IVD category a little further because at-home testing and OTC diagnostics describe somewhat different things, and I want to make sure we're very clear about what we're talking about here.

(00:08:59):

So these are four distinct paradigms that all involve some element of in vitro testing outside of a traditional clinical lab. An OTC IVD, what we're primarily focused on here today, is a test that a consumer runs entirely themselves. They collect the sample, they run the test, they read the results, they decide what to do next. No clinician needs to be involved in that. An at-home collection test looks like self-testing from a consumer perspective. You collect a sample at home, but then it goes to a CLIA-certified lab for analysis. The results come back in days, and that test typically requires a clinician order. The result then will typically go back to that clinician.

(00:09:35):

Direct-to-consumer testing is broader. Consumers can order these themselves, sometimes with a kit, sometimes at a draw site, and then there's no standardized follow-up pathway. Some companies do offer this, but it's not necessarily part of the model.

(00:09:49):

And then point of care or CLIA waived tests, they are fast like OTC tests. They often leverage the same technology that an OTC test uses. But they are performed by a trained staff in some kind of clinical setting, a pharmacy, a school-based clinic, a mobile unit. So not a home test, but you could call it a closer to home test, offers a lot of flexibility.

(00:10:11):

Again, the regulatory pathways, the reimbursement rules, the public health implications, they all differ across these categories. So when people argue about the promise of at-home testing, it's worth remembering they may not be talking about the same thing.

(00:10:27):

So moving into the market itself ... I'm sorry for giving you yet another way to subdivide this market, but I think it's another important way of looking at things, which is just by maturity. The mature core consists of categories that have been on the market for decades. That includes pregnancy and fertility testing. The first OTC IVDs came to market in the late '70s. Blood glucose monitoring, which represents ... That really dominates in terms of commercial value. And the drug of abuse testing and the infectious disease testing, which really exploded during COVID.

(00:10:58):

The rapidly growing tier includes categories that have moved from clinical to consumer setting in the last few years. So at-home STI testing for syphilis, chlamydia, gonorrhea, continuous glucose monitoring being used for wellness and not just for diabetes management, wearable cardiovascular monitoring via FDA-cleared watch features, hormone panels for reproductive health. I could go on. No, don't need to.

(00:11:22):

And then there's more of the emerging or frontier sector, which is where the technology is more novel, kind of exciting, but it's also the least mature. So some examples that I found when I was looking included things like CRISPR-based diagnostics that could deliver PCR level accuracy in a home setting, microfluidic lab on a chip platforms, smartphone integrated spectroscopy.

(00:11:45):

And overlaying all of these, of course, and which has been much discussed in recent years, are rapidly developing AI powered interpretation layers that can synthesize test results with symptom history, potentially other inputs. Diagnostics in this bucket have generally not reached the threshold of FDA approval, but the pipeline's really interesting, and I really look forward to hearing more about that part of the market later today.

(00:12:10):

A quick word on market size, because the numbers can be deceptive. This is nominally a very large market, tens of billions of dollars. These figures are directional, different market reports will tell you different things. But it's really dominated by just a few established categories that have been around for quite a while. OTC diabetes testing alone represents a big chunk of this total. One estimate I found was 40%. Rapid infectious disease tests are significant. They swung dramatically during the pandemic, still finding their floor. And within infectious disease testing, I think it's worth saying that lateral flow assays, the same basic technology as a home pregnancy test, still account for about half of this market.

(00:12:49):

What this means is that the innovation story, the newest diagnostic technologies, the ones with the most potential to change how people engage with their health is still relatively small as a proportion of the market. So the opportunity is real, but it's not yet reflected in the numbers for reasons I'll touch on shortly, and I think others will get into more today.

(00:13:11):

So how did we get here? I think obviously the COVID-19 pandemic is the essential context for this conversation. It didn't create the OTC diagnostics market, but it did transform consumer understanding and expectations about what is normal to expect in healthcare.

(00:13:27):

I've got a few numbers here to try and capture that broader shift. According to one estimate, telehealth utilization surged 78 times its pre-pandemic baseline in April 2020, and then it didn't collapse. It stabilized at roughly 38 times pre-pandemic levels by early 2021. Reported intent to continue telehealth use also grew from 11% pre-pandemic to 40%. I'll note that there's some debate over these specific figures, but not the overall direction, which was big spike during the pandemic and then stabilizing at a higher baseline than before moving forward.

(00:13:59):

I'll also further caveat some of what I'm saying by noting that the behavioral legacy of COVID is a bit uneven. So that survey that found that 72% of Americans reported prior at-home use test also said that 64% of those had exclusively taken a COVID test, right? So significant market penetration, but also a lot of room for expansion in terms of what people could be testing for.

(00:14:24):

Provider attitudes have shifted as well. An AMA survey, for example, found that more than 70% of physicians reported using telehealth in their practices in 2024, which is up from 25% in 2018. So the ecosystem, both consumer and provider, is now much more receptive to home-based diagnostics than really at any prior point.

(00:14:43):

And understanding what consumers want from at-home diagnostics matters a lot, both for product design, but also for regulatory policy. The research points to several value drivers. Convenience and speed obviously dominate. Consumers want to test on their own schedule in their own home with results in minutes, no waiting room, no transportation, no appointment.

(00:15:04):

Accuracy and trust are non-negotiable thresholds. FDA clearance and brand recognition matter a lot to consumers. So the real world confidence that consumers developed with COVID lateral flow tests, that

built some durable trust in that format more broadly, but trust in other types of technologies and treatment modalities really has to be earned through actual performance and ongoing exposure.

(00:15:28):

Affordability is a major driver and also potentially a major barrier. The availability of free test programs drove dramatically higher uptake. The lesson for policy is direct, if a bit obvious, when tests are free or covered, people use them. When they are out of pocket, access stratifies by income. This is true for many aspects of health policy, it's not unique to OTC diagnostics.

(00:15:51):

Privacy and discretion comes up a lot, particularly for stigmatized conditions, HIV, STIs, mental health, that sort of thing. Home testing really eliminates or significantly reduces some of the social friction that comes with presenting in a clinic. So for these conditions in particular, it rates really highly among consumers.

(00:16:10):

I think data control also deserves some attention. There's some evidence that consumer willingness to share health data with technology companies has declined. One survey found that it dropped from 25% in 2020 to 14% in 2023. I think the bottom line really is just that consumers want value in exchange for their data, and they need to trust the entity that is receiving it. Any OTC platform that collects patient data needs to take this seriously and to design for it from the start.

(00:16:40):

And then integration with care, this is more of the next frontier. Consumers increasingly expect that the results will connect to something, to a telehealth provider, to a prescription, to a referral. The test and isolation model is becoming much less satisfying for consumers, and there are companies that are responding to this demand. All right, so I thought I'd wrap up with just a high level overview of some of the obstacles and the tailwinds affecting development in this market, and with the understanding that people would kind of dig into them a little bit more later today, although not all of them, so worth flagging them now.

(00:17:15):

On the friction side, regulatory pathways for novel OTC IVDs remain complex. And for genuinely new diagnostic concepts, they can be slow relative to alternative routes to market. In the IVD space, for example, developers can pursue a lab developed test model, pairing at home collection with a CLIA lab analysis, which avoids the OTC device pathway entirely. Wearable developers have the option of a general wellness intended use designation, which sidesteps de novo or 510K requirements, though that path narrows quite significantly once a true clinical or diagnostic claim enters the picture, obviously.

(00:17:53):

Reimbursement, mentioned it earlier, but worth reiterating, it's almost entirely out of pocket in the OTC space. Most OTC products do not have a clear path to coverage outside of public health emergency frameworks, and that creates access barriers for the kinds of people who actually maybe are most in need of testing.

(00:18:10):

Digital access is another one that comes up. It's growing, but it's unevenly distributed, right? So when the Affordable Connectivity Program ended in 2024, for example, 36% of affected recipients discontinued telehealth or remote monitoring. Access to at-home diagnostics really cannot be fully separated from access to broadband.

(00:18:31):

And then integration into care delivery remains limited. In most cases, OTC test results don't transmit to electronic health records. Clinicians frequently also don't know what patients are testing for at home, or they may receive output from a test they really can't evaluate the reliability of. They don't always know how to integrate it into their care decisions.

(00:18:53):

However, on the brighter side, FDA policy in this space is moving. The ACNU final rule creates some new opportunities to potentially link companion diagnostics with OTC products. I believe we'll be hearing more about that later. The 2026 wellness policy guidance for low risk devices is seeking to advance innovation in the wearable and sensor based market.

(00:19:14):

There's also the TEMP and ACCESS projects, which I won't really get into, but they do provide a signal that regulators are trying to address the reimbursement end of the spectrum.

(00:19:24):

Consumer demand is also high and sustained here. The behavioral legacy of COVID has not fully reversed their significant potential to meet that demand and deliver meaningfully for people. And in response, there are new technologies that are moving towards consumer settings in ways that could fundamentally upgrade what is possible in home testing. I think the tension between these two columns is the real issue that today's conversation will hopefully help to address.

(00:19:50):

And with that I'll close, just by underscoring key takeaways. The market is evolving rapidly. Categories that did not exist five years ago, at-home STI testing, over-the-counter CGMs, wearable ECGs, they are now commercial realities and the pipeline is pretty exciting.

(00:20:05):

Policy is moving. FDA, CMS, Congress, the private sector, they are all working on frameworks that will determine how far and how fast this market can grow.

(00:20:14):

And consumer expectations are, I think, justifiably high. Americans have experienced what fast, convenient, at-home testing can do, and they are not going back to expecting that all diagnostic information has to be mediated with an in-person clinician visit.

(00:20:28):

So the key question is, what does the path forward look like? That question is genuinely open, and I'm relieved that I'm not the person who has to answer it. I get to now pass that question on to my more knowledgeable colleagues for the rest of the day. Thank you so much, I look forward to the discussion.

Susan Winckler (00:20:48):

Thank you, Liz. What a great overview in helping us to understand. I believe you said that we wouldn't recognize this environment a decade ago. And perhaps a decade from now that will be said again. We don't know. That's about the development opportunity.

Current Environment for OTC Diagnostics

Presenters:

- Courtney Lias, PhD, U.S. Food and Drug Administration
- Ramy Arnaout, MD, DPhil, Beth Israel Deaconess Medical Center

(00:21:04):

So let's turn to our next two presentations, and then we will have a panel discussion. So we're now going to hear the regulator perspective. And for that, we have Dr. Courtney Lias, who is Director of the Office of In Vitro Diagnostics at FDA Center for Devices and Radiological Health. She oversees a range of the over-counter diagnostics and is ... I'll just throw my things on the ground. She's a skilled regulator and communicator. And with that, Courtney, take it away.

Courtney Lias, PhD, U.S. Food and Drug Administration

Dr. Courtney Lias (00:21:34):

Well, thank you very much, and thank you for having me here. Once again, I'm Courtney Lias, Director of the Office of In Vitro Diagnostics at FDA Center for Devices. And my office regulates in vitro diagnostics and also diabetes diagnostic devices. So I'm going to focus a lot on my talk today on in vitro diagnostics. However, I do want to get you to keep in mind that a lot of the concepts that I'm going to talk about, the concepts behind them, whether even if you're not an in vitro diagnostic, even if you're a digital health diagnostic or a non-in vitro diagnostic, a lot of those concepts still apply. I'm really going to talk about how do we get these products from the development phase to the market with respect to what makes a good over-the-counter device? What do we look for when we are evaluating a diagnostic and trying to bring it to market?

(00:22:22):

So with that, I'll go ahead and get started. I want to ground this. CDRH has a very large initiative called Home as a Healthcare Hub, really meant to do what I think we're all talking about today, which is how do we get more devices integrated into the home environment? How do we enhance the infrastructure that patients have in their own homes to enable healthcare there? And a piece of that is diagnostics. It's certainly not the entire piece, but it's an important one because you need to be able to have some certain types of information. Can we enhance the way that consumers interact with their healthcare providers? Can we enhance the way that they find information more quickly? Can we enhance the way they understand that information and integrate it into their lives?

(00:23:10):

And how will this affect their greater health management? Will they be able to do this? And I think we just heard people really want to do this. This is something that people are interested in and that the attitudes toward that are changing as people realize that maybe this can be possible for me.

(00:23:28):

We've already heard this. I won't belabor it, but there is increased comfort with home diagnostic evaluation, most likely because of COVID. We certainly had pockets of comfort before COVID hit, but certainly, we've seen a huge spike in the interest of over-the-counter in vitro diagnostics following the COVID testing at home efforts during the pandemic. And people really do want that real-time health data.

(00:23:53):

We noticed this in diabetes more like about 15 years ago, where people really wanted to be able to connect the products that they use for the diagnosis that helps them manage their condition with the

products they use in their consumer lives. Teenagers really wanted to be able to integrate their blood glucose diagnostics with their cell phones so that their friends didn't have to see them checking their blood glucose all day on a meter. They wanted to use CGMs more discreetly. Parents wanted to monitor their toddler's glucose from afar. And technology has enabled this, and I think that these types of opportunities can expand beyond diabetes to a lot of different areas.

(00:24:32):

So we've been doing over-the-counter diagnostics, as was mentioned, for decades. Over-the-counter diagnostics from the perspective of our office is not a new thing. We have authorized hundreds and hundreds and hundreds of over-the-counter tests. For many years, it was predominantly pregnancy, blood glucose, cholesterol, hemoglobin A1C, a lot of the types of things that people are more familiar with these established technologies. But there has been an increase in other types of technologies and interest in other things at home. We have over-the-counter versions of genetic tests now at home. We have over-the-counter infectious disease tests, and certainly people have been able to for a long time do drug screening tests. But we're getting interest now in all sorts of tests, different types of tests as were mentioned before, hormone screens, creatinine, you name it. People have come to us in the last few years asking, " Can we put some of these products over the market?" What I want to talk about today are some of the considerations if you want to move from a laboratory based test or professionally directed testing into the home environment.

(00:25:41):

So just to give you a sense, this is the volume of home use authorizations that we have done over the last several years or whatever. So if you take the blip from COVID where a lot of our resources were focused toward COVID testing out, it's around an average of 40 new over-the-counter tests per year, and that doesn't count sort of high volume tests that may have multiple names or versions on the market. So this is individual new authorizations for tests and of different types.

(00:26:12):

So this is a pretty routine thing for our office to do. And I think that's something that I wanted to mention because a lot of the conversation is around how new over-the-counter testing is. But what I want people to talk a little bit about today is how can we learn from our many years as an industry and as regulators of the over-the-counter tests that have been available to apply that to the new tests that might be coming in the future?

(00:26:38):

The new area that I mentioned is infectious disease. That is where we have the highest volume of interest. We have authorized more than 50 over-the-counter COVID tests over the last several years, obviously, last five years, and also additional COVID tests in the form of multi-analyte panels. Just this past fall, we authorized the first multi-analyte test, which contains COVID, flu A, flu B, and RSV, which put RSV over the counter for the first time. And this is really valuable because now patients at home can distinguish between these similar looking respiratory viruses to help them figure out what to do. If I have an infant and RSV pops up, you really need to get that infant to the doctor versus if I have a 10-year-old with COVID, you might just want to isolate them and watch them and monitor them and talk to their doctor.

(00:27:28):

And as mentioned, there's growing availability of other things. The privacy aspect of STI testing in the home can't be overstated. If we can get more people tested, even if there's a trade-off in accuracy for some of these over-the-counter uses, it still may catch people at the point at which they can understand

what to do, especially for people who may not have a doctor to go to or may be nervous to go to their doctor.

(00:27:57):

So I'm going to shift now into what would we think about? Why can't we just put all tests over the counter? Why aren't we getting interest in putting every single lab test that's over the counter? And the issue is some of them just they haven't figured out how to put them over the counter yet. It's not necessarily a willingness thing on our part or on industry's part, but there are certain things one has to think about when taking a laboratory test, something that may work in the laboratory environment and figuring out whether somebody can use it at home.

(00:28:25):

So I've named a couple of the things here. One is usability. Someone at home needs to be able to use it. In glucose meters, something that comes up a lot is accessibility with respect to how large the numbers are, how big the buttons are. If this is going to be used by your 80-year-old grandmother, can they work the test? Can they manipulate the packaging? Can they read the writing on, which quite frankly, some of the instructions and writing on some of these tests is pretty small. Can they understand the instructions with the educational level appropriate for all lay users?

(00:29:03):

Is the product robust to damage? These over-the-counter products are put through the ringer. They may be stuffed in a grocery bag and banged around on the way home. They may be left in the trunk of somebody's car before coming in in Arizona. They may be accidentally frozen while they may be carried around in someone's purse. So these types of things, one needs to understand what will happen if those things happen and make sure that harm doesn't come out the other end of those things.

(00:29:32):

Stability, these things are often made, they're shipped to Walgreens or CVS and sit on the shelf for a while. So you have to have a product that can last more than two months. Ideally, most of these products have two year shelf lives, and that is to help them have sort of a feasible way to get to consumers. Because if you have a 30-day shelf life, you're not going to be able to be manufactured, stored, shipped, and used within the timeframe that the test will actually work. So companies have to develop ways to make certain types of tests more stable. Whereas in a laboratory, they may have mechanisms to turn product over quickly and to store them in temperatures that aren't available to the home user.

(00:30:14):

And they have to be safe to use at home. There are certain laboratory type testing that use toxic chemicals. And we've had cases where a chemical in sample collection media interacted with bleach and there was chlorine gas released in a facility where it had to be evacuated. There were some injuries. You don't want that to happen in someone's living room because somebody accidentally decides that they need to disinfect the area with bleach before they use a particular product.So reagents sometimes need to be changed. Companies may need to adapt how the test works to put it in the home.

(00:30:52):

We also have to say, what happens if something does go wrong? As I mentioned, if it's left in the car and the temperature's exceeded, does it give you a wrong answer or does it give you no answer?

And ideally for an over-the-counter test, you most often want the no answer scenario. It's not ideal to buy a test and then not have it work, but it is sometimes, depending on the condition. Better to not have it work than to give you the wrong answer. If you're using a glucose meter and you get a result that

says that you're 300 when you're really 100, that's a real problem for someone with Type 1 diabetes and you just don't want that to happen. Specimen is another consideration. So specimen types and how a user might collect it is a big consideration. So some specimen types may be tricky to collect. It may be difficult and you have to have a lot of training to collect it. We don't currently have any tests that require venous blood because at home there's currently no mechanism to get a venous blood specimen. So we have to revert to capillary blood. There are sometimes differences between venous blood and capillary blood for some types of tests. And so you have to figure out, can I account for that or can I choose a type of specimen that's easier? There's certain ways that you collect the specimen. Is it going to affect the results or is it not going to affect the results? And then how long does it take? If you need to apply the specimen right away, that needs to either be very clear to users or we need to have something that's a little bit more robust to the type of natural distractions and delays that might happen in a home environment.

(00:32:28):

And there's pros and cons to all types of specimens. People really like things like saliva and maybe urine in some cases because they're easy to deal with, but some tests, it's more appropriate to use blood. Sometimes dried blood spots might be the preferred specimen so that they can be entered into a little small instrument or in some cases, they're not the topic today, shipped off. However, when you're using dried blood spots, the specimen is altered in ways that's not typical in a laboratory test in a lot of cases where reconstitution and stability become factors. And so manufacturers trying to adapt current laboratory based test into over-the-counter tests have to balance all these considerations.

(00:33:09):

And at the end of the day, validation is what is my test supposed to do and what kind of information shows me that somebody can pick up this test, use it according to the instructions and get the right answer? And so they do testing using lay users to see if they can pick up the box, open it up, figure out what to do with the test, run the test, and then they evaluate whether they got the right answer or the wrong answer. They have to evaluate whether it's robust to shipping that would be expected for the type of test. And then they have to evaluate whether people understand what the result is. Did I get positive or negative? And then what the result means for them, what should they do?

(00:33:50):

And labeling is super important for that. We evaluate the labeling for home use tests. Generally the same way we evaluate labeling, but the questions we ask are somewhat different. We look at the grade level, reading level of the inserts. It should not have words or phrases that somebody with a lower grade level reading can interpret. So we often go for eighth grade reading level or lower for over-the-counter labeling, but that means sometimes you have to adjust the types of instructions you're given. There's a lot of pictures. There's a lot of text that gives examples in order to help people understand what they're getting, what to do and what not to do. You need to sort of evaluate whether or not it's clear to people that they're the people who should use this test.

(00:34:37):

Sometimes that's very easy. This test is for people with diabetes. "Oh, I have diabetes. I should use this test," or, "I need to know whether I have COVID, that one's pretty easy." There's some other things where it's not super clear or it's not as clear to describe who is the correct user for this test and who shouldn't use it. And then as I mentioned, can they understand what to do? What does a positive result mean? Does a positive result always mean that you have this condition or does it merely mean you might have the condition? Is that something that they understand well enough to know what to do? Is

the instruction to call your doctor or is the instruction to take some sort of medication or is the instruction something else?

(00:35:18):

And what are the benefits and risk of that, and that varies by use, but we really work with people to try and figure out for both the individual and society, what is the best balance between those two things? Because there are no tests out there that have no risk and no problems, but they often can have a lot of benefits or potential benefits and we don't want to hold those up for the perfect test.

(00:35:40):

So I'll close with some of the things. What are we doing to try to help enhance the availability of new and good over-the-counter tests for people to use, tests or devices or digital health products, or whatever may come to be? We often will publish... We have a lot of guidances. My next slide is a slide with links of some resources that we have online for over-the-counter diagnostics, including websites and guidances that we already have that exist. But another thing we did, particularly during COVID, is that for manufacturers who want to submit a new test and maybe aren't used to working with FDA, we published the template, basically a form you fill out, here is the information that you should send us on your test to help us work with you when you're reviewing your test. And we believe that that makes things a little bit easier.

(00:36:30):

We also publish after we authorize a test exactly what we did to put a test on the market. We work with NIH's ITAP program to enhance our ability to help manufacturers validate new tests, and five of the COVID multi-analyte tests that are on the market that are over-the-counter went through this program. We do overt industry outreach such as today to make sure we make connections and so people know that we're people that they can come and talk to. We have our Q submission program for any of you who are interested in talking with us about your own products, and we work very closely with our federal partners to understand what are the important things that people need to know and how can we solve problems together. And I know I am over time. So I look forward to the discussion today. Thank you all very much.

Ramy Arnaout, MD, DPhil, Beth Israel Deaconess Medical Center

Susan Winckler (00:37:17):

Great. That was a great overview, Dr. Lias. Thank you so much. I felt like you were talking directly to me when you said that the font size had to be big enough on these, so I'm going to do this next introduction without my glasses. We will turn now to hear more about real world data collection and performance evaluation of diagnostics. And to give that presentation, we'll turn to Dr. Ramy Arnaout, who is associate professor of pathology at Beth Israel Deaconess Medical Center and Harvard Medical School. Take it away.

Dr. Ramy Arnaout (00:37:52):

Thank you. Well, in light of those two amazing presentations, I'm actually going to change up what I'm going to present just a little bit in order to be a little bit less duplicative and give a little bit more of in the trenches view based on the example that changed a lot for OTC diagnostics, which of course is COVID, as we've heard. The interaction between at-home testing and in-hospital testing really mattered a lot in COVID, especially because among other things, as we're trying to develop on the fly, we ended up having to come up with standards on the fly and interpretations on the fly, even as we were trying to

understand the biology and the pathophysiology on the fly. For those of you who are basically evolutionary history buffs, there was something called the Cambrian explosion that happened once upon a time, several hundred million years ago, which is basically when we went from all being little single cell life forms to multicellularity, and this was like a big thing on earth.

(00:38:52):

And I draw an analogy between that and COVID testing because it was a very, very short amount of time where we went from just a single cell to all these crazy, what they call body plans. So organisms with six legs like we see today with the insects and with eight legs like we see with arachnids and with four legs or two legs and two arms, kind of like what we see, but also just weird things like three tri-symmetries and on all these others just like crazy things, most of them which didn't last. And the analogy is a little bit like, well, we came up with this idea that we could handle multicellularity, and so we did, and then we have to figure out, okay, what makes sense and what doesn't and what's going to kind of like work as an ecosystem on earth.

(00:39:37):

So maybe a bit of a tortured analogy as I'm trying to do it on the fly here, but the analogy is very much like, for example, with COVID testing, COVID testing when it first came out was it had the diversity, the explosion of different analyte units, and that was quite a lot of consternation because we at the hospital would see results where we were trying to understand a threshold of detection versus a threshold of infectivity, trying to compare things in units of animals to infectious doses, to things that we're more familiar with. It's like copies of viral load, genetic material per ml of fluid, and then somebody raises their hand say, "Ml of fluid? Well, my kid had a really runny nose and this other swab sample is really dry. So what is the actual fluid?" Oh, it's the fluid that it goes into, but then different tests use different amounts of fluid that the test went into.

(00:40:32):

I bring up all these details just to kind of refresh our memories from time that a lot of us would like to forget about the unbelievable diversity of detailed decisions that need to be made, and Courtney kind of went into this in some detail, not in terms of units of measurements, but all little things that we might not think about when we have to put together an OTC test or indeed any test, labeling, stability, validation and so forth. So I bring that up as an example. A little bit of background about me and the opinion that you're getting here is, so I am a director of laboratory medicine at one of the Harvard hospitals. Laboratory medicine is a specialty that deals with laboratory testing. And so about half of my time I dealt with that, and the other half of my time, I am a researcher where I study not only laboratory testing in various ways, specifically around the democratization of large corpuses of laboratory tests, but also machine learning in order to provide synthetic laboratory tests that really are designed as a way to both get more insight out of tests that we collect and to be able to handle the privacy concerns that both Elizabeth and Courtney touched on. So the impression that you're getting is from that.

(00:41:55):

Like I said though, I'm changing things up a bit on the fly. I don't want to be too duplicative. Why testing matters? The main thing is that it is more convenient and leads to better health for the patient and more convenient leads to more cost-effective care for us at the hospital. Four things that a patient does not need to see a clinician or anybody in the healthcare ecosystem in order to take care of themselves for. It is better for everybody that they not have to go through the extra work of going to a clinic, going to a doctor, heaven forbid, going to an emergency room. Easier for them, easier for us, easier for our economy. We've gone through most of the rest of what's on here. As Elizabeth pointed out, these are highly skewed tests where although there are many, many more coming on the market, it's still mostly

like if you just had to add them up, it's a lot of glucose monitoring in certain populations, and then infectious disease testing, obviously near and dear to my heart, although that is changing.

(00:42:54):

The thing that I want to comment most on, I think, is that the results aren't stored. They usually are noticed by the patient, by design; acted on by the patient, by design; but largely lost to the rest of healthcare. These might be important for that patient's care. They might not. It's hard to tell without having the data. And they might be important to overall improvement of healthcare and they might not in terms of epidemiology, understanding what patient populations may or may not be getting the care that we imagine they should be getting. And the reason is if that information doesn't make it past the patient, then it's just lost. It's dark matter as far as healthcare is concerned. And to really get the most out of OTC diagnostics, that data really needs to become part of the patient's electronic record in some way and not just stay dark matter as most of it is now, which is invisible to care teams.

(00:43:58):

I'm going to skip past this because we've gone through it. So three ways that OTC results reach the electronic health record in those rare cases when they do, and none is ideal. And that's really where I'd like to, or I'd like to focus here. But the three are, first is the provider enters a test. So the patient at some point sees a clinician, either they got a test that said, basically go see your doctor, or they got a test that they were concerned about or they were just talking with a doctor, and the doctor and taking the history asked about something. The patient said, "Oh, yeah. No, I took one of those tests. I think it was... I forget. It was one of the influenzas and I can't remember which, but it was nice. There were a bunch of lines, but it wasn't COVID and that was what my employer needed to know. So I'm just letting you know that."

(00:44:42):

And now the provider is thinking, "Well, did the patient recently have influenza? In which case it might make it more or less likely that that's a symptomatology that I'm looking at now or was this something else?" So in those cases, the provider will enter things into the chart. And something I think that everybody knows, because everybody, whether you're in healthcare or not, is always a patient at some point is that entry is not always done well.

(00:45:05):

Things have gotten qualitatively different and I think better with the introduction of AI assisting in patient caregiver interactions to sort of record these things, but you still have things like I encountered distressingly recently, which is I was asked by a new physician about the color blue and I was a bit confused. I thought one of us had had a stroke, and I said, "Why are you asking about the color blue?" It's like, "Why are you okay with it?" And I said, "I'm not understanding the question." And he turned the monitor around and it said, "Allergic to the color blue in my medical record." So I'm not quite sure how that got in there, but I didn't enter it. So that would have been entered by some provider at some point. And so manual provider entry is also fraught with error.

(00:45:52):

Also fraught with error and difficulty is patient portal entry. So it's kind of better you take one person out of the loop, but it puts more work on the patient, and for all the reasons that Courtney mentioned, that's not always the easiest thing for patients to do. So I would say that of the three things that I mentioned, the third one, image capture and barcode scanning, is probably the easiest and best, but the key challenge here, and here I've just got a picture of a fanciful future potential laboratory test here, in this case for sepsis... Wouldn't it be nice to have a lateral flow test for sepsis that's telling you whether a

gram positive or gram negative and everything else about it doesn't exist, right? This is just a figment of my imagination, but has a barcode on it and that would be scanned and go somewhere.

(00:46:36):

But the important thing is that each method here requires some activation energy from the patient, and so there is a great need for design and emphasis on user interaction and user experience, UX here, in order to make widespread data collection work. This slide is more or less exactly in your records. I'm happy to talk about any and all of these use cases, but the short story is there's a smorgasbord of potential use cases for what one can do here. I'll single out one that impacts both the providers, the patients, test developers, and the FDA, which is something that came out of work that we did in COVID, which is we get a different type of data from lateral flow tests from what we get in the hospital, but because it's the same ultimate analyte that we are looking at when it comes down to it, we can connect those in order to ask questions, decide whether or not there are differences in how tests perform on different populations and whether there should be attention to different components of patient demographics or backgrounds.

(00:47:47):

So for example, it was known that certain minority populations had worse care and worse outcomes in COVID, as regrettably is the case across healthcare, but it was thought that this related to higher viral loads in those patients. It turns out when we did a cross-correlative study, that was not the case. The worst outcomes actually correlated with lower viral loads in that patient population.

(00:48:12):

And you say, "Oh, so are sicker patients, do they have lower COVID viral loads?" This is the amount of virus that a person has on board. And it turned out that it's highly variable and dependent on the particular question you were asking. So if you were looking at patients with lung disease who did worse, you would say, "Well, certainly they had higher viral loads than patients without." "Nope, not the case." And you said, "Oh. Well, the patients who are going to die, those patients didn't have higher viral loads. Is that what you're telling me?" "No, those patients did." And it was like, "Well, you're telling me potentially contradictory things." I was like, "No, I'm telling you subtle things that the data shows that you can only get by collecting all of this information."

(00:48:48):

And then to be able to hook up what you learn from, in general, more sensitive tests that are done under more controlled circumstances in a hospital setting with the vast amount of, again, what is mostly dark matter that you get from OTC data would let you consider how you want to treat patients differently based on, for instance, whether you get a negative or a positive, especially given that the at-home tests are not as sensitive in general, though not always the case, but still very, very useful. So I will conclude with a potential vision, and I know I'm over time, so just a minute here on how we might go from over-the-counter tests to shareable data. And I think there really is a great use for that AI layer in a couple of places. So here I have... I don't know that this is a... It doesn't matter.

Susan Winckler (00:49:41):

It doesn't.

Dr. Ramy Arnaout (00:49:42):

So here, people I think can still hear me and are still being picked up by the microphone if I walk over. We have our test, we have a result, snap a picture with a smartphone. There is a question about

whether it should be a picture that we snap or whether it should be placed in front of the smartphone as the test incubates. Perfect.

Susan Winckler (00:50:02):

But now you have 30 seconds.

Dr. Ramy Arnaout (00:50:06):

... as the test incubates, in which case you can maybe capture how these go positive, which might give you some quantitative information that we didn't know that we could get that you can figure out once you collect a lot of things. Let the patient have control over who can get access and have them able to rescind it. So my doctor who will know it's me, or a database where no one will know it's me, and then they can send or see options. The data will go to one of those two places, or both. And then from there, we now have technology where we can take the data that is identifiable, but de-identified, derive all of the statistical relationships that are in that data to create synthetic data as much of it as you want, which now is, if done correctly, not identifiable. And now this can go for all the use cases that we mentioned to these six big stakeholder groups.

(00:50:56):

So just one vision of the future here. Challenges, incentives for how patients do this stuff, trust, a huge issue. Look up Shoshana Zuboff's Age of Surveillance Capitalism book. Technical questions, how shall we collect the data? What type of data do we want to record? Line intensity, a time to positive, environmental conditions as we heard about before, and the quality of the synthetic data matters. Huge issue, which I'm just going to gloss over is what are the incentivizations and standards for developers and regulators to use all of this data? This picture on the right is just to show that a lot of AI is getting very good, good enough to be able to use on your device. So you don't actually have to send anything anywhere except the actual results. And with that, yeah, this is a large untapped data source that can improve care. Local processing of AI and patient control sharing can address privacy concerns, and synthetic data can bridge the gap between useful analytics and strict privacy mandates. Overcoming these challenges I think will help get us a lot more out of OTC than we do.

Reactor panel:

- Julie Barnes, JD, Maverick Health Policy
- Anita Nosratieh, PhD, Abbott
- Stacey Swartz, PharmD, Neighborhood Pharmacy of Del Ray

Susan Winckler (00:52:05):

Fabulous. Thank you, Dr. Arnaout. So I invite Dr. Lias and Dr. Arnaout and our reactor panelists to come on up to the stage to help us think through what we just heard about. So joining me on stage, I get to sit down with you for this part, we have three additional folks who are coming up to help fill our conversation, Dr. Nosratieh, Dr. Barnes, and Dr. Swartz. Thank you for coming up to this stage. And I first want to say, do either of the three of you have any questions for Ramy or for Courtney? It was just fascinating, and I'm looking forward to that data repository that I cannot be identified in, but that's a good one. So then let me start here with the product sponsor perspective. So joining us from Abbott, where she serves as Director for Global New Product Introduction and US Regulatory Affairs is Dr. Anita Nosratieh. What factors do you consider, you and the company consider when you're selecting a regulatory pathway? We saw a couple of different presentations of what that pathway might be, and how does that shape the development process for diagnostic products?

Dr. Anita Nosratieh (00:53:30):

Thank you, Susan, and thank you, Courtney and Rami for setting up us very well for this discussion. So we see the regulatory pathway truly fundamental and strategic to our development. It helps to inform the early stages of design input all the way through how will this be used in the real world. So first we begin with the intended use and clinical context. Is this product going to be used for screening, diagnostic, monitoring, and how does timing play into that? So for many conditions, like influenza, we know that optimum treatment is within the first 48 hours of symptom onset, and so the true value of that test is not only in speed and access, but also ensuring that we're getting that analytical performance that outside of the lab setting.

(00:54:33):

Secondly, we consider who is the actual user of this, and in what settings is this product going to be used? So rightfully and appropriately, FDA extends its expectations to human factors, labeling comprehension, and the potential of an erroneous result by the lay user, and these are all considerations that we tie in to the very early stages of development. So then finally, we look at the regulatory strategy in what is the analytical performance that is needed and what are the clinical validation that's required to support this? We aren't designing tests for the professional in a lab. We're designing tests for a at-home population that is now a non-traditional clinical setting. So all of these points factor into our design and development process.

(00:55:36):

When we look at at-home OTC tests, we consider usability human factors from the onset. These aren't afterthoughts. So from the beginning of device design to workflow, to labeling, to even the setting of use, we incorporate those factors into our development. And so just one final point is that at the end of the day, we believe that regulatory pathways should be there to help give answers to patients that need them in the time and places where those answers are most needed. And so when regulatory strategy and design and access are aligned early, that helps streamline the development process, which then has a potential more meaningful impact to public health.

Susan Winckler (00:56:31):

Yeah. So as you were saying that, I imagine I'm not the only person who is thinking about the back of their car and the illustration that that might be where the tests have to travel through to get to the consumer's home. But thank you for that, helping us pull together the strategy and the regulatory environment and thinking through that in the product development perspective. Let me turn then to another step in the journey. If the products are developed, then who helps consumers use those? I'm going to turn to Dr. Stacy Swartz, who's a pharmacist and owner of Neighborhood Pharmacy of Del Ray. It's just over the river in Alexandria, Virginia. But Dr. Swartz, what do you consider when you make decisions about what OTC diagnostics to offer in your pharmacy, and how do you counsel customers about how to use those products?

Dr. Stacy Swartz (00:57:26):

Well, one thing about my pharmacy is I'm just a single store owner. My pharmacy's very small. So we have less than a thousand square feet, of which about 500 of that is for the pharmacy part. So we have to be really strategic in what kinds of outfront products that we have. So when I think about it, I think about whether or not the patient's going to pay out of pocket for it or if it's going to be covered by insurance. So I want to say probably 95% of the time for blood glucose meters, that they're covered by insurance. It's just a question of which one is preferred. So in that situation, we'll just order it on

demand. So we don't necessarily keep a large stock of the meters and the strips and stuff like that because we're just going to order it and it'll come the next day.

(00:58:14):

But for things like pregnancy tests and COVID tests, we're not like the CVSs and the Walgreens where there's going to be a variety of things in my store. I'm picking maybe one or two, and I do that based off of price and user feedback and what they recommend to go for. So for example, when you're looking at a COVID test or a flu test, I'm going to get the one that combines them together so I only have to carry one and I don't carry three different models of it, I just carry one, and that is usually based off of our experience and what works best for us.

(00:58:52):

And you mentioned counseling on it. So for counseling, I want to say, and I think it was reiterated from your presentation, that I think that instructions on how to use it are really good. So a lot of times I'm not necessarily helping people through the process of how to use the machine, I'm talking to them more about what they do with their results. So if it comes through as being a positive COVID test, then there's a whole conversation, should I get the antiviral? What kind of effects should I have for that? So that's where I spend the majority of my time.

Susan Winckler (00:59:23):

Yeah, that makes sense, and it's very helpful for us like just thinking about the context where a consumer might access and you actually feed us right into our third panelist because you brought up the access point that was also raised in Liz's presentation about coverage. So to help us think about that payor dynamic, how these products are paid for, Julie Barnes is the founder and principle of Maverick Health Policy, and you have insights into how health plans make coverage decisions, which is one of those things that we want to talk about today. So walk us through what payors consider when they're thinking about coverage decisions for OTC diagnostics.

Julie Barnes (01:00:05):

Yeah, absolutely. And Maverick Health Policy obviously is not a health plan, but we do work for health plans and give them advice all the time, and it's something that we do because I was a litigator back in the day on behalf of health plans, basically helping them defend against what they would and would not cover. So we have a very good sense what health plans will and will not cover in terms of over-the-counter diagnostics, and the answer is it depends. Just-

Susan Winckler (01:00:37):

Spoken like a true attorney, Julie, which I say with a collaborative and-

Julie Barnes (01:00:42):

All kinds of favor, I'm sure. Yes. The point is, is that health plans will pay for what they think is necessary, what is medically necessary, what a provider decides will be the thing to have as a wearable at home that can help monitor a chronic condition because they are trying to prevent desperately something from going from bad to worse, right? So if you are a health plan and you are overseeing a risk product, you are trying to prevent bigger risks, and the diagnostic space is a gateway to what can be the treatment plan for given conditions.

(01:01:22):

So you're really wary of diagnostics. It cuts both ways, right? You both want to make sure people get the right lab test so they can find out about the things so it can be treated at the right time, but you're also thinking, "Okay, but is that really the right test and is it going to open the door to a whole bunch of other tests that are more specific that maybe we should have gotten in the first place?" So over-the-counter tests are particularly tricky because as we just heard, it is not necessarily clinically valid. COVID-19 tests are the prime example of this. It was a forced march for health plans to pay for COVID-19 tests, and they would not do it again unless forced. Why? Because everybody screwed up their COVID-19 test results. They did a hundred or they did one or they did two, and what happens? They show up with the positive test. And what is the first thing that happened when they got to the doctor's office? They took another COVID-19 test.

(01:02:22):

Plans aren't going to pay for things twice. They will pay for things that are a replacement, a Cologuard. So if it prevents a colonoscopy, which is super expensive and super not what we want to do, and they can rely on the poop-in-the-box method, that's what they'll pay for. But it's prescribed. The glucose monitoring devices are prescribed. We're in a whole new ballgame with this.

(01:02:53):

So I don't want to say what's in the coverage plans today and the benefit designs right now are going to last, because with the wearables push and everything else, it is just a totally new day in America. But at the moment, basically on page 64 of all those coverage documents, it says, "Will not pay for over-the-counter supplies." Unless prescribed by a doctor, maybe, but that's as good as it gets right now. But we are in a new day where that is going to start to change.

Susan Winckler (01:03:25):

That's really helpful, Julie. And I think your example on the dual testing, it's one of those that I think is also evolving. I was fortunate enough to use one of those with my teenager, used a test, said she had influenza A. We got to the clinic at the pharmacy and they said, "We'll take that result," and then did the intervention. So she was on a brand name drug that I won't name by brand, within two hours of a positive test.

(01:03:56):

But that I think is still the exception, and probably needs to become... Well, we need to better understand the performance and where that replaces something further. Right, yeah.

Julie Barnes (01:04:07):

Well, it's also a very low-hanging reimbursement model. That is little, little money. When you start talking about bigger, badder tests, like genetic testing, nobody's paying for 23andMe, no health plan. But a more specific genetic test that has been prescribed by a doctor, because you know you have some sort of history with some sort of genetic anomaly, sure. Right? So again, it depends.

Susan Winckler (01:04:34):

Yeah. Yeah. And then thinking through also the availability in an OTC environment, when that works and when it doesn't.

(01:04:40):

So Dr. Lias, I want to turn back to you. Julie raises a point that we haven't talked a lot about, and that's the real-world performance of the tests. You signaled a bit to this. But what is the agency able to

observe from data about use and performance in the real world? I mean, we all have the stories of those who we know didn't do the tests well and then got better at them. But what does FDA see in that space?

Dr. Courtney Lias (01:05:08):

So actually the most adverse events that the center receives is for home diagnostics, but they are for diabetes. So if you take out diabetes, we actually don't get a super high volume of reports from consumers, because they don't really have the information to report. Not necessarily how to report, though some of them may not understand that they can do that and how to do it, but more they're not getting the information on whether the test is right or wrong.

(01:05:38):

So the types of things that we might hear more often are if it has a battery and the battery explodes or there's something wrong with the product itself. But we do get information sometimes, most often because a test is incorrect. But if we take COVID antigen tests, for example, they're 80% sensitive anyway. You're going to expect false positive and false negative tests. And so it is a real challenge to get information about differences in test performance when these over-the-counter testing situations happen.

(01:06:11):

So what happens a lot of times is that information is often coming from the manufacturer. A manufacturer might get some feedback from their consumers or pharmacists and do investigations and find an issue themselves, and then maybe perform a recall of that test or something like that. But I think that emphasizes the importance of more ability to collect post-market real-world data, including for over-the-counter tests. Because when you talk about the use cases you mentioned, to me what comes to mind is the post-market setting, is understanding the bigger effects of test, either migrations in performance or the performance that always was there, and that effect on the epidemiology of some sort of disease or condition.

(01:06:57):

So I do think there's real opportunity there.

Dr. Ramy Arnaout (01:06:59):

And ultimately there's a limit to what can be reasonably expected for a developer to do in terms of the amount of testing, and the amount of testing for the FDA to require of the developer. And so you have to go out, you have to make your best guess, at some point beyond the categorization that you want there's going to be random sampling.

(01:07:23):

Well, random sampling is fraught with statistical sampling error, it's just the nature of statistics. It's not anybody doing any harm. Ideally, you want to have an infinite number of people take an infinite number of tests under an infinite number of conditions, and then you will really know. But absent that, you really do need that post-market surveillance in order to understand, well, any wiggle room, any unexpected things that no reasonable person could have planned for, either on the developer side or on the regulatory side. That is just going to come up because you see how it's used. And especially because how it's used, as you say, might migrate with time and might differ in different subpopulations.

Dr. Courtney Lias (01:08:00):

Right. We can never only rely on this pre-market phase, it's always a balance and one that we try to get better at over time.

Susan Winckler (01:08:08):

Yeah. And Julie, would that... Gathering more of that post-market performance information, is that helpful to payors? Does that help them think through that decision and evolve, potentially?

Julie Barnes (01:08:20):

Eventually, right? I think right now we're not really at a sophisticated way of gathering this information, and definitely putting it in the medical record is a whole nother problem. So the proverbial blood pressure cuff is not necessarily attached to a tracking device right now that goes directly into the medical record, hardly ever, really.

(01:08:43):

But the access model, the new CMMI model that Abe Sutton is pushing as a new alternative to try to pay directly to technology companies for just that kind of a thing, a blood pressure cuff that is attached to a monitor so we can track grandma's blood pressure from afar, they're trying to set that up to be a direct model. And they have gotten payors to pledge, "Yeah, we'll do that too, right along with you, Medicare, to see how this works."

(01:09:11):

And in answer to that, the FDA is basically saying, "Okay, if you are not an already approved blood pressure cuff with a diagnostic tracker attached to it that's been approved yet, we'll let you do it just for the access model. In this one clever pilot demonstration program called TEMPO, we'll let you gather this real-world data and prove that you have proven your safety and your otherwise would have gone through a clinical trial process through that model."

(01:09:44):

So again, the world's a-changing. That hasn't been true before, you always had to jump through very specific FDA hoops, previously. So health plans are not just tracking that, they're going to try to do a parallel model, basically, in order to see if that is a good way to reimburse based on the data they're gathering as you go. I think we're kind of far out from this being just a blanket truth, but that is starting to happen now.

Susan Winckler (01:10:15):

And... Go ahead, yeah.

Dr. Anita Nosratieh (01:10:17):

And the areas of opportunity we really see here too is not just the post-market space, but the test-to-treat piece. So you do a home test, you get a result, now what? And so that data collection piece is something that we really do see an opportunity to solve for, because we recognize that home testing isn't necessarily an option of going to the doctor or taking a home test. For most people it's home testing or not testing at all, given the barriers to access, whether it's time lost from work, childcare limitations, physical disability of going to a doctor.

(01:10:56):

And so we do really want to thread that needle, between getting a at- home test result and the pathway to treatment.

Susan Winckler (01:11:04):

And that brings me back, Stacey, to something you mentioned about when that they get the result. It may often trigger a question and say, "What is it that I might do?" And so tell us a little bit more about that conversation. You mentioned it, but...

Dr. Stacey Swartz (01:11:19):

Well yeah, 'cause in some cases they do have test-to-treat in pharmacies. So you can go and you get a positive COVID or flu, and then the pharmacist can then turn around and prescribe at the point of care. So you walk home and you have the medicine at your disposal. We don't do that there in our store. So in our case, we're often having a conversation about whether or not the medicine makes sense for them, whether it's something they can treat at home and what kind of steps that they have to do it.

(01:11:51):

I think sometimes too, the conversation we're having is people don't necessarily react the way you think they're going to react. So my mom is an example of this. She got a positive COVID test once, but it was light. So she thought she had mild COVID, so that meant that she could go do what she wanted to do. So I don't necessarily...

Susan Winckler (01:12:14):

So she was only mildly infectious.

Dr. Stacey Swartz (01:12:15):

Only mildly infectious, yes.

Susan Winckler (01:12:16):

Ah, okay, okay.

Dr. Stacey Swartz (01:12:17):

And I don't think that that is necessarily... I think that people do respond. Just like when you go to your doctor's office and you get a prescription, you don't necessarily know that they're going to go home and take it. So I think that people are going to interpret tests the way they... what some of their preconceived notions are, too.

Susan Winckler (01:12:34):

Yeah. That's true and helpful and not really controlled for in the regulatory environment. But also trying to explore it. Yeah, did you want to jump in, Ramy?

Dr. Ramy Arnaout (01:12:45):

Yeah, the last couple of comments have really touched on the big difference between in-hospital testing and at-home testing, in terms of process and the layers of training and assurance and validation and checks and documentation that go on at the hospital to make sure that when somebody reads a Gram stain, for example, in the hospital, that it is correct. And even then, with all of these layers and attestations and paperwork and inspections that we go through at the hospital to make sure that all these processes are done right, still there are, all the time... I mean, not all the time, I don't want to scare anybody. But in the course of many thousands of tests a week, one or two will make it to my

rounds and it'll come up and we'll be like, "Oh, well, that's interesting. It was called this, but it was really that. What happened?" And you'll try to go through it.

(01:13:35):

A patient who sees a faint band might not have... I mean, I'd be very impressed. How would any patient know, "Well, how dark should that band be?" 'Cause I'm comparing it to these very nicely written IKEA-type presentations, where it's a cartoon of a very thick, like, five point thick line. And here I'm seeing, "It's definitely pink, don't you think it looks pink?" And the other person will say it looks pink. But if it doesn't look as pink as the paper, is that enough reason to even say... 'Cause there might be information there in terms of like, as we said, about what the viral load is, there might be extra information there. But how on earth can we expect a patient who might take one of these tests once or twice a year to know any of that? It's a lot to ask.

(01:14:21):

And so it really comes down to, are there ways to build these kind of layers of assurance in an at-home test, for a non- professional taking a test that they might never take again in their entire lives, that mimics or ideally even improves on what we have, I don't know how many thousands of FTE hours at work on in the hospital. It is a major challenge.

(01:14:47):

And usually when you say process design people's eyes glaze over. Process design is like, the least sexy thing ever. This is where, especially for laboratory diagnostics, everything, like the rubber hits the road. I mean, laboratory testing, last thing I'll say, is the single highest-volume medical activity there is, period. You can add up all the patient visits and all the surgeries and all the prescriptions and all of that stuff together. It still won't equal just the sheer volume of tests.

(01:15:12):

Well, if we want to get the benefit of that... And it only costs like one cent on the healthcare dollar in the hospital. If we want to get the benefit of that at the home, we have to design processes like our patients' lives depend on it, 'cause they do. It's a major challenge.

Susan Winckler (01:15:26):

Yeah. Yeah. Well, and it strikes me... It gets back to what you raised, Anita, about how carefully you think about that in producing these.

(01:15:34):

But we've illustrated a couple of different things and provided some insights into how to improve this, let's share some more. How might we think about improving the environment for developing diagnostic tests and regulation? There's certainly some opportunities and friction points. But Anita, go ahead.

Dr. Anita Nosratieh (01:15:53):

I think there's some opportunities in looking at rightsizing our expectations around performance. So a screening test that is going to give masses access may have different considerations than a confirmatory diagnostic test. So there are some opportunities there for us to get a little bit more out of our comfort zone, on what does that benefit/risk profile look like?

Susan Winckler (01:16:20):

Because I think it might be helpful to the payors if there were a screening opportunity that a consumer could do on their own, that then led them into the healthcare system for the battery of tests that then

identifies a risky health condition sooner than might otherwise would have been identified. That seems to start to fit your payor dynamic.

Julie Barnes (01:16:42):

Yeah. And again, it's going to take time. 'Cause at the moment, the new interesting thing that we're looking at is ChatGPT health and other things that are going to tell your mom what to think about the faint line.

Susan Winckler (01:16:58):

It's okay, we won't tell her. It's all right.

Julie Barnes (01:16:59):

And it's going to be a really interesting dynamic before we get to a new level of trust. I go back to, health plans are going to decide what they're going to decide as they go, because it's about trust. It's about the clinical validity of a given diagnostic or screening tool or monitoring tool that is helpful and has been proven over time. They're not going to cover things out of the box that they're not going to believe is a clinically valid tool, they're just not. They're not in the business of that.

(01:17:32):

It's like, fire insurance doesn't pay for smoke detectors, health plans don't pay for vitamins. And they're going to pay for the things that are over-the-counter that only rise to the level of preventing real health risk. So that's what the [inaudible 01:17:48].

Susan Winckler (01:17:48):

Right. Which makes some sense, 'cause I don't know that we're looking in the environment that it would all... If all of this consumer-driven care were driven into the payment system, it becomes more traditional healthcare with all that's involved in that. Filing a claim, all of those things. Where it seems that much... What we're really talking about is driving more of that to the consumer to be empowered with information, and make some decisions to go to seek care or pursue something.

(01:18:22):

Is that a way to think about this? That it's more about the empowerment of the consumer in that kind of... It's not outside healthcare, but it's that adjacent to a traditional healthcare system.

Dr. Courtney Lias (01:18:34):

Well it was very powerful in diabetes.

Susan Winckler (01:18:36):

Yes.

Dr. Courtney Lias (01:18:36):

I mean, the diabetic community really worked really well with us and others to push forward the availability of novel products in that space.

(01:18:45):

And so it can work, but what we've found is that there are very few cohesive patient communities that are really able to push in that way. And the diabetes community may be the exception, unfortunately.

But in COVID, you saw consumer demand. You see consumer demand for these respiratory virus tests, so maybe.

Susan Winckler (01:19:05):

Yes. Yes. Well, and that actually makes some sense, right? In that what we're talking about is a broad consumer community that's seeking more information about their health, versus an identified patient community. Although perhaps we would see some, as we've seen with the glucose monitors, more of that moving to an empowerment in over-the-counter.

Dr. Ramy Arnaout (01:19:29):

If I could point out, there's also a big difference, it seems to me, between something acute like infectious disease, and chronic disease. 'Cause in chronic disease, the patient usually has had enough time to become aware of the disease and how the diagnostic relates to treatment and intervention. So diabetes is a perfect example of that.

(01:19:49):

What happens when you have a proliferation of tests in order to empower the home as a medical hub, but patients who might not know when to get what tests. So I might ask, actually, Stacey, how do patients even decide when they might want a test when they come to you? Do they come feeling like they've got the sniffles and ask you, or you see them looking on the shelf with the flu testing or...

Dr. Stacey Swartz (01:20:14):

I think sometimes, when they're not feeling well, they want to know what the reason is. And especially if you have multiple tests, that's really a good thing, so you can kind of pinpoint what it is. Sometimes, especially with the respiratory ones, they'll do it because they're going to go visit grandma or something like that, and they don't want to put grandma at risk, so they want to know what their results are. It really depends, but I would think most of the time it's because they're feeling sick.

(01:20:39):

For things like blood pressure and stuff like that, that's usually after they've gotten a diagnosis or if they're worried, so that they'll do that. One thing that I think about sometimes, especially when we're talking about monitoring and providing data, or I mean, I'm familiar with the thing where they're going... Is that the ability for people to give... They might give it when they're feeling ill or that, but routine, regular monitoring, life gets in the way and they don't always do that.

(01:21:10):

So I think there are some limitations, and I can imagine from a payor perspective there would be, because it is kind of not happening. It's only happening in certain circumstances. So that's generally been what my experience has been with it.

Susan Winckler (01:21:26):

So you would need more of Ramy's... the reporting of the future, where you could have the picture and the reporting at the same time. If you needed to use your camera to increase what you were seeing on the little tiny diagnostic screen anyway, and then it would report on in.

Dr. Stacey Swartz (01:21:46):

Yes, exactly.

Susan Winckler (01:21:47):

That's what I would need to do in the camera.

(01:21:49):

Anita, do you want to say anything else about... as we're thinking about this kind of development opportunity and where that might go?

Dr. Anita Nosratieh (01:21:58):

Sure. I think there's also opportunities around additional guidance or best practices for human factors, usability, that are specific for OTC at-home diagnostics. Right now it's almost everyone, every developer paving their own path or relying on publicly available information. So if we could come together to develop some best practices, that would really reduce that friction in development as well.

Susan Winckler (01:22:24):

That is helpful, and I see that helping not only the regulator and the developers, but maybe even the payor to better understand, okay, what are those things that you're assessing in the consumer's ability to interpret a test or to use the information from it? Yeah.

(01:22:44):

We have just enough time to give you each one minute. I'll start with Ramy, 'cause then I know he won't go over. So if there's one opportunity or one challenge you want to highlight about the development of OTC diagnostics... And I'd say if you're giving us a challenge, then be optimistic about how we might solve that.

Dr. Ramy Arnaout (01:23:06):

Sure. Out of many, I'm going to pick modeling. There are more tests and more presentations and more conditions than anybody could ever do a randomized control trial on, or ever get 30 or 100 patients to test, but where there is information. The only way that you're going to stay ahead of all of those different combinations is if you're able to develop some underlying model of how the presentation and the test and the result, and the downstream care, and the cost savings go together. The only way you're going to do that is with a model.

(01:23:46):

We are getting to the point where we have a chance at that. I think that is a challenge that we can hit and overcome.

Susan Winckler (01:23:56):

Yeah. Okay. I'm just going to go down the line, Courtney.

Dr. Courtney Lias (01:23:59):

I think when I think of the thing I wish most new developers of this type of test would think more about before they come and talk with us, is instead of only coming from it from a technology perspective, "Can I measure this?" To think about it in, "Why am I measuring this in an at-home environment?" And Anita touched on this, there may be a valid situation where you have an imperfect test that really identifies only some people, but maybe that's better than nothing for this thing. But over here, maybe it's not better than nothing.

(01:24:33):

So really thinking through, what am I measuring and what is the situation in which it's going to be used in the home setting? And how do I design it to be able to do that? How well does it need to work? You ought to think about that before you start, like you mentioned. And I think we're seeing people more start with, "Oh, look what I can measure," and then try and figure out what to do with it. So a better balance on that would be, I think, beneficial to patients.

Susan Winckler (01:24:58):

So thinking more of the consumer in mind and the use of that, that...

Dr. Courtney Lias (01:25:02):

Right. Well, get more clinicians involved in that.

Susan Winckler (01:25:06):

Yeah. Stacey.

Dr. Stacey Swartz (01:25:07):

I endorse that.

(01:25:09):

I think from my perspective, when I was hearing about some of the... in the future, it seems a little bit more complicated. It requires more data to be inputted into either like a smart app or something like that, not necessarily just a yes/no answer, positive/negative. Just really remembering about patient privacy and their concerns about where their data is going. That is a real thing, and I think people are very concerned that people are going to be using their information. And certainly when you're looking at fertility and stuff like that, they're going to get to the point where they're not going to want to participate or buy your products because they're afraid of what you're going to do with that information.

(01:25:51):

So I wish I had an answer for that one.

Susan Winckler (01:25:53):

No, that's... Well I think that's an important one to say, that is certainly an animating dynamic in consumer use.

Dr. Ramy Arnaout (01:26:03):

If I could just say quickly, too, it's not just that patients feel this way, they have a reason to. The famous quote is, "It's not paranoia if they're actually out to get you." And I think that applies here.

Susan Winckler (01:26:15):

Yeah, that's so... Very good caution. Julie.

Julie Barnes (01:26:18):

Yeah, I have a data-related response. I think integrating this data, this real-world monitoring and tracking and diagnostic information and inserting it into the medical record is the key and the challenge. That is why payors would start paying if they could see over time that this was real information that was

actually helpful, that actually prevented disease, that actually did what it said it was going to do. That's the rub, and that is not something we are sophisticated enough to do right now, but that is changing.

(01:26:49):

So on the positive note, inter-operative rules are expanding all the time. We just helped a bunch of people comment on the diagnostic RFI, so that people are not carrying around their x-rays on a CD anymore from doctor to doctor. They can actually upload it into the medical record for the first time. So HHS is working on all of these things in earnest so that this data is liquid, and I think that will be a game changer.

Susan Winckler (01:27:17):

And we can look for the liquid data in our traditional healthcare first, that would be amazing, and then this opportunity to integrate another step forward while protecting patient privacy.

(01:27:28):

Anita, why don't you close us out?

Dr. Anita Nosratieh (01:27:29):

Sure. I mean, based on what all of my fellow panelists have shared, it's pretty clear that in order for us to have real progress in this space we need to have continued collaboration across regulators, healthcare providers, consumers, payors and developers, with a shared focus on safety, access and trust. 'Cause that's what's going to be required for us to solve this very complicated new world that we are living in.

Susan Winckler (01:27:54):

What a great framing for us to think through in the safety, access and trust phrasing. So Anita, I'm sure that's going to be said many times as we continue through the rest of the day.

Panel Discussion: Integrating OTC Diagnostics into Care Delivery

James Appleby, BSPharm, MPH, Gerontological Society of America
Deborah Autor, Esq, Hims & Hers
Michael Umbleby, RPh, Walgreens
John Whyte, MD, MPH, American Medical Association

(01:28:06):

With that, let's thank our panel and... I'm going to ask this panel to leave that way, but leave your microphones, they're not a party favor. And our next panel to come up on stage... Yep, he just took the chair and that mic. Hello.

(01:28:37):

So what a great conversation, laying that foundation for this session. And come on up, Dr. Whyte, we have a seat just for you. All right.

(01:28:52):

So I don't know about you all but I found that fascinating, as we think about all of these different dynamics. We now want to talk about what was raised on the earlier panel and get more into how do we think about integrating existing OTC diagnostics, how they are integrated or not into the overall healthcare system.

(01:29:15):

And so we have four distinguished representatives from different domains in the healthcare system. You are all distinguished, I've already declared that so you can... Oh, you are. So we want to start with the physician perspective. And Dr. Whyte, you have FDA experience, and so you speak from the former... having been in the shoes at fda.gov. And now, as your role as CEO of the American Medical Association, tell us how physicians are thinking about OTC diagnostics and their patients' use of them.

Dr. John Whyte (01:29:52):

Well thank you for this opportunity. And I'll also add, up until seven months ago in my new role, I still saw patients in the DMV area.

(01:30:01):

So I'd start by saying, I'm just going to be honest, most practicing clinicians aren't thinking that much about these tools. And part of the reason why is, to your point about integration, they're really not integrated into the EHR. And we've learned a lot about this from COVID, where if patients did at-home tests, which no one ever thought that they would be doing at-home diagnostic tests, but people learned they could do it. If it's not part of the EHR, and it's not in the section where I need it to be, I'm not interested in it. Because I'm not going to go search and see if you had positive flu or COVID, it has to be in the lab section where I need it to be. And a fax, which we still do, or patient attestation isn't going to work.

(01:30:56):

So I loved the example where they said, "Well, patients did a test to check for their grandparents," whatever. But as their primary care physician, I would like to know that. I would like to know that they had flu know a couple months ago. I'd like to know why they took that test. So if the test was negative, what else could it be? I'd like them to understand the testing and the timing. So again, for flu, it's about early on. I'd want to know early on, because then it could be Tamiflu. So I think these have great

potential. And some clinicians are talking to patients, 'cause then they do a telemedicine appointment. Or particularly when they have a positive test, they need follow-up. But it's not done in a systematic, comprehensive way. And that's for most of the tests. There's other tests, and Deb and I were talking about for cervical cancer, for colon cancer, that people still send in to a lab and then the physician can get the record, and sometimes it feeds in to the EHR. And you may think, "Why are we being so picky that it has to be in the EHR?" It's just the amount of time it takes as part of the clinician visit.

(01:32:15):

And I was at a meeting recently where a radiologist talked about how an AI tool could save them 12 seconds per image. And you think, "Really? We're debating about 12 seconds?" And they're like, "When you add it over the day, we're talking real time."

(01:32:28):

So it's the same thing. People aren't going to go looking for the test, they're not going to rely on attestation, I'm not simply going to fill it in. I'm not getting the full utility of the test. And I think physicians want to embrace it, but right now I'm just being honest, they're really not.

Susan Winckler (01:32:45):

Yeah. But I don't hear you saying it's kind of a push away, it's that they don't want it. It's that it's not...

Dr. John Whyte (01:32:54):

Absolutely, that's right. It's a workflow issue. One, I want them to know what the test actually measures and doesn't measure. And we don't have to always use sensitivity and specificity. It's really about positive predictive value, negative predictive value. But I want to know why they're testing in the first place and the results. So I think a lot of physicians, and we know this from data, embrace these kind of tools where the more patients can come prepared for a visit, whether it's virtual or in person, makes the visit better. And there's really a push by clinicians nowadays to empower patients with information. But right now, too much of it is still not connected to your point, and I think we're missing important data points.

Susan Winckler (01:33:42):

Really helpful. So that's kind of where we see it in the physician perspective. I want to turn to the pharmacy and pharmacist perspective. We know that's a place we heard from Dr. Schwartz that there is this interaction about OTC diagnostics. So to help us with that, we have Dr. Michael Umbleby, who is Vice President of Pharmacy Administration and Services at Walgreens. I'm going to guess that Walgreens sells a fair amount of these products and that your consumers use them. Tell us about that.

Dr. Michael Umbleby (01:34:16):

Yeah. Well, thank you again for having me. Yeah, I think pharmacy, and Dr. Swartz alluded to a lot of this, I think it's true, whether it's an independent or a chain or a grocer, but pharmacy in the community is pretty consistent. They're in almost every corner. Many of you probably know a stat, 90% of Americans live within five miles of a community pharmacy. So the access is there, and I think that's the strong suit of pharmacy. But I think, as Dr. Swartz said, patients don't come in and say, "What kind of assay do I need?" They walk in and they say, "I don't feel well. I have a concern and I need help with that." And that's where pharmacists can really lean in and help educate that patient on what type of test do they need? When should they actually take the test and then help them with results, whether it's positive or negative, and be able to explain what the next course of action is.

(01:35:16):

And so in many cases, the pharmacist can refer or consult on over-the-counter medication. They can certainly refer to their primary care, or perhaps even in other cases, they may refer that patient to an emergency room. So I think that's an important part for pharmacists and what they do today. And it's also important to note that, and it was mentioned earlier, but there are some states where pharmacists can in fact test and treat. And I think that's valuable and helpful when they're in a community where maybe access to a physician is challenged or another provider is challenged. And I know we're going to talk about this quite a bit more, but the ability to take that information and share it with their physician or another physician is the key here that we need to talk through.

Susan Winckler (01:36:04):

And close that loop so that the information is shared. Really helpful. So Deb, I think it's time to turn to you because we heard a couple of mentions already today about the emergence of telehealth. So in your role, we have Dr. Deb Autor, who is chief policy officer for Hims & Hers. How do you think about OTC diagnostics in the telehealth model? How do your clinicians use that information generated by the tests when making decisions about remote care?

Deborah Autor (01:36:39):

Thanks, Susan. And thanks for having me here and for putting together this tremendous meeting. It's really been very interesting and informative. So I want to start by painting a picture of why telehealth and home testing has so much potential to improve public health, especially with increased access to at-home diagnostics. And I have a not very hidden agenda here. I'm especially focused on the potential for home blood collection for in lab testing with devices such as this one, this is called the Tasso, which enables painless, easy sampling of upper arm capillary blood by the patients. You put it on here, press the button and wait a few minutes and get a sample.

(01:37:18):

And obviously, given that I work for Hims & Hers, I'm a strong believer in the potential for telehealth to improve care for patients. And we've talked a lot about COVID. Surveys indicate that three quarters of US consumers have used telehealth services at least once, and many healthcare providers continue to incorporate virtual visits into routine care.

(01:37:37):

Obviously, COVID brought a lot of that change. And telehealthcare can be excellent. 94% of our customers at Hims & Hers say their care through our platform is as good or better than their prior in person experiences. But why do we need this? Well, we have a huge access problem in this country. We're projected to face a shortage of up to 86,000 physicians in the coming decades. So millions of Americans will struggle to access care. I will say I live in Montgomery County, Maryland. I have a hard time getting to see a doctor.

Susan Winckler (01:38:10):

I think Dr. Whyte lives there too, but now he's busier running-

Deborah Autor (01:38:13):

Are you accepting new patients?

Dr. John Whyte (01:38:14):

I'm in Virginia.

Susan (01:38:16):

Oh, even better. All right. I'll come see you, Dr. Whyte.

Deborah Autor (01:38:21):

Doesn't help me. So already over 92 million Americans live in federally designated primary care shortage areas where there are not enough doctors to meet demand. Rural Americans live nearly twice as far from the nearest hospital as urban residents. And for many patients, even routine lab testing requires significant travel and they have to go to a doctor, get an order for a blood draw, go to the lab, get the blood draw, go to the doctor for follow-up results, all these separate appointments, childcare arrangements, wait times, logistics. It's an awful lot. And then they get there and they have to sit in a doctor's office for an average of 84 minutes plus 37 minutes of travel. And physicians are spending a lot of time on logistics instead of diagnosis and treatment. Clinics can be bottlenecked with low complexity visits. Doctors aren't practicing at the top of their license.

(01:39:10):

So what I'm talking about is the role that OTC diagnostics can play in telehealth models in order to maximize the ability of patients to take advantage of home care. But what's going on now? What's going on right now is pretty limited. Most remote care is largely done if it isn't done in the traditional have to go to the doctor's office model. It's a doctor telling their patient to go to Quest or LabCorp.

(01:39:34):

And then the clinicians are relying on their patients to schedule those visits, get them done. And often that ball is dropped somewhere along the line. And if the patient follows through, then they've gone and they've had an awful lot of blood drawn for what often can be done at home with a much, much smaller sample.

(01:39:56):

So I am pretty direct. So I will say right now, I think the challenge in this area is that FDA's approach has been to require at-home blood collection tools to be cleared analyte by analyte, which means that in general, you need the company that makes a lance, plus the tube, plus the downstream assay all to come in together usually for a co-submission whereupon FDA's evaluating the lance, the tube, the collection process, the shipping, the stability, and the downstream lab process. That doesn't happen very often because it's a lot of players who need to come together, not at all of whom have the same incentive to actually make that happen.

(01:40:41):

And so what's happening now is some at-home sampling, but frankly with this kind of device, but frankly, very limited based on this approach. Potentially, there can be huge amounts of at-home blood collection. There is a lot of potential to use this kind of device for liver health screening, kidney health screening, cardiometabolic screening, a lot of hormones, genetic testing, antibodies, infectious disease screening. And I'm still talking about on the order of a physician. I'm not talking about a patient walks in, buys a device, does a blood sample. I'm saying a physician who knows what these things can be used for asked for this device to be sent to someone's home whereupon they can take the sample, send it to a lab, have a test done, get a result provided to them by a physician, probably with an electronic component to that, which can hopefully be uploaded into the EHR. So if we can unlink the collection from the analyte, I think there's huge potential for use of at-home testing in telehealth and remote care.

Susan Winckler (01:41:39):

So I just want to double check. Anybody else have props? All right, because we're done with props. Who knew?

Deborah Autor (01:41:49):

You want to try?

Susan (01:41:50):

No, I do not. But I think that does help, because then I think, Deb, what I'm hearing you say is that the current, as we think about the existing OTC diagnostics, there's still a bit of distance from the telehealth. Although as we heard earlier, a positive result might generate interest in seeking a visit, whether that's in person or remote. So now your challenge to Dr. Appleby, as we turn to you, in your role as CEO of the Gerontological Society of America, what can you tell us about OTC diagnostics and their use by older adults? And because I have an image in my head of how that might take place, it's not generated by myself yet. But it is. Yes, go ahead.

James Appleby (01:42:41):

Well, thank you, Susan. Thanks for the opportunity to be here. And I also am curious what the image in your mind is when you think about an older adult.

Susan Winckler (01:42:48):

I know it is me, but that's all right. We all have our own self-delusions.

James Appleby (01:42:55):

We all have to work through these things, and I'm delighted to be here. Fascinating conversation. Just a word about the Gerontological Society of America. We go by GSA as our acronym, which is we're the GSA that everyone likes in Washington DC.

Susan Winckler (01:43:10):

Which only, I just do have to say only the in person audience here got that for everyone.

James Appleby (01:43:15):

Thank you.

Susan Winckler (01:43:16):

Everyone, virtually, it's a federal government joke.

James Appleby (01:43:18):

Yes.

Susan Winckler (01:43:19):

Yes.

James Appleby (01:43:21):

So gerontology, of course, being the study of all things aging. We're a membership organization like the AMA perhaps, much smaller, but mighty, in that all of our members are experts in aging in some shape, form or fashion. They come from 26 different academic disciplines. So all healthcare, biological sciences, psychosocial sciences, law, economics, anthropology, you name it, they're all experts in some shape, form or fashion about older adults. Their care and their long-term wellbeing.

(01:43:59):

I think it's important for this conversation we should probably define older adult because that's a broad term. When you do surveys with consumers and you ask them what age is an older adult, they say it's about 54.

Susan Winckler (01:44:13):

I thought they were ... I'll say someone older than me.

James Appleby (01:44:16):

Yeah, that too.

Susan Winckler (01:44:17):

Okay.

James Appleby (01:44:17):

It's always someone 10 years older than your particular age. But for today's conversation, let's talk about them as individuals 65 plus. And it's important to realize that's a pretty wide range, 65 plus, 65, 75, 85, 95. And we have to remember that as we age, we become more different from one another, not more alike. The heterogeneity as we age is something that people forget about. And I find it all of when people say, "Well, older individuals, well, what does that mean?" Because from 65 to 95, there's a big range there. So we have to keep that in mind because I think it's relevant for home testing as well.

(01:44:59):

And in particular for today's conversation, this question around individuals 65 and older is important because of the demographic transformation that is underway here in the United States. The youngest of the baby boomers is 61 years old right now, and that baby boom population means that as they grow into older adulthood, a much larger percentage of the population will be older.

(01:45:28):

It's also reinforced by the fact we are having many individuals live much longer, that's a blessing. And the fact that we have decreased birth rates. So you put all that together, a lot of individuals, a greater proportion of our population is going to be older, and they will be aging with multiple chronic diseases. And this is the magic of home testing, because this market is so large, we can do a lot to improve the lives of those older individuals, 65 plus. Now, the thing to keep in mind too though, is that we have this perception that older individuals are not as tech-savvy. And you sort of think about, "Oh yeah, everyone knows, older people have a problem with technology." Well, think about the fact that the current 83-year old was 65 when the iPhone was introduced. I think maybe 83 year olds might know a little bit about technology.

(01:46:26):

So we have to keep in mind that that doesn't always hold. We know that three out of four older adults report, as you may imagine, loving the fact that they can do home testing. It's convenient, easy, it's

great, much like the rest of the population. And according to the latest market research, I saw about 60% of the home OTC diagnostic market is for individuals 65 and older for the older population. So that's where the business is right now. And because of the demographic transformation underway, it's only going to grow. So this population is important for us to keep in mind.

(01:47:05):

So the answer is yes to your question. Older individuals, 65 plus use OTC diagnostics, they use wearables. The wearables is a little less of an uptake. The latest research I saw was about 20%. And this is about three years old, so I suspect that's changed, but much larger percentage of individuals are using wearables as well.

(01:47:31):

And I think the one group that's left out, we've been talking about patients, we've been talking about care providers, health systems. When you think about older individuals, 65 plus, caregivers, and we have to realize that there are currently latest data, 63 million Americans are family caregivers providing care to a loved one, 63 million, and that doesn't include the unpaid caregivers. So there's even more. So the influence of those caregivers on the use of OTC diagnostics as individuals age is quite dramatic. And so we should be thinking about how we include the perspective of the caregiver and the role they're going to play in the care of this population as we're having this conversation.

Susan Winckler (01:48:22):

Which strikes me what an intriguing thing to think about. If you were the unpaid caregiver, could you check the wearable or do the combination test and just have a better understanding of what, if you're seeing a change in the individual for whom you're caring-

James Appleby (01:48:40):

100%.

Susan Winckler (01:48:40):

... to have that available.

James Appleby (01:48:41):

Yeah.

(01:48:41):

The family caregiver will be driving the use of these OTC diagnostics and wearables.

Susan Winckler (01:48:46):

Yeah. Yeah. So you each teed up and observe some things about where this kind of data integration takes place, maybe it doesn't take place. Can we talk about some solutions that might help make data move within the healthcare system and get some better information? I think perhaps it could come in the test to treat, that information goes from the pharmacy to the physician, that we could have better information perhaps coming from the consumer into a telehealth provider. So quick response here, let's do Deb and then James, John, and Mike, just thoughts on how to improve that data integration.

Deborah Autor (01:49:32):

Yeah. So better information I think is the key. And obviously, I think the first key is liberate the technology and judge it on its ability to safely and effectively collect a sample that can then be tested downstream in a CLIA regulated lab. Which I think also has potential, by the way, for decentralized clinical trials for helping people with conditions like low testosterone that they might be reluctant to go in to get to talk to a physician about. But I think ultimately what I've heard a lot today is the disconnected pieces of the healthcare system and bringing them together would make everybody more effective in their roles, and most importantly, would make the patients, the consumers optimize their treatment. And I think that's a function of collaboration.

(01:50:18):

I think it's getting groups together to, if we all sort of buy the premise that patients having more information so they can proactively take care of their own health is a good thing. Obviously that could go to extremes, which would not be a good thing, but that we think more information would be better and it needs to have the learned intermediaries have access to that information so that they can help the patient to optimize the utility of it. Then I think we can get together and think about the tech that can enable that. Although more and more, I think AI is going to be able to take all these disparate sources, put them all together, feed them to anyone who you give access to, and that will be helpful. But I think it's coming together to think about how we can reconnect or connect those disjointed pieces.

Susan Winckler (01:51:01):

To provide more of that information. James, any thoughts on the data side?

James Appleby (01:51:06):

Yeah. I mean, I think a lot's been already shared around this, but to really make it work, we've got a lot to figure out. And I believe Anita used the word collaboration in one of her closing comments. We've got to figure out how to make it easier for the user, especially, I think about the older individual, to provide test results to the system and figure out how to make it automatic or passive perhaps. In advance, they could tick, yes, I approve this to be uploaded. So it doesn't have to happen each and every time. It automatically gets uploaded. That data then has to get tied to the right patient record. It has to then go into a workflow in which, as Dr. Whyte said, the clinician can clearly pick up on it and take action on it that leads to perhaps a quick prescription or an e-visit, whatever it might be.

(01:51:59):

There are a lot of things that have to be worked out there, and it can be done. But we're going to have to get together insurers, electronic health records, health systems, clinicians, patients to figure it out. But it can be done. In the meantime, we've got to encourage and figure out how to teach patients and caregivers how to upload data and then how to make the clinician aware. Maybe it's something, I know that Dr. Whyte, you probably don't want another email and message, but hey, I just want to let you know I uploaded this result or something.

Susan Winckler (01:52:35):

It's WhatsApp. It'll be fine.

James Appleby (01:52:36):

It's what we have to work with right now. It's what we've got to work with.

Susan Winckler (01:52:39):

Yeah. Yeah. Well, it struck me. I was really intrigued by Dr. Lias's observation about the wanting the continuous glucose monitoring to show on your phone so that you didn't have to look at something else. There's clearly solutions here. We can make progress. Well, I think that James threw it to you, Dr. Whyte to ...

Dr. John Whyte (01:52:59):

Sure. And we can tell you are chief of staff because you're very much like, "You're going to do this, you're going to do this, and this is how we're going to run it." Which is very helpful. And what I would say, I'm going to be a little more provocative. I'm concerned that there are folks that don't care as much about data quality, right? And half of us on the panel actually worked at FDA. And I would argue that there's a reason why the FDA does require a certain level of data quality in terms of we're making health decisions on that. I don't think we try to weaken that quality of the data for convenience, but we have to ensure the rigor, the reproducibility, the fidelity of the data. That's why sometimes physicians aren't that interested in these tools because they either don't understand or don't know the fidelity of the data.

(01:53:50):

And I could argue on the concept of wearables that the FDA gave out guidance recently that talked about wellness apps, which I would argue are almost being considered the supplement industry, right? If they don't have a medical claim and these other elements, that they're good enough. They don't need to be clinically great. And since when are we in a system, when we're talking about care of patients, that it's good enough that we can misinterpret the data. So I do think when we talk about these issues, we really do ... And I'm trying to pick on Deb. We really do have to have good discussions about the quality of the data. We don't want a regulatory process that is overly burdensome, but I could argue on the issue of COVID tests early on, there were some missteps in terms of how that was done by several regulatory agencies.

(01:54:57):

So we don't want to dumb things down. We don't want to weaken the data. We don't want to have all this hormone testing of patients that may or may not need it, to be fair too. So we have to do it in a very thoughtful, methodical way where everyone in the ecosystem, the patients, the insurers, others can understand the fidelity of the data. And if we're going to discuss aspects of convenience, we also have to address the issues of equity that not all of these tests are covered. It can be great that everyone lives within five miles of a pharmacy, but for some people, five miles is far and to be able to get there is a challenge. So I think this has enormous potential. But there are still a lot of questions to work out, including the most critical point about the data and how good the data is.

(01:55:51):

And there is an effort by some, particularly on wearables and other aspects for things at the home that the data doesn't have to be clinically great. And it can be good enough if you have the appropriate disclosures in marketing. And I would argue that AI and digital health and other tools make the home the future doctor's office and the hospital. So we shouldn't be weakening data.

Susan Winckler (01:56:16):

Which is very helpful to remind us that as we talked about data flow and wanting to integrate the data, we also want to have the reliability of the data that has been generated as a cornerstone of that. Well, Mike, I don't know if you want to jump in on the rumble here or lean back. It's all okay.

Dr. Michael Umbleby (01:56:36):

Yeah. I mean, today's been great because I feel like from a pharmacy perspective, everything that's been said, we've either experienced or have the same wishes. I wanted to give Dr. Arnauot a high five as he was talking about the future state. Because to me, what I see with patients is we need the ability to have consistent machine-readable information, go from the test, the results, positive/negative, the date and timestamp, what type of test it was. All of that needs to just be captured and then sent to wherever it needs to go, whether it's a provider or whomever. I think if it takes the patient more than 30 seconds to try and do any of that, it's not happening. And so I think that has to be done in a very seamless way without a whole lot of intervention by the patient. And again, I mean, it comes down to with those results, what do I do with them and how do I help the patient actually determine the next step, whether it's an over-the-counter therapy or referral to a doctor?

(01:57:41):

And then as we talked about, we need to connect all the various systems. I think of vaccines today. So pharmacies administer vaccines every single day, but we push into a state registry, maybe not the most ideal example, but we push that information to a state registry that can then be consumed by other healthcare providers so that they have some visibility into what types of vaccines their patients have had. So there is a pathway here for sure. I think exactly what the answer is, I'm not sure. And then when I think of the public health aspect and the test monitoring from those manufacturers, agree patient privacy is a concern, whether it's a push or a pull, I think is probably up for debate, but I think we can't lose sight of that either. And we need to make sure that that's integrated into the testing and the results and et cetera.

Susan Winckler (01:58:39):

Which ties back, it reminds me as you observed some of the challenges we had with early COVID tests, the way to then kind of determine which ones we're performing well versus not is to know what test was performed. And that's another kind of gap that we acknowledge in this space. And so having a solid test that is accessible to the consumer, that we could then share that data into the healthcare system, appears to help all of the ... Whether it's from the caregiver or the patient, helps with more of that integration into care delivery that probably isn't happening today, but we see we want to make it happen.

(01:59:22):

So let's then pivot to talk about what we might want to see new in this space. Deb already laid out, I know the answer you're going to give to that question, so you gave it, of what you knew you might want to see in that space. Mike, what do you think might be something that would be intriguing to see in a pharmacy?

Dr. Michael Umbleby (01:59:48):

Sure. Yeah. I mean, ultimately, I think as it relates to future tests or the opportunity, it's really when time is of the essence or access is constrained. And so I think that's the consideration of any new test that is developed. It's how do we get that patient on therapy as soon as possible. So I think that's first and foremost. So whether that is the new wave of testing is something unique that I know Deb will speak to, I just go back to usability. It needs to be usable. It needs to be something that patients get clear action, how to use the test, the results, and then how do we take that information and get it to the right provider. So I think that's the big thing. I also, I know it was mentioned and I know the health plans are jumping up to cover OTC testing as much as possible, but-

Susan Winckler (02:00:48):

Is that what you heard? I'm not sure that's what Julie said.

Dr. Michael Umbleby (02:00:51):

Did I misunderstand?

Susan Winckler (02:00:52):

Yeah, it's all right.

Dr. Michael Umbleby (02:00:53):

But I do think it's important to reflect back on COVID when testing was affordable. Yes, there was zero cost testing. Yes, the health plans were sort of strong armed into coverage, but I think that was important though because it actually drove uptake of testing and I think innovation's going to come from more testing. I think it was also discussed in that first panel. The more testing you have post trials and FDA approval, the more you learn. And so I think we have to continue to think about how to make testing affordable so it drives that uptake.

Susan Winckler (02:01:27):

Right, right. Very helpful. And I think that in thinking about particularly in infectious disease diagnostics, that makes a lot of sense. Dr. Whyte, when you think about that, are we engaging physicians in the healthcare system enough in what should be an over-the-counter test or something that's delivered closer to home?

Dr. John Whyte (02:01:52):

I don't think we are. And I think it's a great example, particularly in terms of infectious diseases, in terms of a patient being able to go to a pharmacy or order a test online and determine whether or not they have COVID or flu with some reliability, right? That helps everyone in the ecosystem. But there's also incentives that we have to be honest about. And folks talked about telehealth. The reason why telehealth exploded was because there was payment parity, that you were paid the same, whether or not you went into the office or virtually. And there was recently an extension that the AMA helped lobby on. It's crazy that we're talking about two year extensions for something that is now kind of a mainstay of health, but it's the same aspect that I wanted to also point out. And you kind of pointed out to it a little, Michael, that if these tests aren't covered or people have to put out a lot, that in some ways it's cheaper to then go to the lab depending upon your copay.

(02:02:59):

And that's insane, that if you can have the same test or your device tool that you could do at home and convenient and the cost differential doesn't exist, that's a good thing. But part of the challenge is for physicians, we're still thinking, how's this information getting to me? How do I understand the fidelity of it? And that in some systems, whether it's fee-for-service or more a managed care plan, that can change physician behaviors. And when we're talking a lot about value-based care, I don't hear this talked about quite that often in terms of how we can provide value to patients and to the healthcare system.

Susan Winckler (02:03:50):

If you think about it, if a well-regulated wearable could help me predict a chronic disease, isn't that precisely what that financially at-risk healthcare system needs in a value-based payment-

Dr. John Whyte (02:04:03):

This is a whole nother meeting, and I'd agree. But I just want to say, I think that thinking, and that's why I've always liked you, because you're always thinking forward, is revolutionary. What I would say, if we had good wearable data that we're actually looking at continuously, and we do not have a good wearable device about blood pressure. But if I had a good reliable one, and I can even just look at trends, so it's still clinically great, but it doesn't have to be absolutely perfect. I could reduce cardiovascular risk, which is still the leading cause of death. And I don't know if there's not a will, or there's not an interest, but the technology you would think would exist. And what we could then be doing, Susan, is moving from risk that's based on populations that I could actually tell you your personal risk and your personalized treatment, because I have all your data points.

(02:05:01):

Because do I really care what your blood pressure is the once a year you come in the office, or twice a year, or once every other year, and the first time you say, "I had coffee," or you say, "It was hard to park, I was waiting." Because nobody wants to start on a blood pressure medicine, and it's five years until we started it. Or it's the same thing for lipids, which we now know we should be treating earlier. And it's always like, "I'm going to change my diet. I'm going to exercise."

Susan Winckler (02:05:24):

"I got this, doc."

Dr. John Whyte (02:05:26):

I'll come back in six months and it's two years. So it's, to your point, that then we're actually using this ability to collect the data on a continuous basis in your real life, and make real, personalized treatment decisions. And even further to say, we could do more screening at home. We see that for HPV and cervical cancer. We see that for colorectal cancer. We should be doing more of that. But sometimes there are incentives that promote that you want to come into the healthcare system and get it done. So we have to address those. And that's an element that's not adequately being addressed.

Susan Winckler (02:06:09):

Is that broader, thinking about what it might be, and then the more full integration. Let me go to James, and then Deb, I am going to let you speak. I guess I do want to hear more, James.

James Appleby (02:06:22):

Well, I think as I look at what I hope will come down the path is new wearables, new OTC diagnostics that give the patient more power over their own health. And I think we've got to keep that in mind. There are plenty of patients out there that need a nudge to get to the doctor, and they put it off and they put it off. And the next thing you know, oh yeah, it's developed into bladder cancer, whatever it is. People need the opportunity to do some of their own assessment, and to maybe give them the courage to then make an appointment to see their provider.

(02:06:59):

So I hope that that will be part of what we see coming in the future. I also think it's interesting, based upon some of the language coming out of representatives at FDA, around wanting to make it easier for RX to OTC switches to happen. And maybe easier is not the right word, but encourage everyone to lean into that, something.

Susan Winckler (02:07:24):

For medication use?

James Appleby (02:07:26):

Yes, I'm sorry. Yeah. Thank you for clarifying. For medication use. But that has implications for OTC diagnostics in terms of, hey, if we can make statins available without a prescription, what would that mean for what we want to have in terms of an OTC diagnostic so people can help assess, are they really a candidate or not? And where does that stop, then? What about for bone health? Will there be a home diagnostic for bone health so we can decide, well, do we need to be put on a bisphosphonate, or what have you?

(02:08:00):

So I think that's interesting. It really opens up a lot of opportunities. Certainly continued exploration of home diagnostics for infectious disease would be helpful. We've learned so much through the COVID pandemic. There's also an emerging interest in aging and longevity sort of screening, where you can compare your biological age to your chronological age and then try to take steps around that. That's a growing area. I'm not sure how validated some of the different metrics are out there that people are using to make these decisions. But the sky is really the limit in terms of what could be done.

Dr. John Whyte (02:08:45):

I took one of those tests, just so you know.

James Appleby (02:08:48):

How'd you do?

Dr. John Whyte (02:08:49):

You had to give your age to begin with, your date of birth.

Susan Winckler (02:08:52):

Oh.

Dr. John Whyte (02:08:53):

Yeah. I lied on it.

James Appleby (02:08:54):

Like a true patient.

Dr. John Whyte (02:08:58):

There's no data to show your heart age versus your others. But I did think it was clever to ask your date of birth on the registration.

Susan Winckler (02:09:06):

Right. Did they intentionally make you feel better? Or did they make you feel worse?

Dr. John Whyte (02:09:09):

They already know what your age is. So when they give you the results, I think they try to make you feel better.

Susan Winckler (02:09:14):

Okay. I would hope so, from like a marketing perspective, not clinically.

James Appleby (02:09:19):

And I should clarify, there is real science around biological age. There is a difference between the biological age of your organs versus your chronological age, and has a lot to do with behaviors you choose to demonstrate across your life course.

Susan Winckler (02:09:33):

You just probably can't access it through a social media mechanism, is my instinct.

James Appleby (02:09:38):

Or a selfie.

Susan Winckler (02:09:40):

Indeed. Indeed. Indeed. So Deb, we know you really want the point of the home blood collection. What else in kind of just thinking about ... Because we do want to empower consumers with more information. And so yes.

Deborah Autor (02:09:54):

Yeah. Well, I mean, a couple points I want to pick up on. First, I think the opportunity of preventative care, I was actually struck by the statement that fire insurers don't pay for smoke detectors. And I'm thinking, why not? Why wouldn't that be better in the long run for the buildings that don't burn down and the insurers that don't pay on those claims? But that's just my perspective.

(02:10:15):

But I actually think there is incredible potential. I mean, I just have to use a little bit of imagination. I look at my smartphone, and I think back to watching Star Trek. And I think what we saw on TV in Star Trek, those of us who are old enough to be watching it, actually sort of came true, right? That one device where they could talk to people and read things. And why can't we get there?

(02:10:36):

Right, exactly. Why can't we get there? Why can't understanding your health be as intuitive as checking the weather? That you have the access at home to the data through wearables, through biomarker testing, through artificial intelligence, and a clinician, learned intermediary, to be able to say, "Today you need more protein, and you didn't get enough sleep, and you've got to go exercise, and you need to hydrate more." All of these things that actually do contribute to longevity in the long run, how do you take care of yourself, and how can we get there? And I believe that's the vision we need to be going for.

(02:11:10):

And I do want to ... John called me out a little bit, so I want to get on the accuracy standpoint. At first I want to say, I think there is very high-quality testing that can be done at home, period, without sacrificing the integrity of those results. And I'm sure that John won't agree with me on this, but there may also be a circumstance where we go, "You know what? Maybe we sacrifice a little bit in accuracy,

but from a larger public health perspective, having more people have access to information," as opposed to no access to information because they can't go to the doctor, won't go to the doctor, won't go through all those hoops, "may be better for patients, for the public health to enable people to empower them." And it might depend on what you're testing for, right? If you're just testing-

Dr. John Whyte (02:11:54):

But individual patients are not basing decisions on populations. They're looking at themselves.

Deborah Autor (02:12:00):

Correct.

Dr. John Whyte (02:12:00):

That's the issue that I have with it.

Deborah Autor (02:12:02):

But that individual patient might not otherwise get treated. So if it's something that I want to know how I'm doing, what my counts are, because that will enable me to enact a positive change in my behavior, in my health, and I will be empowered, that is much better to me than the world where the only time I can ever figure out what's going on is once a year try to get an appointment with my doctor, by the way, six-month waiting list to get a physical, that to me is not the right result. We have to think about that with both perspectives. What's in the best interest of patients? What's in the best interest of overall, how many people will get treated as well as possible, and make a reasoned decision, which is what we are set up to do within our regulatory system writ large.

Susan Winckler (02:12:42):

Right. Which I don't think it was we want bad tests. It is that we very much so want good tests that generate information that a consumer could use.

Deborah Autor (02:12:54):

Well, I think this is an important distinction and a good conversation about it, because if I'm a treating physician, I want the data that that patient used to be reliable in terms of the positive predictive value and the negative predictive value, which as you know, is based on a prevalence. I don't want it to be okay, from the perspective of individual physician, I'm not interested in the population. I'm interested in the person right in front of me. If I make a wrong decision, I'm liable for that. So I have to have a test that is rigorous.

(02:13:32):

Now, from a public health perspective, I might have a different view, in terms of the number of people that could have access to it, the number of people that it could provide important information. But in some ways, what we're really saying is these are also point of care. And at that point in time, I'm basing it on the individual, not on the population. And it's an important discussion to have.

Susan Winckler (02:13:55):

Right. Because it might be the difference in what's the screening that generates me to seek care? And then when you as the physician or the pharmacist are making the decision, there might need to be something else that's occurring, but you'd need to know that that was some sort of a screening-

Dr. John Whyte (02:14:13):

But this is the same data where we see in supplements that I've seen, where people take the information ... Consumers take the information as reliable. So if it's a positive test or a negative test, or it says your glucose from a CGM is 92, then you assume that's what it is, with no variance. I have had plenty of patients come to me, and their watch told them that their heart rate was 48, and they're very, very worried about it. And that's a worthwhile discussion, but it's not exactly that number. And you have to clarify that for folks.

(02:14:51):

What I'm concerned is that people then make the decisions, and sometimes that's not to come in when they need it to come in. That's the challenge, if we lower standards, or we think more about populations than individuals. I mean, but it's a discussion that is needed, but it all depends where you're standing. So from an individual physician, I rely on that data from the lab that I know that's their number, not that it's within a range.

Susan Winckler (02:15:22):

Right. Because I think we're talking about, you're making a different decision-

Dr. John Whyte (02:15:27):

Correct.

Susan Winckler (02:15:27):

... in saying that, yes, this is the situation, versus it's worth a screen to go [inaudible 02:15:36]-

Dr. John Whyte (02:15:36):

People are interpreting it, whether it's right or wrong, as quantitative data as opposed to qualitative.

Deborah Autor (02:15:44):

I think there's a distinction between a wearable, and a supplement, and a CLIA lab validated test. They're not the same thing. And in fact, I would say all the time, physicians rely on lab developed tests in their practice. They are pervasive. And so I just don't want people to leave with the impression that this is unknown technology that people are just kind of guessing about. This is validated lab testing. And I think it's also really important. I mean, I think the right question is, how are patients better off? And is this information that patients are better off with? I think John is saying there's circumstances where patients aren't better off, because they're misunderstanding information they're getting, or being misled by information they're getting. I don't think anyone's advocating for those circumstances. I think there are situations where more information is better, and having more people have access to information leads to better results for patients on a whole, although sometimes I think when the doctor is ... I'm still having doctors in the loop, so it's not actually a problem for the doctor at all.

Susan Winckler (02:16:49):

Yeah. But I do think it's the what is the purpose of the information? And is it dispositive in the physician's perspective? And then we would expect the test. I think there's some right places where an over-the-counter diagnostic is in fact dispositive, versus something that might be more of a screening, that then stimulates that greater intervention.

Dr. John Whyte (02:17:12):

There is nuance to what we're talking about in terms of lab-developed tests, and CLIA tests, and wearables, more nuance that's needed for this meeting. But it is about, again, the fidelity of the data, and how consumers use that information, how clinicians use that information, and how it's integrated into the healthcare system as well.

(02:17:36):

And what I'm saying, we don't want to lower standards, and I'm not saying anyone necessarily is, and wearables is different, but the FDA does have a recent guidance on wearables and software as a medical device and how we utilize this information. And I don't think it's where we need to be, unless it's adequately interpreted as such by patients, for which we have data that shows ... And I knew you would like the supplement reference industry in terms of, again, it's the whole issue, as you know, and others know here, whether you first have to be shown that you harm someone, and then the FDA takes action, or do you actually have to show upfront that it's safe and reliable, and then you can come to market? And that's a discussion that's often had.

Susan Winckler (02:18:28):

Yeah. Yeah. And so I am always fascinated by these discussions and how we can think about what might be used. And I think you're bringing us back to Stacy's mom seeing the light pink line. Does that make a difference or not? And how do we help consumers understand that in a diagnostic or in an over-the-counter diagnostic test environment?

(02:18:54):

All right. So time did pass quickly, which means that I'm going to give you each ... I'm going to tell you it's a minute, and when you get to a minute and a half, you're done. So I'm going to start with you, James, and would you share what one element you think would be most helpful to better integrate OTC diagnostics, both existing and potential into healthcare delivery?

James Appleby (02:19:22):

I think in order to integrate the data from OTC diagnostics and wearables, we've got to figure out the right people to get together to talk about the collaboration, but we have figured out how to get the data from those two sources input by the patient, or somehow input in a passive way so that it's there in the medical record, and so that it's in the workflow, and the clinician can then see it at the right time and act upon it in a timely manner.

(02:19:51):

When I think about all the chronic diseases of aging, that the 65 ... Well, no, 45 plus population is experiencing, it's an enormous opportunity. The number of different conditions that we have to manage, I think for the OTC diagnostic marketplace and the wearables, it's extraordinary. If we can figure out how to tap into this to manage those chronic diseases of aging, it's going to help all of us as we age. And that's the important thing.

(02:20:19):

At the end of the day, I see this, though, as an ecosystem, and that's why getting all those collaborators together, it's not just going to be one device, one test. It's got to be device manufacturers. It's got to be technology companies, patients, caregivers, clinicians all working together to make the entire ecosystem work. So it's not just one device, one test at a time. It's got to be an ecosystem approach.

Susan Winckler (02:20:50):

Very helpful. Deb, Mike, Dr. Whyte. Deb.

Deborah Autor (02:20:54):

I guess I'd like to challenge us to ask the question of how can we truly make the home the healthcare hub? I mean, think about it. We've all become so accustomed to access to our banking, to everything we want to buy, to our groceries, to any need you have, you can basically satisfy immediately or almost immediately. And so-

Susan Winckler (02:21:16):

Except getting a physical.

Deborah Autor (02:21:17):

Except getting a physical. Right. Exactly my point.

Susan Winckler (02:21:20):

We can find them.

Deborah Autor (02:21:22):

And so I think we've had a really good discussion of some of the challenges along that way, but I think we also have to flip that question on its head and ask, "How can we facilitate this? How can we make it happen?" while thinking about what's in the best interest of patients?

(02:21:36):

At this point, the richest 1% of American men can expect to live 15 years longer than the poorest. So we have huge health disparities, huge access challenges in this country. And we have a lot of the technology coming together to address all that. I'm not saying everything could be done at home, but I think there is an incredible opportunity. And I think about my 90-year- old mom who spends so much time going to doctor's offices. How much of that can we bring home and save the risks that come with that of a fall along the way, save people from the inconvenience, from the cost, from the parking, from all of the things that can go wrong in that process, and think about how we can do it? Not everything will get there, but I think a lot of things can, and I think we should try to make it happen.

Susan Winckler (02:22:22):

And you'd get the better blood pressure data that helps the physicians make better-

Deborah Autor (02:22:26):

100%. And better blood pressure.

Susan Winckler (02:22:27):

Yep. Indeed.

Michael Umbleby (02:22:28):

Yeah. I think it's the theme for this panel, and even the entire day, has been about OTC diagnostics have to be portable, they have to be trustworthy, and then especially for a clinician, they have to be

integrated into their patient care. So I think just doubling down on the statement of the collaboration that needs to happen, it's got to be pharmacists, it's got to be physicians, got to be telehealth providers, and then all the other stakeholders that are involved in that in order to truly drive patient care, patient delivery, and even further test innovation.

Susan Winckler (02:23:07):

Excellent. Give you the last word.

Dr. John Whyte (02:23:09):

I'm just going to add to that, that the only other element I think is insurance and reimbursement. None of this is going to adequately happen unless it's paid for. And I think we can look at the life insurance industry in terms of how they embrace this, that you need a physical from the life, you're signing up for life, they'll come to your home tomorrow or next week, and they'll draw your blood there.

Susan Winckler (02:23:37):

And they bring a scale

Dr. John Whyte (02:23:38):

That's right.

Susan Winckler (02:23:38):

Everything.

Dr. John Whyte (02:23:39):

And many of them actually now are giving people wearables, because they want you to live longer. It's in their financial interest for you to live longer. But all of it's covered. There's no copay. They're making it convenient for you. They're using tools that are reliable, because they want to make sure they get the most accurate data in terms of how they estimate how long you're going to live, and the costs, and people have good experience with it. And that's what the health insurance industry has to take that model from the life insurance industry.

Susan Winckler (02:24:17):

With those validated tests that we can incorporate.

Dr. John Whyte (02:24:19):

That's also about doing it in the home, and being convenient, and being responsive to the customer.

Susan Winckler (02:24:26):

Yeah. And have a consumer-centric system.

Dr. John Whyte (02:24:28):

And they're not charging you for it.

User Perspective

Tanya Altmann, MD, FAAP, Calabasas Pediatrics

Susan Winckler (02:24:30):

All right, everyone, let's thank this panel. Thank you all. So moving from that lively discussion, we had asked for an end user of OTC diagnostics to share a perspective. So we have a pediatrician who is going to tell us about how she uses these both as a parent and a physician. So I'm going to turn it ... It's a brief video from Dr. Tanya Altmann, who's the founder of Calabasas Pediatrics in California. So let's roll that.

Dr. Tanya Altmann (02:25:09):

Hi, I'm Dr. Tanya Altmann. I'm a pediatrician in the Los Angeles area and a mom of three. And today I want to talk to you about over-the-counter testing. And I find over-the-counter testing to be incredibly helpful in my practice and with my own family, both at home and when we're traveling.

(02:25:28):

I really think the more opportunities that families in our country have to be able to test when they're not feeling well or their kids aren't feeling well and get an answer can really help in many ways. First of all, knowing what you have at the beginning of the symptoms can really help direct, do you need to call your pediatrician? Do you need to go to an urgent care, or a medical office to be seen and get treatment? For example, if you have the flu. Do you need to isolate? For example, if you have RSV and not be around infants or elderly who might be more at high risk.

(02:26:04):

And also, when can you return to school or work? Because we know that can also vary infection to infection. And it's not only when you're fever-free for 24 hours and symptoms are feeling better, which is what we always say, but if it is a more serious illness, we might want to be a little more cautious and keep you away from high risk people for extra days.

(02:26:26):

So let me tell you a little bit about how I use these tests in my office. For example, a family last night called me because their child had a fever of 102 and they said, "Do I need to go to the emergency room? What should I do?" I talked to them about their child. Their child was not having trouble breathing, was drinking fluids, was otherwise doing well. And so I recommended giving a fever reducer. And I said, "Do you have an over-the-counter test at home? Because if you do, I would like to start with that, because that'll help me identify what time I want to bring you into the office tomorrow, because I might be seeing newborns in the morning and don't want to bring in a case of RSV or the flu right away."

(02:27:02):

If you have COVID, then that's something we can often treat at home and do symptomatic care, unless you are having more severe symptoms that do warrant a visit in the office. And I think this is how these tests can be useful. When my families travel, I always have them bring with them a pulse ox, as we all ended up getting when we were during COVID, which is another over-the-counter tool that parents have, thermometers parents also have. And now adding these over-the-counter tests are also very helpful.

(02:27:36):

In fact, I was a big advocate initially for COVID testing, and getting it set up in schools and for families, because my goal was to get kids back to school and parents back to work. And for that reason, we needed over-the-counter COVID testing. Flu was also an incredible addition that I advocated for,

because there are antiviral treatments for the flu. And RSV was something right after the flu was added that I started asking around, "Who can do this, who can get it done with a good quality, reliable test?" Because we want to make sure that when toddlers and older kids come home from school with a cold, that it's not RSV, because then they really need to be isolated from their newborn siblings or from their grandparents.

(02:28:22):

As a pediatrician, I would love to see more over-the-counter testing options available. And if I think about what that would look like, things that have actually treatment or that need specific treatment and are causing serious issues in kids would be a good idea. For example, strep throat, we know that needs to be treated with antibiotics. We know that that is also a major cause of PANDAS, which is an illness and disease that we are seeing now more and more in kids. I do recognize the challenges for parents of swabbing their child's throat or even swabbing your own throat to do a test, but if there was a way to figure out how to do that easily at home and get an answer, so that way anyone who has strep throat could be put on antibiotics right away, that would be extremely helpful.

(02:29:10):

Another case I can think of would be mycoplasma pneumonia, which is something else that we are seeing a lot of now and can look like RSV, COVID, flu, or any other cold virus, yet it also needs specific antibiotic treatment, and it is also causing cases of PANDAS in kids, and so it does need to be treated and that would be a nose swab. So I think that might be one of the easier ones to implement, along with the current over-the-counter respiratory panel that we have. As a pediatrician, I am doing a lot of full respiratory panels now, and I think more that we can add to that nose swab testing for parents at home to help quickly identify what their kids have, so that way we can start treatment right away when it's needed. We can also give guidance for what to do at home to help relieve symptoms when they do need to come to the office, and also help minimize spread of these infectious diseases. I think all of that would be very useful and helpful in the future.

Next Generation OTC Diagnostics

Susan Winckler (02:30:06):

Excellent. Thanks. We are grateful to Dr. Altman who, as we were asking her about these things, we said, "We just need you to put that on tape and help us with that." So let's turn to our final discussion of the day. So we've been thinking about what might be next and that future for OTC diagnostics. So we're going to have three rapid fire presentations, and then we're going to bring six people up here for another panel discussion that might be another rumble, I don't know, which is what we like in having robust interaction and engagement.

Paul Wardle, MA, MMath, Klick USA Inc.

(02:30:41):

So let's first start our first presentation. We're going to hear from Paul Wardle, who is Senior Vice President of Innovation Consulting at Klick. And Paul, I'll ask you, when you finish, just go ahead and take a seat on the panel so we can roll into discussion after our other two finish up.

Paul Wardle (02:30:57):

Thank you, Susan, and thank you for inviting me. I love the topic today, Advancing Home as a Healthcare Hub. I've got to ask the question why. And in the blurb on the website, it's about accessible healthcare solutions. That's an important thing to remember. We have to frame this, not of what consumers can't do, but what they can do, which consumers, which households, and for what things can they do that?

(02:31:25):

Oh, there was a disclaimer there. These are my opinions, not necessarily my company or the FDA's. But I want to start with a statement. Effective healthcare actually requires access. Yes, almost perfect care in a provider's office, but we have to think about the care that doesn't happen. That's why we need more solutions. That's why we're having this agenda. Many conditions, diagnostics, on a standalone, they're inseparable with access to medicine. We have to think about not just the diagnostic, but the intervention that follows.

(02:32:06):

Diagnostics help us determine who to treat, when to treat, whether treatment's working. When you think about ongoing treatment for a chronic condition, measurement often helps inform whether to continue to adjust or escalate. This is frequently not a one-time transaction. Yes, there are situations where it is, but I'm going to focus a little bit on the chronic healthcare needs in the US. There's a continuous closed loop between diagnostics and interventions. When access to diagnostics is delayed, medication access becomes less timely, less precise, and less effective.

(02:32:53):

Our needs are pretty extensive. Roughly half the population has a chronic condition. Around a quarter have multiple. Those aren't the same people. When you start thinking about diabetes, cholesterol, blood pressure, asthma, they all depend on measurement over time. So in other words, for a large part of the unmet healthcare needs in the US, diagnostics, treatments, medications are not separate steps. They're actually two parts of the same system.

(02:33:29):

And despite the fact we have effective treatments, which you can get if you go to a doctor, many consumers don't get them, and there's lots of reason for that. There's gaps in diagnosis, gaps in treatment, gaps in non-adherence, delayed care. And when you actually look at those gaps, many of the reasons for those gaps can be traced back to access. People can't get measured, they can't get treated, and they can't easily do both. And those gaps are compounded. So what are the reasons for these gaps? They're certainly real. Many people today have talked about the opportunity cost of going to a doctor, going to a lab test. I'm not going to repeat that. 75, 92 million people, that's a roughly a third of the population live in a community where there's a shortage of providers and pharmacies. There's a real cost that that creates.

(02:34:24):

So there's an important place to kind of make a statement. People do make proactive, good health choices when care is easier and convenient to access. And we can see that with RX to OTC switches. When those have happened, on average, there's been a 30% increase in appropriate utilization of medication. That's not by chance. It's a good regulatory process that got those medications. And consumers actually are looking for different choices, their different ways to manage their health.

I want to point to the right-hand side. We talk about the patient, the consumer. I'll always talk about the consumer, hopefully. They're not the same. Roughly 40% are actually pretty happy with their provider based care. 35% would rather do everything on their own. Whether they should or not is a different question. They're not the same people and we force them all down the same route. This isn't about

replacing providers. It means we need solutions that recognize the needs of individuals, their condition, the severity of that condition, and the stage in treatment. So there's a real question here. Should we all get access the same way every time? I would say no. People differ in capability, health history, medical complexity, their needs and preferences change over time. Someone early in diagnosis with a condition has a very different need for support, from somebody who's in a stable condition after five years. If our access models stay fixed while the consumer needs evolve, we create further unnecessary friction and barriers.

(02:36:16):

It was mentioned earlier today, a new mechanism maybe for Rx-to-OTC switch. I'm just going to say it's not Rx-to-OTC switch. It's ACNU. Thank you, Dr. Michelle. Lots of the things I've just said are the reasons for why this new pathway matters. For those not familiar with this pathway, an ACNU drug is like a prescription in that there are enforced criteria before a consumer can get access. However, the gatekeeper of that access is no longer a human healthcare provider. So it's classified as a non-prescription drug. A non-prescription is not the same as OTC. OTC is a subdivision. So there are criteria that have to be validated. For an example, a digital self-selection questionnaire, which has gone through behavioral studies that show that people can do the right thing. Same thing we do with devices with human factor studies. That may trigger whether a consumer can treat on their own or whether they should be treated by a provider.

(02:37:19):

The ACNU condition can support selection or diagnosis. Could be during use, monitoring. It may be as simple as confirming a biometric measure, A1C, cholesterol, blood pressure. Are those in the right range? So again, I see the same interdependency, medication and diagnostics go together. If we want access, if we want better healthcare, we actually have to think of both of these together.

Susan Winckler (02:37:49):

Yep. So that's great. Close out with that.

Paul Wardle (02:37:55):

They can do this. We have lots of reasons that in the past have done it. We're going to hear about wearables, but just think about this. Consumers don't care about a screening device, a wellness product, a diagnostic, they care about getting a solution that helps them maintain or treat a condition. It's about access.

Susan Winckler (02:38:19):

Yeah. Great. Thank you, Paul. And if you take a seat right up there. So our next rapid fire presentation is from Patty Post, who is the CEO and founder of Checkable. There you go.

Patty Post, BA, Checkable

Patty Post (02:38:37):

I'm going to put my timer on here, Susan.

Susan Winckler (02:38:39):

Yeah. There's one right down there.

Patty Post (02:38:41):

All right. Hi everyone. My name is Patty Post. I'm founder and CEO of Checkable. We are solving the first mile problem of healthcare. Full disclosure, we are under an active FDA review at this time. In 2017... Oh, boy.

Susan Winckler (02:38:57):

Big green arrow. No. Big green one.

Patty Post (02:39:01):

There. Oh. It couldn't be more simple there. I'm a mom of three. In 2017, I found myself in the doctor's office four times in the same week because myself and my three kids had a sore throat. I figured there has to be a better way for this, and that was an at-home strep test. But I thought, "How many moms are like me? How many dads, caregivers?" It turns out I'm not the only one. 36 million people from claims data go in to check for strep every year. 26 million strep tests are administered and 5.2 million people have strep. So I looked at this as, is there a big opportunity here? Yes, indeed there is. We didn't invent a new strep test. We're using a strep test that's been used since the '80s to diagnose 98% of the positive strep cases out there. The technology is very simple, it's lateral flow. It's single use, it's self-contained. We have a reagent pod with a dual chamber. We're selling it in a pack of two. We will sell it in a pack of two if FDA approved. Two tests, two swabs, two tongue depressors, two reagents.

(02:40:12):

It's start to finish in 10 minutes. Instead of going into the doctor, and as we said earlier in multiple conversations, 86 minutes for a visit from start to finish, the waiting room, the exposure. There's lots of reasons to have an at-home strep test specifically. And I know what you're thinking, "But how are we going to collect that sample, Patty?" Let me tell you that it can be done. We've done hundreds of patients in a clinical research, human factors research, and it's all about comfortability. Our children want to be in the home rather than in a clinical environment. I know that parents can be trained to do this as well. You have intuitive design. You have great instructions. We did something different rather than having a quick reference instruction that they're paging through, we have it nicely on the box. So instead of looking through, we say, "Open up and say ah." That's how we collect that back of the throat sample. As well as when we look at a character, a kid is going to feel much more comfortable with something that they can relate to like creative design.

(02:41:21):

So considering considerations for expanding this at home testing, just like Dr. Altman said, let's look at what are some tests that are already proven in clinic right now that we can bring, as I say, over the counter. So if it's pneumonia, right now we have the RSV test. There's opportunities that we can do this that are proven by our healthcare providers that if with the right design, that parents can run the tests at home. Straightforward interpretation, clear follow-up action. We aren't taking a physician away. We're simply extending their reach, whether that's telemedicine, whether that's our pharmacist, or whether that's our clinical practice healthcare providers. So regulatory pathway. Are we looking too much at the risk of the false negative? If we're screening and if my child has a fever, has a sore throat, has redness, and I have a negative, I'm still going to go in and see a provider and all labeling should recommend the same thing.

(02:42:27):

And our too many OTC rapid strep tests, they work exactly as they do in the clinic. So consumers can feel confident and they can be familiar with that technology. Because how many of us have gone to the clinic

for a sore throat? I would say almost this entire room or someone that you know, so we are familiar with it. And benefits outweigh the risk. We have an access problem, as Paul said, and this is a definite solution. Thank you so much for your time. And the last is your healthcare begins at home. Thank you, Susan.

Susan Winckler (02:43:02):

Thanks, Patty. And as we said, we're pursuing these as just examples. It's not a discussion about specific products, but thank you for illuminating a possibility. We'll turn now to our final quick presentation of a case. We'll turn to Sam Surette, who is US regulatory affairs manager at Apple.

Sam Surette, BS, Apple

Sam Surette (02:43:28):

Thanks, Susan. So I wanted to talk a little bit about the unique opportunities available to wearables that may present some different approaches to product design than traditional over-the-counter diagnostics. And at Apple, we call this opportunistic detection. All right. So what is opportunistic detection? This is a product that can detect signs of a chronic condition like sleep apnea, as you can see on the left. It analyzes passive sensor data from consumer wearables like the Apple Watch. It returns a positive result only. And this is a really important concept for us in terms of opportunistic detection and is what makes it most different from some of the other diagnostics that we've seen today, where a user is going to a pharmacy and selecting a test that's right for them. One of the things that's so great about wearables is that the user's wearing it or purchasing it for a variety of other reasons. So when you go to the Apple Store and buy an Apple Watch, there's a number of reasons why you might purchase that, whether it's tracking your fitness, whether it's checking messages, whether it's telling the time even. There's very few people who are going to go in and specifically buy it so they can find out that they have sleep apnea. But since they're wearing it, tracking their sleep with it, one thing that Apple can do is we can analyze that passive sensor data from the consumer wearable, and if we detect signs of possible sleep apnea, we can deliver a positive result to them and nudge them for further care. And that's a really important concept as well because this is upstream from screening and diagnostics. This is really about expanding that funnel for underdiagnosed chronic diseases like sleep apnea, and prompting someone to make an appointment or have a conversation with their doctor, who otherwise might have ignored their symptoms.

(02:45:27):

And the positive result only, you might have more familiarity with it than you think if you've ever received a push notification on your phone. It is the exact same thing. You're not going in every app to see what changed. If there's something that's new, it'll prompt you. It'll send you a notification. And that's exactly the way that we approach our opportunistic detection features as well. Now, in terms of regulatory considerations, this also creates different priorities than a traditional diagnostic test. And I think the most salient one for this group is around operating point when you're balancing between sensitivity and specificity. So when you go out and you seek an answer to a specific question like, "Do I have COVID?" And you go out and purchase a test and take that test, you want them to have a good balance of sensitivity and specificity because you're getting either a positive or negative answer.

(02:46:22):

With a wearable feature like hypertension notifications, which was just FDA cleared last fall, really what we're focused on is high specificity, which means we're unlikely to send a false positive alert to the user, which maintains a good positive predictive value. So when you get a notification, there's a good chance

that you actually indeed have the condition. And that's why it's so important that this is a push notification as opposed to a positive or negative result. And from Apple's extensive clinical studies, human factors studies, as well as our post-market surveillance, what we've seen for our three opportunistic detection features, all of which are FDA cleared, is that they can be safely used, they can prompt correct user behavior and getting them into the care. And we get emails every day about people whose lives have been changed in some way or another from a diagnosis of AFib or sleep apnea or the latest of hypertension. And so, this is a really impactful thing and it's an exciting next step in terms of over-the-counter diagnostics. Thank you.

Reactor panel:

- Kathryn Capanna, MBA, U.S. Food and Drug Administration
- Marcia Howard, PhD, CAE, Consumer Healthcare Products Association
- Michael Mina, MD, PhD, HTR Advisors

Susan Winckler (02:47:39):

Thank you so much, Sam. And so from Paul, Patty, and Sam, we have some ideas of what that future might be. And let's bring up our last panelists who are going to help us distill the day. And so, as they get settled, I'm going to step up here because there's not room for me to sit among you. But really appreciate the presentations and then our final three folks joining us for the conversation. So I'm going to begin with Dr. Marcia Howard, who serves as vice president regulatory affairs and quality at the Consumer Healthcare Products Association. Dr. Howard, what are you hearing from CHPA's members about opportunities for innovation in OTC diagnostics? So building from these great examples that we've just heard, what are your members' priorities?

Dr. Marcia Howard (02:48:30):

So a lot of the information that has been discussed already today, such as the impact of COVID-19, the fact that consumer expectations have changed because of COVID-19 and our ability to test at home, and the deficit of healthcare providers in rural areas, in urban areas where there may be a lack of healthcare professionals, but we haven't talked about the changes to the current healthcare system that mean people are either losing their healthcare or maybe are having less access to healthcare because they have to make significant changes to their policy. So that's another subset of the population that could potentially benefit from having more OTC diagnostic tests available to them. So our companies that are in the medical device space actually are twofold. We have some that make standalone devices. So Patty is a member of CHPA, as you heard her working on her OTC strep test. But we have companies that make standalone devices like blood pressure cuffs, digital thermometers, UTI test kits.

(02:49:41):

And so they're looking at opportunities to bring more OTC diagnostic to the forefront to hopefully decrease the health disparities and the gap in health coverage that we may be seeing because of the changes in the current landscape. The other element has also been mentioned, and that's about the possibility of ACNUs. Because our companies, we have a lot of members that manufacture OTC drug products, but as this new marketing pathway and approvability pathway for OTC drugs that might use an additional condition of use, that potentially uses an OTC diagnostic may drive additional switches for chronic conditions for those diseases that are undertreated. And so, there's an intersection of OTC diagnostic with the potential for future OTC switches.

Susan Winckler (02:50:30):

Fabulous. Thanks, Marcia. I imagine those are fun conversations to just be engaged in with your members.

Dr. Marcia Howard (02:50:39):

Yes, it is. We have confidential conversations with our members individually, but we also have conversations with a lot of our CROs like ClickHealth and others, because they get to see a lot of the overarching research programs, and look for synergies and common threads that might help the industry as a whole to continue to develop these products.

Susan Winckler (02:51:03):

Right. To think about the research angle. Great. Let's then turn to a colleague to your left for a physician scientist perspective, as well as someone who is working directly with a number of companies developing at-home diagnostic products. So Dr. Michael Mina, you have a leadership role with HTR Advisors. What would you identify as necessary to drive progress for OTC diagnostics and how might we describe progress?

Dr. Michael Mina (02:51:35):

That's a great question. We've heard a lot of it here, I think payors are a big part of it. Figuring out how to get payors to want to pay for OTC diagnostics, I think is huge. I'll give an example of an approach that I think could work that solves... Or at least that was attempting to create a pilot of something that could solve some of these issues. In the pandemic, I led the Biden administration's home test to treat program. It was the only home test to treat program that the government funded and drove forward. And the goal there was to say, "What can we do with all these over-the-counter tests and make them more valuable than they currently are?" At the time we had public health labs were generally refusing to accept OTC results. There were some efforts by the NIH to try to change that, but let's be honest, most labs chose not to accept results, for good reason. There was no validation of those results. Was it true? Was it positive? Negative? Who knows?

(02:52:37):

And so, we created a system to essentially validate when somebody took a result, essentially brought a CLIA-waived lab into the home through software, but allowed people to use an OTC tool. They were essentially all antigen. We used Lucier at one point. But we were using all sorts of tests. And then immediately just brought people and handheld them directly into a telemedicine visit based on the result. So that accomplished a number of different pieces. It accomplished validation and verification that in a future state, maybe a pair would want to say, "Hey, yes, this was actually my covered individual who used the test. We got a confirmation." The physician felt good about actually having the results saying, "Yes, this patient is X, Y, and Z patient. Their result was actually positive. We had confirmation if it was COVID or versus flu and we were able to get them treatment." So that was all using OTC/telehealth products, but just really putting software in the middle to help solve some of these problems.

(02:53:45):

And I would say it was a resounding success. And then at the back end, a lot to what Raymond was talking about, we got much more data. There was initial pushback that we would lose public health data by bringing OTC tests to market. And I've battled for the first couple of years to try to help identify how these tools could be used. And what we found when we started linking through software was that we actually were able to provide back to the NIH and the CDC and the White House much more information about who was using OTC tools, what was the speed that people were or were not getting access to

treatment with or without this program. It's a little bit surveillance data if you will, but we're able to get a lot of socioeconomic information passively through understanding what sorts of technology they're using just to access the program. We made it accessible through an 800 number all the way up to iOS and things like that.

(02:54:43):

And so, it provided a lot of information. And it's just one example of, I think, how we can at least start to close the loop a little bit for a lot of what we're talking about here and make OTC tools. I don't think that they have to be interpretable on their own. And it doesn't have to be this one thing or another. We can actually supercharge them based on technologies today. And AI is only going to make it much more fantastically easy and much better. But I think that's one. And in just 30 seconds, I'll say the other big piece for OTC is I do think we need to really think about, from a regulatory perspective, how to formalize our understanding of access relative to accuracy. And I put accuracy in quotes because accuracy is also dependent on what the goal is. If your goal is isolating somebody based on a positive and the PCR is a terribly not specific test and antigen tests are highly specific. So there's lots of goals there.

(02:55:48):

But to actually formalize what's the benefit and value of improving access and at what point. If we could regulate and certainly approve an electron microscope to identify a SARS- CoV-2 virus and it might treat or enable one person to get care per year or something, and on the other hand, we might have a test that is 2% sensitive, but everyone can use it every single moment of the day. Somewhere in there is something that we would actually want to see. In the span of those two extremes, is something that we actually want. And it has to do not just with the sensitivity and specificity, but access is actually a measurable and quantifiable component of care. But we haven't really formalized that or even have a lexicon for it. And I do think we have to start identifying what that language might actually be, because there are truly quantifiable metrics where you can say, if the test is just 60% sensitive, but it gives a result in five minutes, it turns out that that's actually a much more effective test than a 100% sensitive test that gives a result in three days for a virus like SARS-CoV-2.

(02:57:06):

And so, when you bring those together, you... But we don't have a language for it. And I do think formalizing some of these pieces around... Like the whole discussion here is really around access. That's what OTC is about. How do we bring that into the regulatory discussion in a more formal way?

Susan Winckler (02:57:25):

Right. Because then that plays into our panel earlier in the day and thinking what is it that a healthcare professional needs to know about that test and what it means. As well as for the consumer, what does it mean getting some of that terminology. And I'm glad to know that I wasn't the only person who tried to report their home COVID test to a state. I tried to get the State Department of Public Health in Virginia to take my data, and they refused.

Dr. Michael Mina (02:57:55):

We eventually succeeded, but certainly the OTC attempts without the extra pieces, I would say, were a... I wouldn't say it was a failed program, but it was actually a really important learning lesson. I'm glad the government... That was a different program of the NIH, but it's interesting.

Susan Winckler (02:58:13):

Yeah. But having that interface makes some sense for what we've been talking about, the challenges here. I want to turn and make sure that we hear more from a regulatory perspective. So thank you, Dr. Capanna, for joining us. Your day job is leading strategy development for cross-cutting initiatives in the Office of Strategic Partnerships and Technology Innovation within FDA Center for Devices and Radiological Health, and as executive sponsor for the Home as a Healthcare Hub initiative. That is not the longest title at FDA. But Kate, you have a lot that you are responsible for in there. So what are the opportunities and challenges that you see? We've been talking a lot about different parts of the ecosystem here and what's working and what's not. What do you see in that leadership role?

Kathryn Capanna (02:59:05):

Well, we could just use the alphabet soup of acronyms [inaudible 02:59:09] signature block. Well, first of all, thank you for the opportunity to participate. One of my goals in this meeting has already been accomplished, which is to hear a lot from different stakeholders in different organizations, different parts of the ecosystem, and different places in the innovation pipeline from concept to care, that see things differently in terms of where we are, what the challenges and opportunities are and how we can work together. Healthcare is a team sport, regulation is a team sport, innovation is a team sport. And when we're in a paradigm shift like we are in this space, it really takes a coordinated effort. And so, these kinds of conversations, I think, are really essential.

(02:59:52):

I was at a startup before coming to FDA and I was inspired by the dedication and the expertise that all of my colleagues at the FDA had. And was humbled by an appreciation, that I only gained after switching perspectives, that successful regulation is not faster access. It is not 100% safety. Because those things need to be balanced. Successful regulation is striking the right balance. And the challenge with any regulatory paradigm that's shifting is, we all chuckled at the, it depends, but there are hundreds of thousands of devices that fall under CDRH's regulatory responsibility. And those devices are also iterating and evolving more so in these spaces that we're talking about today than traditionally has been the case. We do what we can to be nimble with our regulatory frameworks. We move at the pace sometimes of congressional statutory revisions and other things, but we do try to keep a pulse on what's happening in the community and where the innovation is moving.

(03:01:06):

And I think when we do the best work in this team sport, it's when we are thinking about how can we collectively think about the opportunities that lie before us as technology advances. And the technology, certainly in this space, more and more so in all of the medical device arenas that we work in, it's the technology human interface. And so, we've heard about this in a lot of different flavors today. It's the consumer comfort level has really changed and expanded where it was smaller populations of folks that were comfortable using testing at home, diabetes, other conditions, where folks already knew they had a condition and were managing their care. But with COVID, just massive change in the paradigm in terms of consumer comfort level. But what that comes with is, there's heterogeneity in that consumer and patient market in terms of their health education, their commitment to really monitoring or understanding what comes next. Can I use it correctly? Can I read the results? Can I interpret them? What do I do when I get a certain result? That's variable in different populations, in different disease condition states.

(03:02:25):

And so, it's the technology and the person together. And if you look back in time, most of the traditional medical technologies that we have more experience regulating, the person was the clinician primarily using the technology. And so, that's a really fundamental shift from a regulatory perspective when you

think about what do we think we need to see to check that the person and the technology can work together correctly to get to the health outcome that we want? There's been lots of discussion about that today. And so, the Home as a Healthcare Hub initiative is our response at the FDA Center for Devices to a confluence of several of these trends, the consumer comfort level, the technological advances, the access challenges, the stresses on the healthcare system. This provides this constellation that is showing us that we need to rethink, clarify regulatory pathways, and continually reevaluate how we strike that right balance. Because going in either direction too far will cause unintended consequences that we all want to work together to avoid.

Susan Winckler (03:03:41):

And keeping pace with the technology and the changes in consumer behavior.

Kathryn Capanna (03:03:46):

That's right.

Susan Winckler (03:03:46):

I think, as you said, that regulation is a team sport. It's also a team where you have, it seems, different players developing different skills at all times. So navigating how you deploy that team is challenging too. That's why you have so many words in your title, to navigate that. So let's build on what we've heard so far and broaden the conversation. So Sam, Patty, Paul, you're in the mix now as we turn to the next question. I want each of you to give a pithy response to where you see OTC diagnostics playing the most meaningful role from a public health perspective, particularly in early detection or disease monitoring. So Dr. Mina, could you turn to you first and then we'll do Paul and Sam. And then I'll tee up our last three. But Dr. Mina first.

Dr. Michael Mina (03:04:45):

Sure. I think public health is in some ways both central to this discussion we're having here, but it's also absent from so many of the conversations that have been happening today. So I'm really happy to have the question. I think early detection and early... I don't even want to say early detection or diagnosis. I mean, early data and awareness of our own bodies and what's happening inside our bodies is central to keeping us healthy. And I think when we think about healthcare today, we're really talking about sick care for the most part. We're usually talking about, do we diagnose a disease or an ailment or something? I think OTC tools and just whether they're... I think there's a spectrum between wellness and up to OTC tools. And really just tools that are accessible to us are going to be, I think, foundational. As we move into an era of AI, people are... We're not even moving into it, we're already there. Most people, I would say, with access to a computer or phone have used it, are asking it health questions.

(03:05:52):

So we're already in this weird amalgam of how people are accessing and trying to make themselves healthier. I think the more tools that we can get out to people that accurately give them information on themselves, whether we call that a diagnostic or just a measurement. I think it's foundational to keeping, to allowing us to monitor ourselves and stay healthy. AI is going to help support people through all of that. It's also a major, major accelerant when people... It's really easy to sit back and say, "I think I've eaten okay for the last 20 years of my life. Yeah, I think this is fine."

Susan Winckler (03:06:30):

And then there's data.

Dr. Michael Mina (03:06:33):

Yeah. And we look at, I wear a CGM every once in a while just because it actually has really reinforced and taught me a lot about just how my body responds to sugars in a way that my wife's body responds very differently. And I think these pieces are going to be just absolutely essential to help not just give us information, but accelerate our willingness and interest to engage in proactive healthcare as well.

Susan Winckler (03:06:58):

Very helpful. Paul?

Paul Wardle (03:06:59):

You asked for public health and pithy.

Susan (03:07:02):

Microphone.

Paul Wardle (03:07:04):

Sorry, I'm going to stop. Public health and pithy. So I'm going to actually just say heart disease is the leading cause of death in the US. 34 people die every second. Every second, I think it is. Seven of the top 10 most prescribed drugs in the US are actually for heart disease. They're actually all generic as well. It's not that we don't have low cost therapies. When you actually look at the barriers, people... And it was kind of laughed about earlier, but I feel good. I don't want to go to the doctor. There's a trade off of going there. Consumers take supplements for a reason. They can get access to them. So we laugh about it, but they do it because they're accessible.

(03:07:42):

When you think about monitoring, yes, you could argue that taking the drug, you get the benefit of a statin 99%. You don't need to measure it, but there is a benefit of measuring. It links actually to insurance because affordability we have to worry about. Payors care about is at a covered life. If the consumer gives them back the data and it's covered, there's a relationship here that could work. Because if we reduce the number of heart attacks, strokes, et cetera, then we reduce costs. There's a benefit to the insurer. So number one, I'm going to say that. I could go to another 27, but that's-

Susan Winckler (03:08:18):

That works. Thanks, Paul. Sam?

Sam Surette (03:08:22):

Yeah. I would say breaking down that barrier between health and wellness and making it feel less like you have to make an appointment to deal with your health. I think passive, actionable insights are really key. And then I also would say privacy at the core, people owning their own data, being in charge of what happens to it and how it's used, portable, on device, secure, all of those things will help make this happen.

Susan Winckler (03:08:50):

Very helpful. Let's do Marcia, Patty, Katie.

Dr. Marcia Howard (03:08:53):

Oh, okay. So we are talking about public health, but public health is based on individual health, right? I live in the DC metropolitan area and work here. So clearly we have adequate access to healthcare professionals, but I also spend a great deal of time in West Virginia taking care of aging parents. And most of you know that West Virginia is not the hotbed of healthcare.

Susan Winckler (03:09:23):

It is a hotbed of other things. Mountaineer spirit, all there, but yes.

Dr. Marcia Howard (03:09:27):

Other things, but not healthcare. Exactly. But you also know that it is not known for having a high level of income for a great deal of the population. So they're making very careful decisions about, am I going to spend money on a doctor's visit and a copay? How much is my gas now going to cost me to get to the doctor because I live 50 miles away from the nearest city. And then if they tell me I have to take a prescription or buy an OTC drug, or then they tell me, "Oh, you could have just taken a test at home." I've now spent money out of my pocket that now cannot be used to maybe feed my family or go to work the next day. And so I see OTC diagnostics at the front end having the potential to help me make the decision. Do I need to make a sacrifice of maybe not going to the movies this weekend because I need to go to the doctor because I know now that I need to seek treatment. Or I can take this test at home, know that I can get care at the marketplace in my local town and still have fun with my family or buy the groceries that I needed or have gas money for next week's commute to work. So I'm looking at it from the standpoint of what does it help the individual do who may not have the means to always make decisions without thinking about the impact of my day-to-day life because I know I have the means and the resources to make both decisions without thinking of them being linked.

Susan Winckler (03:10:59):

What a vivid picture. Thank you, Marcia. Patty.

Patty Post (03:11:03):

I would echo what Marcia said. I live in North Dakota and we have more access to a pharmacist. And if I can go into my pharmacy to choose an OTC diagnostic, run the test at my house, and have my self interpret it, have my pharmacist prescribe a treatment plan, that gives me so much freedom and allows me to make the next decision. Should I keep my kids home or myself home? Should I go in and see my physician? And I'm not spending so much money out of pocket because I am on a high deductible healthcare plan, which 85% of Americans are. So when I think of cost, convenience, access.

Susan Winckler (03:11:45):

Great. Thank you. Katie, as you think, you're thinking about these things all the time.

Kathryn Capanna (03:11:51):

I think of early detection and monitoring in terms of that space, I think it was Julia that said payors want to prevent things going from bad to worse. That makes sense for patients too. And I would think of it through the lens of access barriers. Where are the access barriers causing the biggest friction points for

patients who potentially are not acting the current standard of care with other means? But also, we've thought a lot at the center about patient preference or choice, how different patients will have different thresholds, different reasons why they will be more active in their healthcare or less. There are many conditions, cancers, progressive degenerative conditions where you could see these two factors kind of coalescing and identifying a variety of different conditions where there could be a lot of potential. Again, if the technology works well and the patient factors can come together so they use it correctly and then take the next step, I think that's where we all hope the unlock will come.

Susan Winckler (03:12:59):

Yeah. Yeah. And that unlocking, I'm also struck in listening to everyone that there's also a power in having these tools available in the home pre-positioned. And so less of a, I don't feel well, I go and get the test, but have other things that are just always in my medicine cabinet provided that's in a climate controlled environment other than my bathroom. Right, that it could be available.

(03:13:28):

So let's talk then about that integration into consumer's homes and daily routines. How should we think about integrating OTC diagnostic tools, standalone devices, wearables into consumers' homes and daily routines, and what benefit might that have for those individuals in the broader healthcare system? Our last panel talked a bit about this, but I'd love to hear you all build on that. Sam, I know you're shocked. I'm going to call on you first for this one.

Sam Surette (03:14:01):

Yeah. I mean, at Apple, we try to deliver value to our user base and try to make our products as useful as they can be to help people live a better life and a better day. And so we're looking for opportunities to meet people where they're at. So one good example is with our hearing aid and hearing test features on AirPods Pro2, this is not just an over the counter set of devices. They're actually over the air because if you had AirPods Pro2 and iPhone prior to our release, you would just download them to your phone and to the firmware on your AirPods.

(03:14:35):

And so being able to say, "Hey, you're already wearing something that can serve as a hearing aid and can do a clinically validated hearing test," that's much more powerful. And it solves one of the big problems of access, which is actually stigmatization and people not wanting to perceive themselves as needing help in the first place. And so we're able to nudge people in that right direction, make it as easy as possible for them to assess their own hearing in the comfort of their home in five minutes. And it avoids the... A lot of us have stories with ourselves or with our family members of saying, "Hey, you have to go get your hearing checked, go to Costco."

Susan Winckler (03:15:15):

And they don't hear you when you say that.

Sam Surette (03:15:19):

Exactly. So that's one good example. I think it's about meeting people where they are and trying to make it as consumer friendly as possible. And I think that's something that Apple in particular is excellent at.

Susan Winckler (03:15:30):

So that's the power of using something that is part of a consumer's life and having an opportunity to deploy providing better information.

Sam Surette (03:15:40):

Exactly. And I think one other example is that Apple's also a platform for other manufacturers via our app store. And Courtney mentioned some of the interoperability between CGMs and the iOS system or other smartphone operating systems. And so that's also a big thing that we think about in terms of access, making it easy to download the latest CGM app to your phone.

Susan Winckler (03:16:05):

Marcia, would you pick this up as we think about the integration and how we get this into kind of daily routines and thinking about it?

Dr. Marcia Howard (03:16:12):

Well, I'm going to take us higher level.

Susan Winckler (03:16:15):

That's okay.

Marcia Howard (03:16:16):

One of the challenges that I think we could potentially have and maybe solve is making it easier for consumers to know that a device is available OTC. I don't know. There may be. Maybe Katie can tell us, but I don't know if there's a-

Susan Winckler (03:16:36):

If there is, this is a great place to share the resource.

Dr. Marcia Howard (03:16:38):

Exactly. So an easy way for consumers to understand that a particular medical device is available as an over the counter device from a trusted source.

Kathryn Capanna (03:16:52):

So FDA posts lists of various... We have AIML enabled lists. We have AR/ VR lists. We do lists that are oriented for innovators and consumers. Courtney's slides, which are available to everyone had a variety of links in her last slide. So I would direct folks to that or to our website directly.

Dr. Marcia Howard (03:17:17):

Well, I know that FDA, sometimes they'll do press releases or announcements when they do a release or approve or clear a new device. It would be nice if the press release would state right up front that a device was available over the counter. Because a lot of times if you don't know that those database exist, it's going to be kind of hard to find them. And as a consumer, you might search once or twice, but you may not know what words to search for. And if you're-

Kathryn Capanna (03:17:46):

It sounds like we have a collaborative conversation to follow.

Dr. Marcia Howard (03:17:47):

Exactly.

Paul Wardle (03:17:49):

Yeah, exactly. But just even the press releases that often appear on the first page of the FDA's landing page, if you look at the press release, they'll talk about the first time that a device has been cleared, but it never really clearly states that the device is available, OTC. Sometimes it does, but it's not a routine statement. And maybe that's an opportunity for consumers to start understanding that these devices are being brought to market.

Susan Winckler (03:18:14):

Yeah. That's a great way of thinking about the home as a healthcare hub. What can I use in my home? Yeah. Patty, you wanted to jump in.

Patty Post (03:18:22):

I think that's the opportunity for the distributor or the manufacturer. And being a US-based company with a marketing budget, you should be sending education to your healthcare providers. They should be your partners. They should be making their patients aware of what those therapies are that are available over the counter. And that's where media comes in to make the consumer aware. And if your retail partner is willing to put you on display in, it's called a racetrack, those are opportunities that you need to take advantage of. And that's the opportunity of being over the counter is that you have that broad awareness. So I do agree. I see your point, Marcia, but that's our responsibility and that's what we are in business for.

Susan Winckler (03:19:09):

Yeah. Yeah. Some of that obviously in reaching the consumer where they might be. Michael or Paul, do you want to-

Paul Wardle (03:19:17):

Yeah, I'm going to jump in. And I think for most of the last three decades, healthcare has been the number one searched item on the internet. People want to access information. And what is a diagnostic? It's providing information. As of 2021, it could be 2022, we now actually have legal rights to the results on diagnostics without it having to go through a provider. So I actually wonder if the question shouldn't be, why aren't they in a home? What is the reason why a doctor is necessary? Now there may be financial, there may be other reasons for doing it, but actually the provocative question is, why isn't there?

(03:19:58):

This actually leads to the second reason why a doctor is necessary. At the moment, the doctor is the validation of insurance. So we have to find the other way of saying, "You know what? A consumer's doing a test for the right reason. How do we ensure either it's an appropriate price that they can afford or that there is appropriate coverage because it makes sense?"

Susan Winckler (03:20:17):

Which plays into that it is a test that can be used by the consumer that gets-

Paul Wardle (03:20:23):
Which is the validated process which we need to ensure still exists.

Susan Winckler (03:20:27):
Yeah, yeah. Michael, did you want to add anything in, or Katie?

Dr. Michael Mina (03:20:30):
Yeah, I think we're sort of in a pretty ugly duckling phase of all of this.

Susan Winckler (03:20:38):
Share more.

Dr. Michael Mina (03:20:40):
And I think we're going to work our way through it, but I really believe that what it's going to take is analogous to what has happened in the hospital system. We have a remarkable number of instruments and devices and clinic visits and all these things that have been brought together through software over the years to a point now where it's like just healthcare and hospital settings are just finally exiting the ugly knuckling phase, I would say. Epic doesn't feel like it's 30 years old anymore. It feels like it's 15 years old, but in terms of like how aged it is in the software interface, but-

Susan Winckler (03:21:17):
So it's getting better.

Dr. Michael Mina (03:21:19):
It's getting better.

Susan Winckler (03:21:19):
Okay.

Dr. Michael Mina (03:21:20):
And I think OTC is going to get there and we're going to see it. I would love to snap my fingers and say, A, I have a solution or B, I would be a trillionaire if I did. I don't have a solution, but I know the solution is probably going to be some combination of these remarkable leaps that are happening in AI, large language models. And that's like the ultimate accelerator of all this because all of a sudden people can start thinking, wow, these things can actually come together.

(03:21:47):
Apple's done a great job in its own ugly duckling way with the health app, but it is as like not super useful as it currently is, it has been a massive leap forward. And that's just the ecosystem we're dealing with. It's a challenging ecosystem and a challenging nut to crack. I think it's going to happen and I think we'll be having this conversation in 10 years still, but it's going to be massively different. People are going to be using all different company's things and they're going to be integrated in a way that doctors and AI doctors and real doctors trust it and rely on it. And of course, patients rely on it.

Susan Winckler (03:22:27):

I actually flashed forward to this meeting 10 years from now and everybody really like pulling out a device and saying, "Well, no, I just got this and I learned this." Katie, anything you want to add on this before we're going to go to a lightning round to close us out?

Kathryn Capanna (03:22:43):

Just briefly, I think the integration happens at several layers, right? It happens within the home environment. So can the patient use it? Does it integrate with... Are we talking about seven different sensors doing different things? How do those integrate? But there's also the integration with the healthcare system. The prior discussion about it getting into the EHR. Are the physicians getting the information, the clinicians, the pharmacists, what have you? And so I think those are lots of technical challenges to crack as this field moves forward, but those opportunities will be unlocked as those challenges are solved for.

(03:23:24):

I think with the regulatory lens, again, striking the right balance is our goal. And so part of our responsibilities to think about unintended consequences, not for the purposes of stymieing innovation, but rather to shepherd responsible innovation to the forefront.

Susan Winckler (03:23:42):

Yeah, that's great. It reminds me, we did have someone submit an online question. I think it was more of a hypothesis that was, should regulators help with some sort of standardized structure to get the information into EHRs. So just put that on the very long list of things that you might do. Might not be FDA, but might be a role for-

Kathryn Capanna (03:24:04):

Someone have a magic wand?

Susan Winckler (03:24:05):

... other entities. Indeed. If you find the magic wand, let me know. I'd like it myself. So I want to give us a final wrap up so you each have just under a minute to help us have a reflection on what you would highlight from today's meeting or would want to make sure we address in the future. So this is back to pithy response and just help us think about the day. Sam, are you okay if I start with you and we just go down in order?

Sam Surette (03:24:38):

Sure. I'll keep it pithy. I think oftentimes prescription use is seen as the default, the de facto, and over the counter is extra. And I don't think that's always true. And I think we should start thinking about from not just protecting public health, but promoting public health, whether there's a role for regulators to question whether prescription use should be kind of the default box check on that indications for use form.

Susan Winckler (03:25:03):

Right. So even kind of reframing how we consider interventions. Patty.

Patty Post (03:25:09):

Looking at OTC products, excuse me, consumer empowerment gives physicians the opportunity to practice at the top of their license. And when we are empowered at home, it empowers us to make the decision whether we should use them or not. Affordably, conveniently.

Susan Winckler (03:25:29):

Thanks, Patty. Paul, pick up your mic.

Paul Wardle (03:25:32):

Yeah. Oh, sorry. The mic. I was just loving the affordability. So access and accuracy, I think is a tension. And whether we talk about it as a screening tool, but if it's screening, you still have to go to the doctor, you haven't addressed access. But that gets into the approval process, which gets back to accuracy and the cost to develop. That tension is fundamental because we don't develop the most accurate if it takes us 40, 50 million to do it. The screening tool, which isn't really getting us to an end result to do something different, isn't actually as useful as we want it to be, but those tensions really come together. And the other one, it has to be we're not all the same as consumers. Every one of us has a different medical background, different need. We can't treat it as one cohort. We have to think about access in populations versus access as a whole.

Susan Winckler (03:26:25):

Great. Thanks, Paul. Marcia.

Dr. Marcia Howard (03:26:27):

I'm going to say cover two elements. One is trust. Trust that the consumer can do the right thing at the developer and the regulators come together and put a product together on the market that is safe, that works, that can be relied upon, but also trusting that the consumer can do the right thing, but also that you trust the consumer to do the right thing. And the consumer being able to trust in that device, trust in the standards behind it, trust that when they get a result, whether it is positive or negative, that they can make a decision that is right for their particular situation and their healthcare needs.

(03:27:05):

But then I'm also going to challenge the regulators and the developers to be bold and think about what can be done and what possibilities are out there for new OTC diagnostics in the future. And I am definitely not a technology person, but I also know that in this field, that with the development of technology moving so quickly, think about what can be done, not just today, but what might be possible two years down the road or five years down the road. And so to think boldly about how we might deliver healthcare differently and in particular, OTC healthcare.

Susan Winckler (03:27:41):

Fabulous. Michael.

Dr. Michael Mina (03:27:43):

Yeah. For me, since we're with the foundation here, I'll keep it to a regulatory answer. I think trying to reimagine what regulatory landscape could look like that maybe isn't RX or OTC, but is in the same vein. And it's not as far as unregulated wellness, but I think OTC unlocks some of the most powerful public health interventions and tools we could hope for. I hope that everyone in this room is kind of rooting for moving true healthcare to be upstream more and more so that we're not getting sick so much. And that,

I think, forces us to start thinking, is there a public health pathway? That's just different where your metrics are literally different.

(03:28:32):

We're kind of dancing around accuracy versus access. And maybe medicine isn't the right venue to have that discussion. Maybe public health is. And right now we don't really have a regulated public health pathway. Everything is forced through a medical bottleneck because of our laws. And I would be very interested to see FDA open conversations around like, is there actually... At least have the open the space and dialogue. Is there a room for a public health pathway that's actually bonafide this is a public health tool? This is why we're creating it. And it's less about any one, individual's medical diagnosis and more about how do we make a population healthier? And I feel deeply that there's room for those technologies and they might look different or they might look the same, but have different metrics on the backend to evaluate them.

Susan Winckler (03:29:27):

Intriguing. Katie, you get the last word.

Kathryn Capanna (03:29:30):

Well, I'll end where we began. I think in the opening remarks, we ended that portion with a view of the landscape and a challenge to answer the question of what does a path forward look like. I think I'm coming off of this panel somehow with more on my to do list. I'll put one out to the whole-

Susan Winckler (03:29:49):

It's an ecosystem. It's shared.

Kathryn Capanna (03:29:51):

I'll reciprocate and put one out to everyone. I think early in the home as a healthcare hub initiative planning stages, I became a student of what worked in the diabetes community. I think there's lots of learnings there. There are learnings in the sectors that we've dove into today.

(03:30:10):

One thing I would be very interested to see crop up in other areas is an innovation roadmap that resulted from repeated convenings of multiple stakeholders who were looking at the issues from all sides and thinking about... In the diabetes community, one thing I think that was an unlock was thinking about those technology development milestones alongside the consumer and patient readiness, comfort, skill level, usability factors, as well as regulatory risk thresholds. And when you layer those together, you start to see a pathway with milestones that instead of trying to boil the ocean, you can start to see what's the next step? What's the next step in this ecosystem shift that we're all trying to grapple with together?

Susan Winckler (03:31:02):

I see an innovation roadmap emerging even just from the conversation. Let's thank this panel. And I'll just close us out. We should thank all of our speakers today. I think each one of them was illuminating in their own way. Thank you to the audience for your attention and to our sponsors for making the meeting possible. Just a reminder that the slides from today's event are already available on the foundation's website and a recording and transcript will be added early next week. Thanks so much. Enjoy the rest of your day.