

Mary: Good afternoon, everyone. My name's Mary Dwight. I'm the Senior Vice President and Chief Policy and Advocacy Officer of the Cystic Fibrosis Foundation, and I'm also the President of the Alliance for a Stronger FDA. We're so thrilled to have you with us and thank you for joining us, whether you're live with us on today's webinar or listening to the recording.

First, a quick word about the Alliance for a Stronger FDA. We're a multi-stakeholder coalition that advocates for increased appropriation resources for the Food and Drug Administration and educates the public and policy makers about the agency's mission and responsibilities. We're strongly committed to strengthening the resource base needed to advance the FDA's regulatory and public health mission. And as an advocate for the FDA, we've been an important force in doubling the agency's budget authority appropriation from \$1.6 billion to more than \$3.2 billion.

The Alliance is the only advocacy organization focused on resources for both food safety and medical products, as well as the many other components of the FDA's mission. Our members include consumer and patient groups, research advocates, health professional societies, trade groups, and industry. We're about 150 members strong.

For guests at today's event, we welcome new organizations to further strengthen our advocacy and educational efforts and we're glad to have you. Just a few housekeeping notes on procedures for today's conversation. First, as I noted, we are recording this webinar. Also, you may submit questions at any point in the webinar by clicking on the Q&A button at the bottom of your screen.

Our moderator for today's discussion will be my fellow board member and Alliance Vice President, Emily Holubowich, the Vice President of Federal Advocacy for the American Heart Association. She joined the Heart Association in 2019 and has more than 20 years of experience in health and fiscal policy, government relations, strategic communications, and coalition management. She serves as a lecturer in health policy and management at the GW University, was a senior vice president at CRD Associates, the director of government relations for Academy Health, and a senior health policy analyst with the US Government Accountability Office. Emily, the floor is yours.

Emily: Thank you so much, Mary, and thank you all for being with us today. It's my honor to moderate today's discussion about the intricacies of the FDA's budget and the important public health functions the

agency supports. I'm so pleased to introduce my friend and colleague, Steven Grossman, who is going to lead our discussion today. I don't know anyone who knows more about the FDA budget, so you're in for a real treat.

Steven is a policy and regulatory consultant whose experience crosses all areas of FDA and public health issues. As co-founder and Executive Director of the Alliance for Stronger FDA, he is an expert on FDA funding, the agency's mission, and its responsibilities. Prior to becoming a consultant and association executive, Steven spent a decade in public service. He was the health staff director of the Senate Labor and Human Resources Committee, now the Health Education Labor and Pensions Committee, or HELP. Subsequently, he was a Deputy Assistant Secretary of Health at HHS, responsible for policy, planning, and evaluation for the seven public health service agencies.

Steven also serves on the Board of Directors of the National Organization for Rare Disorders or NORD. So, Steven, I now turn it to you.

Steven:

Thank you. One of the things that makes FDA who it is and what it is is the variety of stakeholders, the number of issues it covers, and the variety of funding. I've often observed that including user fees, FDA's budget is about \$6 billion. NIH is about \$42 billion. Yet, FDA funding is probably easily four times as complicated as NIH funding. Simplifying the topic is the rationale for today's presentation.

A bit about the Alliance first. We support a strong and well-funded FDA. The key here is we have both the breadth of membership and the depth. Our members include consumer and patient groups, health profession society, trade groups, and industry. We also represent all the different FDA stakeholders: food safety, medical products, cosmetics, and on and on and on. The FDA regulates about, and we'll come to this in a minute, about 20% of all consumer spending, about \$2.6 trillion out of our national economy. So, it's a big job FDA has been given.

We have about 150 members. We would enjoy having more members. So, please get in touch with us if you're one of our guests and want to consider chatting with us about being members. The Alliance has existed for about 15 years now. FDA in the same period of time has also grown enormously. But it's always important to remember as much as FDA has grown in funding, its responsibilities

have also grown even faster..

This is just an overview of the presentation. The first part, the overview, is really going to address the issue of why does it matter. The next section talks about the five different sources of FDA funding. We'll review each of them. I think that on the one hand, it's pretty clear. On the other hand, I anticipate a number of questions because most presentations don't address some of these different sources – they deal with one or the other. Perhaps, part of the value of this presentation is it shows you the differences and the relationships between the different types of funding.

Finally, we'll conclude by looking at the missions. FDA, for budgetary purposes, does have charts that divide the agency between food safety and medical products. It means some things that we don't think of as food safety are indeed food safety. And it means some things that we don't think of as medical products are probably in medical products. But it is a useful way to look at the way in which the agency is configured and what the funding by mission looks like.

As I mentioned, FDA is everywhere. Every American touches something FDA regulates every day. One of the little-known facts is it's not just the food, it's not just the medical products, or pet foods, cosmetics, or dietary supplements. FDA is also responsible for all radiation-emitting products. So, even your TVs are, in a sense, regulated by FDA through the standards that FDA establishes.

One of the points that is important is that we've enjoyed tremendous congressional and administration support over the last 15 years. It has provided monies that really have been necessary. I don't think there's any question that we've experienced an acceleration of medical progress. I'll get to that a couple of places ahead. It doesn't happen unless FDA makes sure it happens by working with sponsors, by reviewing what comes in.

Also, not to be mistaken, there's potential for a dramatically safer food supply. And FDA is deep into that and has already been the champion of a number of changes. There are plans, literally a blueprint, going forward for making our food supply dramatically better.

I want to dwell on this for a second because one of the questions that gets asked often is: Why FDA? Why does FDA get increases? What is the case for every year coming back and saying, "That was

wonderful. We think we got a lot accomplished. But there's more to do." A lot of it concentrates on this: No other federal agency's mission and responsibilities are more affected by changes in society. By that, I mean advancing science, technology, innovation, and social change. All of them, sooner or later, come back to FDA and to what FDA regulates. It has to be ready to take care of all of it. Certainly, promising science advances and gene therapies are one example. But the number and complexity of sponsor submissions has to be met by more well-trained and qualified FDA staff.

The agency has grown, but so have the submissions that it needs to review in order to fulfill its purpose. The Alliance had Wilson Bryan speak in December. He's the head of the Gene Therapy Program at FDA. He said he has about 300 people on staff and that there's no question they could use more than a hundred new reviewers – just reviewers – in order to meet the workload that's occurring.

FDA is more complex as well. Budget authority comes from the taxpayers. It provides FDA with the broadest and most flexible means of supporting its activities. All of the public health activities are paid for through budget authority, and also, some of the product reviews in drugs and more of the product reviews in biosimilars and devices, etc. The user fees are very important. The Alliance was not created around user fees. The feeling then, and I think still now, was that user fees don't have to have a separate organization to advocate on their behalf. They have an organic process that drives them forward.

When we started, that wasn't true of budget authority appropriations. FDA had been underfunded for a number of years. At the time we came about, FDA had had a number of missteps, recalls in foods, drugs, devices. And we really came out with the recognition that those problems were not problems that were representing anything specifically wrong about FDA. They really were all funding derived; that is the agency did not have the resources it needed. That's how we came about.

FDA also has a unique public health mission. We talk about public health and safety. It's also important to the economy. It's important to the balance of trade. There are commercial aspects of FDA; I mean this in just how much of the economy revolves around food, and how much of the economy revolves around healthcare. In addition, they're a very important part of homeland security. That's through both medical countermeasures and also pandemic response.

As of last year, the appropriation was \$3.241 billion. This is great compared to where they were, but there still is a need for more funds as the responsibilities continue to grow. As we'll go over, it's taxpayer funds, user fees, plus one-time funding, plus a couple of other sources.

With that, FDA is responsible for 100% of all medical products, from bench to bedside, 75% of our nation's food supply, farm to table, and as I mentioned, the role in consumer spending. It's also has a critical role in the pandemic, as I mentioned, and in setting global standards. It's really important that world commerce, to the extent possible, works around standards that the FDA has either promulgated or has had a role in promulgating. That facilitates commerce in a way that isn't much talked about but is really important. And FDA really is part of the commercial picture, the business life of the United States.

The taxpayer funding is \$10 per American per year. For that, you have a high level of confidence in the food you eat and drink, in the cosmetics, in the personal care products, in the therapies that are available in the healthcare system, whether they're drugs, devices, biologics, vaccinations, and, of course, diagnostics. Diagnostics is one that comes to mind as having grown rapidly..

User fees supplement those activities. They pay for specific functions and it's important to note, they're unavailable for general agency activities. Again, user fees are incredibly important, but, at the same time, they're allocated even before they arrive for specific functions. They were never meant to replace budget authority taxpayer funding.

Here's the FY '22 budget cycle, which is a good foundation. You'll notice every number I've used throughout the presentation is based on FY '21, which ended last September 30. The FY '22 funding, which is this year, October 1 through September 30, is on a Continuing Resolution that runs through February 18, which is just about two and a half weeks from now.

How did we get there? The Administration proposed a \$343 million increase in budget authority funding for FDA. That's an increase of a little more than 10%, 11%. Obviously, we're thrilled with that. Administration support is critical to FDA fulfilling its mission and responsibilities. The House came back and proposed a \$257 million increase in budget authority funding. The Senate Appropriations Committee came in at a \$200 million increase. I note all of those are

consistent with our FY '22 ask which was that the agency receives no less than a \$200 million increase.

For FDA, advances in technology and science are behind a lot of FDA's growing needs. d of them.

An example I often use, and this was actually said to me by an FDA employee, he said, "To put blockchain into our plan for safer food supply or for its use in medical field, we need staff who understand and can see the pros and cons in any application of blockchain. Those people are not readily available and their willingness to work for a federal regulatory agency may be limited. But FDA has to have those resources to have those people." Things continue to change that way.

Completion of the FY '22 funding bills. There's still a lack of an agreement on overall spending levels and there are also disputes over the inclusion and exclusion of policy riders that are on the appropriation bill. Right now, the agency works under the Continuing Resolution. The most important thing to know about a Continuing Resolution is the agency gets only the amount of money it received the prior year. So, it doesn't benefit from any of the proposed increases from the Administration and supported by the House and the Senate. There are limits on new program starts. This also, it makes it difficult for the agency to plan its policy program and personnel needs.

The agency is 18,000 people. It's close to a \$6 billion budget. To plan that, to plan it well, to plan it smartly, to make sure federal dollars as well as user fees are well spent is thrown off completely by a Continuing Resolution. The last I heard, they're making progress on this. They hope there will be appropriation bills soon. They're starting to work on extending the Continuing Resolution so they can work it out.

One of the questions that's come up in the last few days is what are the prospects of a shutdown. It's a scary thought, isn't it? I think the answer is there really is no risk of a shutdown. Although, technically, if there's not a new Continuing Resolution or funding bills at the end of February 18, technically, there will be a shutdown. The way I look at it, shutdowns are catastrophically characterized, and none of us are proud of how many there have been of over the years. It's a really bad thing in terms of how government functions and it's costly. It doesn't save any money.

But if you look at the history of shutdowns, they've all been around somebody taking a willful posture, somebody who had the power to stop the process and they dug in. Sometimes that's the House, sometimes it's the Senate, sometimes it's the President, and sometimes it's just a set of individuals within each body. I don't see any of that willfulness existing right now. I believe there's no one involved in this process who thinks a shutdown will be a good thing. At minimum, I feel confident the FY '22 Continuing Resolution will be extended, hopefully not for the whole year, but enough time for them to get to the bills. So, that's CR funding and the '22 cycle.

Okay, now we're into the five streams. As I mentioned, budget authority, \$3.2 billion. It's appropriated annually from the Treasury. It's to be noted that most federal agencies are funded solely through budget authority appropriations, maybe a couple of small fees come into the revenue. So, for most federal agencies, this would be the one slide. Yet, I'm going to talk about four other important sources of funding for the agency. That's the beginning of what makes it important and different.

It's important to look at the budget authority funding. What does it pay for? It pays for the implementation of laws and regulations. It pays for what's in the President's Budget Request in the sense that the things that are in the request may not be mentioned again. But to the extent that the money is not allocated by the appropriations committees or there's nothing in the report language that says don't spend it on this program, it is to be expected that the FDA will spend the money it's been given in rough accordance with what's in the President's Request.

That, of course, excludes the fact that there are often new programs in the President's Request. If those don't get authorized, then they aren't going to be funded through.

What BA can pay for is also found in the enacted appropriations bills' committee and conference reports. Plus, and this is meaningful in the day of COVID-19, the budget authority appropriation pays for any activity required or necessary for FDA to carry out its public health and safety responsibilities. The pandemic has gone two years, so there have been supplemental funding and other things to help pay for the activity. But originally, when those kinds of challenges come in, and they come in all the time, they're not always as deep and long as a pandemic, but they come in all the time. These all-purpose dollars are what pays for everything that is necessary to

maintain the FDA's role in public health.

The second category everyone's familiar with: medical product user fees. They're particularly in the news right now because they are funded in a five-year cycle. This is the year in which the existing user fee agreements expire and they have to be renewed before October 1st.

In fact, because this is going to be relevant in a lot of the discussions soon, as a practical matter, they have to have the legislation at the President's desk or close to it by August 1. The rationale for that is twofold. One, FDA needs to go out with invoices for a lot of these fees. While it can do it prior to the fiscal year for funds that will come in and be used in the new is not yet authorized for that next year.

That, by itself, is a process that disrupts the agency. The other is federal law requires a 60-day layoff notice. A. If user fees were suddenly to disappear, there would need to be large layoffs. When August 1 comes and that notice is given, I think everyone pretty much knows that the user fees will be renewed. It's not so much that as it's bad for morale, bluntly and truly, to get a layoff notice, even if you know it will never be implemented.

Now, there are seven – depending on how you count – there are seven user fees. Over-the-counter drugs are new. Biosimilars were the newest before that. And then generic drugs. Prescription drugs started in '92, generics in 2012, and so on. They're only available for specific purposes that are in the five-year negotiated agreements. That can be broad, but it is still very specific. When FDA uses both BA and user fees to undergo medical product review programs new initiatives, it has to track and audit to ensure that user fee funds are only allocated to permitted purposes.

User fees will be renewed. I don't think there's any question about that. Even though the lingering medical device user fee proposal hasn't come in, it will get resolved. It's too important to FDA and it's too important to industry, and, frankly, it's too important to the American public. But it's important to emphasize that these are supplementary funds. It was never meant to replace BA funding.

Just a simple example would be FDA has a need to do 300 reviews in a certain segment in a year and it really only has staffing for 250. That would be a place where user fees could be part of a solution. There's nothing very complicated about it. It supplements the BA

funding that's coming into those activities.

Tobacco user fees, you'll notice that I've separated it. Most times when you see charts or texts, tobacco user fees are merged with medical product user fees. The annotation is: this is the portion of the agency paid for by user fees. But in fact, tobacco user fees are not at all like any of the medical product user fees.

For one, it's appropriated annually. It's based on a section of law that is permanent, section 919 in the Federal Drug Cosmetic Act. The entire tobacco program is funded by user fees. There's no taxpayer money in that. It's intentional. It's a self-contained regulatory program that is not negotiated with industry. Notice the distinction. A permanent program appropriated annually versus a negotiated program, the medical products, that's in five-year cycles and in which there's a useful, helpful, beneficial negotiation of goals and plans over those five years and how they'll be funded.

When we, at the Alliance, talk about funding requests for FDA, we always talk about BA. We never talk about tobacco for that reason. It's all user fees and not BA. A reason to make this distinction with medical product user fees, which I hope reporters and the Hill, and others are going to start to adopt because it's really important: when people say how much of FDA is paid for by user fees, they really mean the traditional food and drug responsibilities. They don't mean tobacco. With tobacco excluded, because it's not a traditional responsibility, FDA is approximately 60% budget authority, 40% user fees.

That's not distributed evenly throughout the agency, but overall, for traditional responsibilities, it's 60/40. If you include tobacco, which is \$700 million of user fees but then covers more than the traditional responsibilities, then FDA is approximately 52% BA, 48% user fees. People are justified then, or think they're justified then, to call it nearly a 50/50 agency. I hope if people come away with one thing that's important here, it's that BA is still the dominant source for the agency, not for every function, but overall. And that it needs to stay that way. User fees will grow, budget authority, hopefully, will grow, but the idea that budget authority drives the agency as a whole is important. Thinking of it as a 50/50 agency really sends a different message than the reality.

Now, the fourth source of income is 21st Century Cures funding that was set up two years ago. It's on a nine-year cycle. Funds are available for various and specified cures, primarily medical product

development programs. There's a per-year peak that was \$75 million. It declines each year until 2025, when it's \$50 million.

Now, why is it separate? It's separate because it's not budget authority appropriation, and it's not a user fee. It's what's called "savings through changing in mandatory programs". On the Hill, these are called CHIMPS. I don't remember the specifics, whether it was some surcharge on Medicare, whether it was payment rates, whether it was something involved with Social Security, or some other program that's mandatory. You make changes, it generates some savings, and the committees chose to make those changes and in this case used it to fund NIH and FDA activities under 21st Century Cures.

I know it's a fine distinction, but there is a difference between BA and user fees on one hand and savings through changes in mandatory programs on the other hand. It's quite different. Actually, that's recognized by the fact that the appropriations bills, all of FDA BA, and user fees are in one long section. And then a whole new section after that in which Congress appropriates the money from the Cures Act pot of money.

There is a fifth source. One-time, no-year funding that is not counted against annual spending limits. It is usually BA but it has no year limitation. It becomes an important function in terms of generating additional monies for specific things that Congress is involved in. Currently, the agency has \$500 million in COVID-19 emergency activities. But that money will be spent over time according to the way it is generated. In past years, there's been other times when one-time no-year money has been spent.

I'm going to go through this quickly because I know there are questions, and we want to get to them. This is the part where we're doing it by function. We'll be circulating this slide deck afterward. Basically, food safety is paid for by budget authority appropriation. There's a very modest amount that comes in that are called user fees, but they're really certification and inspection fee programs. You can see the way in which it is divided.

If there are questions that are generated by this, we'll circulate them. People can ask questions them later and we'll be happy to answer them. So, that's food safety funding.

The second is medical product funding. That's \$1.7 billion in budget authority and that's \$2 in user fees. And that supports an array of

functions. You can see that every portion of the medical product continuum receives budget authority monies. And also, it contributes to rent and other overhead.

I'm definitely not going to break out this slide. But every time you look at the agency budget, you will see a large amount of money that goes to rental costs and to fix-ups that are required for buildings and facilities. In fact, the overall FDA has seen about 80% or a little bit more of the monies come into FDA are spent on salaries and overhead money, things like training, travel, rental, buildings. Most of it being salaries, obviously. But it makes it different from other agencies.

For instance, NIH, which has all of its own overhead items to take care of, but it's far more a grant-making agency. They have many fewer employees. The last I checked, the cost of running NIH is about 24%-25% of all the money that's appropriated to the agency. That makes sense. That reflects the grants are an overriding purpose of NIH.

Key points here about FDA funding. You have congressional and administration support. This is not a controversial or a partisan issue. More change is coming. That's the point I made earlier. BA funding that is broad and flexible pays for the needs. Everything else, all the other four sources come with restrictions. User fees are important, but they don't support the full range of activities and responsibilities. Across the breadth of this, the Alliance exists with varied membership to support a strong and well-funded FDA. Everybody benefits from that. I think that concludes the presentation. Emily, are you ready for me? Got some questions?

Emily:

I sure am, Steven. Thank you so much for that really comprehensive overview. I've done this a couple of times with you, and I learn something new every time. So, thank you for that. I'll start off with a couple of questions. Before I do that, I just want to remind our audience that you can enter your questions into the Q&A box. We'll be taking those there.

But I did want to pick up on one thing, Steven. I thought you did a really nice job of talking about the shutdown or no shutdown. Will there be a shutdown? Won't there be? We're now five months into the fiscal year; we're 16 days away from when the Continuing Resolution expires. It made me feel better that you agree that a shutdown is probably unlikely. So, in the absence of a shutdown, the question is, I think, if we'll have a Continuing Resolution and if so,

how long will that last.

You talked a lot, I think you did a very nice job comparing the impact of a shutdown on the agency. But I was hoping you could share a little bit more about the impact of a Continuing Resolution on the FDA, and particularly a year-long Continuing Resolution, and what that does in terms of the agency's ability to fulfill its mission.

Steven: Shutdown, there isn't going to be a shutdown.

Emily: CRs.

Steven: Yes. There's not going to be a shutdown. There will be another CR. I think it's probably going to be for a couple of weeks. I think they're going to want to hold out hope that they're going to be able to do the appropriation bills quickly. If there's anybody who is either a guest or for some reason isn't receiving our Friday Update, these are the kind of questions we cover there. One of the things we've written a lot about is: why is there not going to be a full-year Continuing Resolution, which is dreadful because you don't get your increase, you're limited in new starts, and it plays havoc in planning?

So, that's really very undesirable. And FDA would truly miss the \$200 million because I don't know how those responsibilities would be paid for without it. In Friday Update, we've talked a lot about why we are leaning so much into the fact that there will be appropriations bills this year. The most important reason is that the Defense Department and the Pentagon are really badly hit by a Continuing Resolution. Remember, it's not just the total dollars, which obviously matters, but they're also concerned about program starts and new initiatives. So, by far, the most vocal advocate on the Hill for not having a full-year continuation is the Defense Department.

I can't say that anybody cares in that global sense for FDA. But certainly, Defense has people's attention. When you have four-star Generals and staff going to the Hill and saying this is the consequence, I think there'll be bills. I think it will really be two to three weeks, no more, beyond February 18. It's the best crystal ball I've got.

Emily: Great. Thank you, Steven. The next question in the Q&A box is actually one I had for you. Of course, headlines of late of the agency are on the status of the President's nominee for FDA Commissioner,

Dr. Robert Califf. So, we're now a year into the Biden Administration without a permanent Senate-confirmed Commissioner. Can you talk a little bit about what that means for the agency and why it's important to have a confirmed leader? And share more about the Alliance's position on that.

Steven: Thank you. The Alliance's position, let's start with that, is that we're always for the prompt nomination and prompt confirmation of a Commissioner of FDA. It's not candidate-based at all. It's that the agency needs to have permanent leadership. In the interim, where there's been Actings, FDA has been blessed with really well-qualified people. Dr. Woodcock is, obviously, a prime example.

But what it comes down to is no matter how good she is, she's Acting. Most of all, an Acting cannot make commitments for the agency that extends beyond a very narrow window. The agency – whether there's COVID or not, but especially in COVID – the agency needs to have somebody who can make long-term commitments. Do we need to have another 500 people doing X or Y or Z? That needs to be decided and that needs to be somebody who is Senate-confirmed.

So, we've been out there on this a lot, but taking primarily the institutional view of it, which is that this is bad for the agency.

What else did you have – Oh, I was going to talk for a second about Actings because I was just asked about this. Confirmation was first required in 1988. There have been nine Commissioners since then, which means there has been at least 10 breaks in which there was somebody Acting. Remarkably well-qualified people. They've done a good job. Some of them were replaced fairly quickly, and there were some other instances, like this, where it did run a long time.

Here's what's to know: when there have been delays like this one, almost the entirety is a delay between the vacancy and the nomination, not between the nomination and the confirmation. Generally, confirmations take two to four months. Scott Gottlieb and Peggy Hamburg were nominated in March and were sworn in near the end of May. Dr. Califf is still in that window. The long part of not having a Commissioner is the part before the nomination was made. We certainly hope we will have a permanent Commissioner soon and that it won't exceed that two- to four-month window that actually is historically typical.

Emily: That's so helpful, Steven. Thank you so much. We do have a couple

more questions in the Q&A box. The first, and I don't think the Alliance has a position on this, but you may have thoughts, having worked so closely with the agency for so long, on having FDA employees return back to White Oak in-person versus enabling fully work-from-home options. Any thoughts there?

Steven: I know a lot of FDA time is being devoted to what the work-from-home policy should be. My personal view is that we're never going to go back to the way it was. I don't have any problem with that. What the right mix is, there'll be people who'll want to work five days a week in the office, or more than five days. There'll be people who don't have any particular use to be in the office. What can we do to accommodate them?

The myth that people can't be productive from home is gone. And FDA has run its efforts against a pandemic, basically, from home. I think decisions are coming. I don't have any insight into them. They're very difficult. And I don't think there's any part of society that has office buildings that isn't torn as to exactly where the right line is.

Emily: Indeed. I know all of our organizations are probably grappling with that question. I imagine in the long-term that may have implications for their budget, particularly around their facilities and rent, as you were talking about.

Another question in the Q&A is a great observation. The FDA budget is one of the few in the federal government that has grown consistently over the past 10 years or so. I think we in the Alliance would like to take some credit for that. What do the American people need to know to justify the compelling need to continue increases in that budget for that next fiscal year? I guess related, a question for me is kind of what do you see as the top budget needs for the agency to continue to modernize and continue to be able to develop for the American public?

Steven: That's two questions.

Emily: I know. I added on the extra one at the end.

Steven: The elevator version. Right now, it's \$10 per taxpayer per year. It's that the FDA and the products it regulates touch every American multiple times each day. No one wants innovation and science to slow down. I keep emphasizing that that's as much an issue and opportunity on the food safety side as medical products. I could talk

for hours, as many people know. It really comes down to the fact that the cost is extremely reasonable, the benefit is large, and we value safety. If you go back and read history, safety for these kinds of products has never been delivered through an unregulated market. I'm sorry, the second question was?

Emily: Related to the compelling case for continuing increases, what is your thoughts on urgent or emerging needs of the agency that would require funding going forward.

Steven: That's great. There's a couple of items. The key item, the centerpiece of the Administration's request for FY '22 revolved around data and technology modernization. FDA is working with a lot of legacy systems. We had a meeting with one Center director, and he said we have 30 different data systems, none of which talk to each other. The next week, we visit with another Center director, also 30 systems, but they're not the same 30 systems. So, we're talking about 60 systems. So, this is a priority.

The Congress has been skeptical about a lot of data modernization and upgrade projects. A lot of them haven't gone very well. In this case, it has to go well. It has to be a place where data can be turned into information and insights. Right now, there's a piece here, there's a piece there. We're never going to be better, we're never going to be more efficient, as well as more effective without them. That's a centerpiece.

I think everyone's aware of cell and gene therapy. The agency plotted out the money it needed based on certain assumptions about growth in the field. Instead, it's been multiple times quicker to goals. Right now, I think the last number I saw is there are 1200 INDs in cell and gene therapy currently. That's a lot of projects to monitor. It's a lot of projects to be responsible for. And it's cutting-edge science. It's not like they're making aspirins. If we had 1200 aspirin manufacturers, so what? Every one of these is unique because they're dealing with the unique cell and gene therapy problem.

On the food safety side, I think what's needed is for there to be broader buy-in to the vision that food safety is not static and particularly not static relative to technology. Whole genome sequencing, which I couldn't even explain to you, has become critical in food safety. We're going to go down to the genomic level in order to protect food safety. That's my answer.

Emily: That's great, Steven. I will just say the dirty little secret of public

health all along has just been how antiquated our data collection systems are, often using 20th century or sometimes even 19th century data collection methods. I think this is a theme, particularly after the pandemic, when everyone is asking: why don't we have the data we need, when we need it, on the people we need it for. This is why. To your point, I think it requires continuous investment. This is not a one-and-done. It's expensive. It takes time to build. And you have to maintain. That's a really great point.

We probably have one last question. I know you have thoughts on this, Steven. I think it speaks to clarify where the Alliance takes positions and where we don't. But it's around 21st Century Cures and do we have an official position, which I know you'll be able to answer. But then also, maybe thoughts you have about 21st Century Cures as it relates to FDA.

Steven:

I'm assuming we're talking about 2.0, the one that's in front of Congress. The Alliance from the very beginning has been very clear that we have 150 organizations who couldn't be more diverse. Maybe our best selling point is when we walk into a congressional office, and we have a consumer group and industry group, and they sit there jointly arguing for more money for a federal regulatory agency. It's rare that any congressional staffer has ever seen that before. So, we need to preserve that. With 150 members – and I encourage others to join who are listening to this presentation – we need to stick with what they all agree upon.

Once we get into policy, there is a potential, and often is, disagreement. What we have every segment committed to is a strong and well-funded FDA. So, we're very careful to stick with the money and not, for the most part, other items. If we get involved in authorizing issues, which at the moment we haven't, it would only be because it connects in some fairly direct way with the appropriations process. There are provisions that deal with that that come through the authorizing side.

Now, Cures as a policy issue. we've not taken a position on it because it's authorizing policy. It's outside our mission. It's not that we're for or against it. I think the public health community, for the most part, and the patient advocacy community have been fairly clear about their own positions. . I'd add, as well, there's probably no particular reason for us to wander away from the mission of which we all agree.

With regard to the legislation, I think one of the parts that isn't being

considered is: is there going to be a user fee bill with a lot of extra titles? If so, what part of Murry-Burr, what part of Cures 2.0, what part of Congresswoman Eshoo's policy positions are going to be incorporated in that? In years past, there's like three titles of the legislation that are about user fees and there are about eight or nine titles of all these other things.

So, I think that's what's going to happen with one caveat, which is there's an argument, I'm not making it one way or another, but there's certainly an argument that they want to address the Murry-Burr issues that relate to COVID-19 and the pandemic. They may not want to wait until June to address those and possibly August before they become law. The assumption is that everything gets rolled into one bill. . In the end, you have some things that may be more urgent and then also I have heard it reported that the committees are trying to keep the user fee bills slimmer. Good luck with that.

Emily:

Good luck with that. Yeah, especially it may be the only train moving on a number of things. Well said, Steven. Thank you so much again for this incredibly thoughtful presentation. Thank you to our participants, to our President, Mary, and the entire Alliance team for pulling together today's event. As a reminder, we'll be sure to share the slides, which are an incredible resource, as we are wrapping up FY '22 and coming into FY'23. And I thank you again, all, today for joining us. We hope to see you soon.

If you're not yet a member, please consider joining. It's a wonderful group. Thank you all.

[End of Audio]