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A CONVERSATION WITH FDA COMMISSIONER SCOTT GOTTLIEB ON HIS TENURE AND POLICY REFORMS

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Introduction:

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Keynote:

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P R O C E E D I N G S

MR. WESSEL: Good afternoon. I'm David Wessel. I'm director of the Hutchins Center on Fiscal and Monetary Policy here at Brookings. And on behalf of our center and the -- I have to look at it -- USC-Brookings Schaeffer Initiative for Health Policy, a name not chosen for brevity, I want to welcome everybody here, and particularly welcome Scott Gottlieb and Anna Edney.

Scott's biography is so long that I had to write it down. It's hard to believe he's only 46 years old because he has done the following things: he's been a financial analyst, a practicing physician, a think tank fellow, a venture capitalist, a drug company consultant and director. He's done three separate stints at the FDA, first as an assistant to Mark McClellan, then as deputy commissioner for medical and scientific affairs. And of course, since 2017, he's been the commissioner. And as most people are aware, he's also a cancer survivor and sometime along the way he managed to have three kids, but he did it very efficiently because two of them are twins. (Laughter)

I think the most --

COMMISSIONER GOTTLIEB: My wife did it efficiently. (Laughter)

MR. WESSEL: Let's talk about that later. I think the thing that's most intrigued me about Scott Gottlieb's tenure at the FDA is I was looking at what people said when he was appointed. One of the milder comments was that he's a shill for pharmaceutical corporations for much of his career. And I think he's impressed everybody, even people who don't agree with him, with the integrity that he has shown as FDA commissioner, his ability to manage a large bureaucracy, and the fact that he's gotten so much done in such a short time. Although as Scott was telling me, "short time" is relative. He's in the top 20 -- he's served longer in a Trump administration Senate-confirmed position than any except for the 20 top people or something. I probably got that wrong, but you get the point.

COMMISSIONER GOTTLIEB: It's your quote, not mine.

MR. WESSEL: The entire Cabinet has turned over and he was still at FDA. So we are really glad to have him here.

And as he leaves Scott has shown another thing, which is that you can be a good regulator and be very active on social media. So I expect that Scott will be live Tweeting his own remarks for the next hour in case you don't feel like listening. (Laughter) He only has 40,000 followers, so I hope that we can help build your audience with this thing.

I really appreciate Anna Edney coming on short notice to interview Scott. Anna's been nine years at Bloomberg and before that she was at *National Journal* and *FDA Week*. She's been writing about health policy and FDA for all that time, so we're particularly lucky to have her.

Anna's going to interview Scott for 35, 40 minutes or so, and then we'll be happy to take your questions.

So with that, Anna, the floor is yours.

MS. EDNEY: All right, thank you. Dr. Gottlieb, good to see you.

COMMISSIONER GOTTLIEB: Good morning or afternoon.

MS. EDNEY: So obviously I think the one place I wanted to start out is tobacco is on a lot of people's minds as you're leaving, particularly, and it's a pretty hot topic. So one of the questions I had actually is HHS Secretary Azar sat down in front of senators last week and was asked some pointed questions on particularly nicotine and menthol in e-cigarettes. So on nicotine he said absolutely he's committed to reducing nicotine levels in cigarettes to non-addictive levels.

When do you think we'll actually see a proposed rule on that? It's been a while since you talked about it.

COMMISSIONER GOTTLIEB: Yeah. So we issued the Advance Notice of Proposed Rulemaking probably almost a year ago. I think we put that out in March of 2018; solicited comments. And we've been going through, drafting the NPRM. I would expect that the Notice of Proposed Rulemaking would be out sometime later this summer. And when I

say “out,” out of the agency to HHS. That’s the timeframe we have right now.

And again, this was the -- this would be the proposed rule to regulate nicotine levels using a product standard to minimally and non-addictive levels. And the idea here was to try to transition smokers more rapidly off of combustible tobacco products.

MS. EDNEY: And when you say “out” of FDA, you’re saying to HHS to review?

COMMISSIONER GOTTLIEB: To HHS. You know, this is a big rule, so I think it’s going to go through careful review by both HHS as well as OMB and OIRA. The tobacco rules historically, if you look even in -- going back to the Obama administration, have undergone long reviews typically. And even the rule that we have, we have a rule right now, it’s in ROCIS, people are aware of this, the SC Rule that’s been undergoing careful review, as well. We hope to have that out very soon, also. But, you know, this is a longer rulemaking process, but this should be out of FDA, right now the timetable that we’re looking at is sometime late this summer.

MS. EDNEY: Would you think within a year, like a year from now we might see an actual final product on nicotine levels in cigarettes?

COMMISSIONER GOTTLIEB: Yeah. So it would be a Notice of Proposed Rulemaking, so if you get the Notice of Proposed Rulemaking out of FDA late this summer, building in some time for that to slip. The last time we were committed to get the ANPRM out in January, I think we got it out in March instead, so it slipped three months. And so you have to allow some time buffer in these. You know, if you get that to the department and OMB it’s hard to predict how long it would be under review, but that would just be an NPRM, so it’d be out for probably a 90-day comment period and we would have to solicit comments and then look to finalize the rule. So it’s a long rulemaking process.

You know, the average rule from proposed to final is two to three years if you look historically just at the average FDA rule. And when you look at more complex rules that are highly novel, it’s a little bit longer than that. The rulemaking process is long for a

reason. We build very good administrative records.

We've been sued on the deeming rulemaking, the reg, and it's been sustained in court I think a number of times now because FDA develops very careful administrative records around its rulemaking process.

MS. EDNEY: One of the other things that the Secretary told senators was there are complex legal issues around banning menthol in cigarettes. You sounded a little less sure that that was something that was going to move forward, at least easily. Can you explain what some of those legal issues are?

COMMISSIONER GOTTLIEB: Well, I don't want to prejudge the rulemaking process and some of the questions that would come up in that process and some of the questions that we would ask for comment on. What I would say is that we're committed to removing characterizing flavors from combustible tobacco. If you saw the draft guidance that we put out last week, that sought to ban characterizing flavors, including menthol, in non-grandfathered cigars. So cigarillos, which we know there's a lot of youth use, in fact, cigars is the fastest-growing category of tobacco use among African-American teens. So we don't believe characterizing flavors, including menthol, should be in tobacco products. It's a vehicle to attract youth to tobacco products historically. And you do see overuse of flavored tobacco products by youth. So that's the long-term goal of the agency, whether it's menthol or other characterizing flavors.

We're also going through a rulemaking process to try to seek to ban the flavors in the non-grandfathered cigars. And so that's also moving through the agency.

MS. EDNEY: Are you confident that menthol will be banned in cigarettes?

COMMISSIONER GOTTLIEB: Well, I think the long-term trajectory is to remove characterizing flavors in combustible tobacco for public health reasons. And I think that there's a building consensus around that. If you saw the issue of menthol in particular, but characterizing flavors more broadly, and you look at this issue five years ago, there was more of a split opinion around that. I think the overwhelming consensus both politically and

from a public health standpoint certainly is that there's no role for flavors in combustible tobacco.

And look, Congress in the Tobacco Control Act affirmatively banned characterizing flavors in cigarettes. It was cigars where they didn't' take the action because those weren't regulated products at the time. They were newly deemed products. And menthol, they didn't codify menthol in cigarettes, but they deferred the action to FDA to take the decision through a process that they defined in statute.

MS. EDNEY: The other tobacco issue obviously that's been a big deal is youth vaping. And you just took some action in that area to restrict sales. I wonder when you look back on what you've done on tobacco, do you think if you hadn't moved the date for the PMTA reviews for e-cigarettes that youth vaping may not have gone up as much as it did?

COMMISSIONER GOTTLIEB: I think it's hard to draw a direct line between us deferring -- so we implemented the deeming rule. And all the provisions of the deeming rule were put into effect, so the manufacturing inspections, the labeling requirements. What we deferred were the application deadlines.

I think it's hard to draw a direct line between -- I think it's very hard -- between us deferring the application deadlines and what ultimately occurred six months later. You know, the epidemic was clearly getting underway at the time that we made that decision. We were unaware of it. We didn't have the 2018 National Youth Tobacco Survey.

We started to see the anecdotal reports of a Juul epidemic early in 2018, in January 2018. If you look at the press you started to see those reports, but it really wasn't until we saw the data from the National Youth Tobacco Survey in August of 2018. It first was revealed to me August 31, 2018, when my Senate director came to me with that data that we had sense of what was underway. Within two weeks, I was giving the speech in September calling it an epidemic, alluding to the data, I couldn't release it at that time, demanding action from the manufacturers. And then we followed that up in November with

an announcement of what we would do.

In hindsight, getting to probably your next question, if we had known what was going to ensure in 2018 when we made the decision in 2017 to put forward that comprehensive vision, would we have done the same thing? Absolutely not. But we didn't have access to that data. Once we did, we pivoted very quickly.

I don't think the decision stoked that fire. I would have liked to have known that that was underway at the time that we did it. But remember, the vision that we put forward was to regulate -- to use the Tobacco Control Act and the product standard to regulate nicotine in combustible cigarettes to render them minimally non-addictive. And, at the same time, we recognized that there were other opportunities for currently addicted adult smokers who still wanted to get access to satisfy levels of nicotine to do it through vehicles that didn't have all the risks associated with them as combusting tobacco, with medicinal nicotine products being least risky.

And we've opened up new pathways to get medicinal nicotine products onto the market. We've issued guidance to try to open up those opportunities. And the Electronic Nicotine Delivery System, the ENDS products, which include e-cigarettes representing something in the middle of that continuum. Not safe, but less dangerous than combusting tobacco.

So the way we saw it was at the very time that we're seeking to regulate nicotine in combustible cigarettes, we can't foreclose the opportunity to potentially use new technology to allow currently addicted adult smokers who want to inhale nicotine to get it through vehicles that are less risky. That was the vision.

I think the vision still holds. We still believe that e-cigarettes could be a useful tool for currently addicted adult smokers, but it can't come at the expense of all this youth use. And where it's predominantly happening is with the cartridge-based and the pod-based systems. And depending on what we see in the 2019 National Youth Tobacco Survey, and I've said this very clearly, we could be in a position where we have to take

action not against just the flavored products, but an entire category of products. And, in fact, we're currently in the process of looking at developing a guidance document that would define clearly what a pod-based and cartridge-based system is in case we have to take action against that category.

MS. EDNEY: Do you have the political support to move forward on the sales restrictions and anything further should the need arise?

COMMISSIONER GOTTLIEB: I think there's broad -- well, the Secretary's extremely supportive. I think there's broad political support across the administration. If you saw the announcement we made last week, we made the announcement, the Secretary put out a very supportive statement. He's been extremely supportive of this. You had a factsheet put out by the White House that affirmed what we were doing. You had the deputy press secretary re-Tweet the message. You had Kellyanne Conway this weekend re-Tweet my tutorial from Sunday talking about the action. You had a statement from the President's Chief of Staff and the head of the Domestic Policy Council affirming that we were going to take action to address youth use, that it wasn't going to be tolerated and there would be additional tobacco regulations.

So I don't know what you could ask for for a more affirmative statement from the administration across the board than what you saw, you know, roll out in the last week. I mean, from sort of the top down you had affirmative statements from the administration. And in my press roll-out material you had very clear statements saying that the White House supported the policy and the President was mentioned, as well. And obviously, when you're building that into your press material, you've gotten clearance from the highest levels.

MS. EDNEY: One question, one more, on tobacco. You mentioned Juul and Altria took a stake in them and you seemed pretty concerned about that and said you were going to call them into your office to talk. Will that happen before you go?

COMMISSIONER GOTTLIEB: Well, it happened. It happened last week. You know, this was because -- when Altria -- when we asked the companies to submit

voluntary plans for how they proposed to address this crisis, we gave them 60 days to submit plans before we announced what we were going to do in November. And then we ultimately followed that up by implementing that plan last week. And I think we went further than what we had announced in November by moving in the dates, the application deadline dates, by a year for 2021.

I was concerned that at the time that Altria had talked about the fact that in their view, and they sent me, I don't know, a 15-page, 16-page letter saying that they felt that the youth addiction crisis was being driven by the pod-based systems in particular and especially the flavored products. And they said -- they agreed to withdraw their pod-based products from the market at that time voluntarily and said that they wouldn't put flavored products on the market other than menthol in tobacco until they either have an authorized PMTA by the FDA or otherwise have evidence that the youth addiction crisis has abated.

So, you know, I asked them very plainly, do they believe the youth addiction crisis has abated? And I forget the exact language that they used in the letter, but that's the essence of what they said.

So it concerned me that a company that affirmed what we believe, which is that the pod-based flavored products are driving the youth use, and went so far as to take their product off the market and publicly make that statement, at the time I put out a supportive message about that. We acknowledge that they were taking that voluntary action. Then made a substantial investment that -- and also guaranteed that they were going to expand the market share of the leading pod-based flavored products that's being used by children. So there seemed to be a disconnect there and I wanted to understand whether they had new data that was driving that decision.

MS. EDNEY: Did they have new data? How did the meeting go?

COMMISSIONER GOTTLIEB: Not that they brought to me. Look, I think it was a difficult meeting as far as meetings have gone. I have had probably in my time at FDA certainly less than 10 meetings with manufacturers. And I can't remember a meeting

that I had with a single manufacturer that wasn't with a tobacco company. If you remember when we announced the plan, we very publicly said we were going to meet with the manufacturers of tobacco products to give them a chance to come in to the agency and present their view. And in part we met with the individual companies because they don't have a trade association, but we felt it was important to give them a chance to present their views after we announced that comprehensive plan in the summer of 2017.

So, you know, we've heard from them a number of times now and I think I continue to have concerns that some of the activities that they're taking in the market are not necessarily consistent with what they're telling us, but certainly not consistent with what we think the broader public health objectives should be and also what I view as the existential threat to this category, which is I'm having debates about whether or not flavored products should be sold in convenience stores. And I think the real debate is whether or not any of these products should be sold in convenience stores.

I think we're sort of losing the forest through the trees and not understanding what the real risk is here. And the risk is a category risk. And I don't want to see it come down to that because, again, I do believe that there's a role for these products for currently addicted adult smokers. We do see evidence now that adult smokers are transitioning. At least you see dual use certainly, but you see adults fully transitioning to these products. But it cannot come at the expense of the growth in youth use that we're seeing.

MS. EDNEY: What was the outcome then of the meeting? I mean, will you talk again? Are they supposed to present you with more data?

COMMISSIONER GOTTLIEB: No, I don't think that there was a specific outcome. You know, the objective was to try to understand their decision-making from a public health standpoint and whether anything has changed in their view. And I didn't hear anything from that discussion that leads me to believe that they've seen something different in the market and that there was anything from a public health standpoint driving their

decision, so I assume it's just a business decision that they made to withdraw a product that wasn't -- didn't have good market penetration and then to go make an investment in a similar product that did have good market penetration. But I don't know exactly what their decisions were, but it certainly wasn't guided by anything that I heard related to any data or any kind of public health conclusion.

MS. EDNEY: Does that change how you look going forward at the category? You kind of hinted at that, I think.

COMMISSIONER GOTTLIEB: No, I don't think that in particular changes who we look at the category. Again, if the 2019 National Youth Tobacco Survey, which we're in the field doing right now, we're doing it between March and May, so we're currently conducting it -- I got the results of the 2018 survey on August 30th or 31st. That was early. I suspect that FDA will get the results earlier this year because they'll be looking at that data. They'll accrue that data first, so I figure sometime in the July/August timeframe, early August, late July.

I think if you see an increase in the youth use, high school use, of 20, 30, 40 percent, I don't know what the exact number is, I think the action at FDA is going to have to very carefully contemplate its action against a category of pod-based products. And maybe it's just the flavored pod-based products or maybe it's the entire category, where you take them off the market and require them to have authorized PMTA applications before they can come back on the market.

Because at some point, regardless of your view on whether or not these products could help currently addicted adult smokers transition off of cigarettes, the youth use is so widespread, so rampant that whatever redeeming public health value these tools could potentially have, and they haven't demonstrated that yet, it's offset by the youth use. And remember, the statute requires FDA to overweight tobacco use among kids. It explicitly says when you're looking at making a judgment about the public health utility of a tobacco product that could potentially be a modified risk product, you have to overweigh youth

initiation as a component of how you assess the overall potential benefits for that product being on the market.

So we explicitly have to look at the youth use and it doesn't take a lot of complicated math to overweight this youth use. It's pretty rampant. We'll be at levels -- if you see e-cigarette use go up 40 percent next year, which isn't out of the question, and you will see cigarette use among kids go up because at that level of e-cigarette use you're going to start to see cigarette use start to creep back up.

And, in fact, we saw that last year it went from 7.8 to 8.1 percent. It wasn't statistically significant, but you'll see tobacco use across the board go back up. You're going to be at levels of overall tobacco use among children in this country of 40, 45 percent. That's simply intolerable. I went back and looked at data going back to 1950 and we haven't seen that level of tobacco use among kids.

And e-cigarettes are a tobacco product and nicotine is addictive and nicotine does have direct effects on the developing brain of a child. And we do know, now we have evidence, that some proportion of these kids who are now newly addicted to nicotine are now going to migrate on to combustible tobacco products. So all the dramatic gains that we've made in reducing smoking rates in this country, particularly among young people, will be reversed as a result of these products.

So I wanted to switch gears and talk about, you know, you faced some difficult situations as Commissioner. One of those most recently probably was the shutdown. How is the agency bouncing back? Is there anything that's still kind of -- I don't know if "backed up" is the right word or that you're still kind of digging out of from the shutdown?

COMMISSIONER GOTTLIEB: Well, this I think, in my view, this was the biggest operational challenge we've faced in sort of modern times in my observance of the agency over the last two or three decades. I mean, we've faced operational challenges, but they were in a discrete area of activity. This was across the board.

I think the agency has recovered from the shutdown very admirably and very effectively. You know, the long-term impacts -- we haven't seen immediate impacts on hiring. We haven't seen an immediate increase in departures. I think the long-term impacts are going to be judged by what impact it does to the perception of government service overall. The people who might have stayed on for another couple of years or might not have retired, make a decision to retire on the margins. That's going to harder to measure. That's going to take some time to figure out. You're going to have to look back at data going back -- you know, when you look out over six months or so, we haven't seen that impact yet.

I think certainly the budget being passed and the budget being a very good budget for FDA, we had substantial increases in budget authority, maybe the biggest increase in budget authority in sort of modern times for the agency that wasn't tied to any specific new initiative. So that, I think, helped. We're going to be able to hit most, if not all, of our user fee targets for the year.

I think the place where we're going to see some slippage is in the overall inspection numbers for the year. They'll be down, you know, an amount that's not fully commensurate with the period of which we were shut down because we were able to get a lot of the inspections back up. But they'll be down some portion, so you'll have, you know, a two- or three-week decline in inspections. So whether it's between 5 and 10 percent down from where we would have been, it's probably the case that inspections would have been up overall this year. And so you're going to come down from a number that would have been up, so it's not going to look like a big drop. But that will be one place where you see some impact because you just physically can't make up for that lost time.

MS. EDNEY: And that's across the board. This is food and drug inspections?

COMMISSIONER GOTTLIEB: Well, we got the high-risk inspections back up, so it's some of the routine inspections where we would be down, that didn't go on. It's routine inspections that aren't covered by user fees. So the generic drug inspections are

paid for by user fees, those continue. So it'd be routine drug and device inspections that wouldn't have been covered by user fees.

And it wouldn't have been a big period of time because, remember, this was over Christmas. And so we wouldn't have been doing inspections the week of Christmas and we probably wouldn't have been doing them between Christmas and New Year's and we wouldn't have been doing them the week after because they take some time to schedule. So that would typically be a slow period of time for the agency anyway, so the impact was mitigated by that. So you're really looking at three weeks where things weren't full tilt.

MS. EDNEY: And obviously, inspections is a topic I've written a lot about.

COMMISSIONER GOTTLIEB: Really? I haven't seen that. (Laughter)

MS. EDNEY: One thing I wanted to ask you about specifically is valsartan, the ARB's recall that's been still going on. There's been a lot of focus, particularly even just in the last few days with the Boeing crashes, on the government relying on the industry heavily for kind of a self-policing role. And in drug manufacturing that happens, as well. And with valsartan, the Chinese company that started this recall, they were inspected in 2017 and found that they were -- they found impurities in their products, but they weren't figuring out what those impurities were. Come to find out, you know, down the line that some of their products do have carcinogens or possible carcinogens in them.

COMMISSIONER GOTTLIEB: Right.

MS. EDNEY: Do you think the FDA relies too heavily on the industry to tell them what's going on?

COMMISSIONER GOTTLIEB: Well, I don't think that's an accurate conclusion from valsartan in particular. I think that to sort of trap that narrative and thesis you'd have to look at other examples.

We're going to be promulgating the first real modernization of our GMP regs in very long time, looking specifically at the requirements that we put on API manufacturers because that's where the vulnerabilities have been, not just with respect to potential risks,

but also with shortages. We've seen shortages precipitated by problems with API manufacturers.

With the valsartan situation in particular, we, over the last couple of years, have grown up an Office of Pharmaceutical Quality with a lot of organic chemists. We have dozens and dozens of organic chemists who basically review manufacturing changes to look for manufacturing changes that could create steps where impurities get introduced through changes in organic chemistry.

And that, in fact, looks like what happened here. There was a change in the manufacturing process. It was published, it was patented and published. A lot of the manufacturers of the ARBs adopted this simultaneously, not all of them. And in that change in the manufacturing process you were literally trying to close a ring, so if you go back to organic chemistry, using certain solvents and, in doing that, this impurity was being created. And it was at very low levels, so it was hard to detect. But for some of the manufacturers, and this is a theory, who washed the API over and over again with the same solvent, the impurity built up over time.

And so it's a long way of saying that if you didn't know to look for this, this would have been very hard to detect. And certainly the impurities that were found during that inspection were not relate to the ultimate impurities that causes this, which was -- this is tragic and it's deeply concerning that people were exposed to this. It shouldn't have happened.

But the way to fully police this, because when you don't know what you're looking for, which is what happened here, nobody knew that this specific process change could produce this specific byproduct until it actually happened, you know, the only way to mitigate that is to do what we're doing. And this is why we've done it, which is to employ people who have expertise in looking at chemical reactions in organic chemistry and being able to impute how changes in chemical reactions can introduce certain risks.

That's why we've built out the Office of Pharmaceutical Quality, made a

conscious decision to employ organic chemists in this way. What we're going to do with the GMP regs is a number of things, but it's going to impose more requirements on manufacturers for reporting process changes, so we have full information in advance of when these things are put into place, so we could do that proper evaluation.

I don't think this was a case where we didn't know that the process change was made. It was patented, it was published. I think this is a case where we didn't know that this particular impurity could be introduced from the change that had been made.

MS. EDNEY: Could the FDA have done anything better on the ARB recall?

COMMISSIONER GOTTLIEB: In the ARB recall? You know, I think after it was detected, I think the world regulatory agencies -- I mean, we collaborated very closely with world regulators, worked very quickly to test other products within the class. FDA worked very quickly to develop a standardized test for detecting the impurity; they made it available.

So I think that the direct response was admirable and efficient. But you're going to see rolling recalls as you -- and you've seen it. I don't know if we're fully the way through it. We're probably through most of it as there's additional testing of additional products and additional lots and you find some that had this impurity introduced into it.

I mean, I think it's important -- and isn't to dismiss the risk -- the absolute risk here is exceedingly low. I mean, this is an impurity that's found naturally in other food products. And you would have had to be taking maximal doses of the contaminated products over the maximal period of time to really have any kind of measurable risk.

And I forget -- you remember the math that we published probably better than I do, but it was a pretty low incidence of, you know, what was your absolute risk of cancer if you had been exposed, fully exposed to this. And it was very low and that's not to dismiss it. But it's important to put that in perspective for patients who have concerns around these products.

MS. EDNEY: Another abbreviation that I guess is completely different,

CBD. I know that's something that you've been working on that probably won't be done before you leave, or will it? Is there something there?

COMMISSIONER GOTTLIEB: No, I mean, I don't think that'll be done before the next guy leaves, too, but setting that aside, because this is a long process. I mean, the issue for us is the Farm Bill was passed, hemp's now legalized. Farmers who grow hemp want to be able to put CBD -- extract CBD and sell it as a commodity, CBD oil.

And food producers, packed food companies, legitimate food companies want to look at putting CBD into the food supply. But because CBD didn't previously exist in the food supply, and it exists as a drug -- under the statute it's either a drug or subject to substantial clinical experimentation, I think that's the statutory language, the term of art; I might be a little bit off there -- it can't just be put into the food supply. The only circumstances in which it could is if it previously existed in the food supply.

So the law only allows for FDA to contemplate putting a drug that wasn't previously in the food supply into the food supply if it goes through a rulemaking process. We've never done this before. It would be a highly novel rulemaking process. I just told you that a normal rule takes two to three years. That's common rules. When you think of a more complex rule like this, where we haven't done it before, would take longer.

And so one of the things we're going to do is we're putting together a work group right now. We're going to announce it probably within a week. We're going to have a public meeting around this issue to solicit public comment. But I think what the work group's going to be charged with doing, and it's going to be a high-level work group co-chaired by the Principal Deputy Commissioner Amy Abernethy and Lowell Schiller, who's the associate commissioner of policy.

What the work group's going to look to do is also look to what some potential legislative pathways might be to create a framework for allowing CBD into the food supply. We think Congress, some in Congress, intended for that with the Farm Bill. There is precedent for Congress legislating on a one-off basis around specific substances. I believe

they did it with human growth hormone, but there's other precedent. There's precedent for drugs that are sold as pharmaceuticals also existing as products that are put in food and dietary supplements. You think of fish oil, for example.

I think you need to come up with a framework that defines concentration levels where you would create some kind of cutoff and that would be up to the agency to do. Congress would obviously give direction to the agency to do that because CBD in high concentrations isn't risk-free. In low concentrations it probably is safe. I don't want to make a declaration here. It's also questionable whether it's providing any kind of therapeutic benefit in those concentrations, although, you know, people seem to believe that it has some value.

But this is a process that the agency would have to work through. I think the most efficient way to get to a pathway would be through legislation. Probably that would just be legislation that would specifically address CBD.

MS. EDNEY: Do you know when the working group would want to try to get that proposal to Congress?

COMMISSIONER GOTTLIEB: Oh, I don't want to prejudge the outcome of that, but we're getting started right now. We've been briefing staff on the Hill around this. So what I said just now, we've briefed staff on our thinking here.

Every meeting I go into on Capitol Hill, almost every meeting, I get asked about this. So I think that we would work through an efficient process and probably have some recommendations certainly this summer.

I think there's also a question of DEA hasn't formally de-scheduled CBD derived from hemp. I think the view is, the prevailing view is, that the plain language of the statute intended for that, but I'm not sure DEA has done that yet. They might have, I just haven't been tracking it that closely. But that's another step that would have to take place. DEA would have to formally de-schedule CBD derived from hemp.

Then there's also, of course, the question of how you differentiate between

CBD derived from hemp versus CBD derived from marijuana. And that's a whole separate question.

MS. EDNEY: What other unfinished business are you leaving behind that you think, you know, are the most critical things that you want to see get done?

COMMISSIONER GOTTLIEB: Well, the things I wanted to see through that I won't be around to see through is some of the legislative initiatives that we worked on. So OTC reform and the IBCT build that would have sort of fashioned a modern framework for the regulation of diagnostics. Those are on a longer time horizon; clearly not going to happen within my timeframe. You know, I'm hopeful that they will happen within the next 12 months and won't sit out there waiting for another PDUFA cycle to get put onto a PDUFA bill.

OTC in particular I think is ready. And I think it would be a very productive modernization of the pathway for getting OTC pharmaceuticals to the market and open up a lot of innovation on products that can be sold over the counter and open up new categories of products. Not just different formulations of products that could be more convenient, potentially lower cost for consumers, but new categories of products, as well.

MS. EDNEY: What about biosimilars? You've obviously talked about the market not taking off the way that the U.S. would have wanted. One of the things actually that Azar talked about last week with senators was he's very concerned about evergreening and the patent that gets. What do you think could be -- can the FDA do anything there or what should the government be looking at?

COMMISSIONER GOTTLIEB: I think that, you know, I would point first and foremost at some of the commercial obstacles of biosimilars and the fact that the incumbent biologics have large royalties associated with them. And the manufacturers are smart, they amp up the royalties on the eve of sort of biosimilar entry. And if you're a health plan and you adopt the biosimilar onto your formulary, you lose all the rebates. And so to offset the lost rebates, you have to be able to move enough market share to the biosimilar to take

advantage of the discount that the biosimilars entering the market at to offset that lost revenue from the rebates. And that's hard to do in this market because the plans seem to have a difficult time converting physicians and patients over to the biosimilars.

And it's not just a question of interchangeability and automatic substitutability. It's a question of some physician resistance right now, particularly for biosimilars that are being used in curative therapy. I think as the market developers, as doctors gain more acceptance and comfort with biosimilars, as more biosimilars are developed against chronic therapy biologics where I think there'll be more clinical comfort in converting patients over to them, I think this market's going to evolve and be very robust.

It's been slow to develop, but it's not -- it hasn't surprised me that it's been slow to develop. You know, I think some of the early expectations, if you look back at the debate around biosimilars and you were around for this in 2003 and 2005, I think people were a little bit bold in terms of the predictions that they made and how much the biosimilars would penetrate the market once you had a viable pathway. If you look back at the early days of Hatch-Waxman, you know, it was slow for generic drugs to penetrate the market, as well. So I'm still optimistic.

But I think the biggest impediment is a commercial impediment. I think the health plans should look beyond the next quarter and look at the long run and recognize that if they put a biosimilar in formulary, they might lose money for a quarter when they lose the rebates, but if they can convert their population over a two-year period to the biosimilar, they're going to create a lot of competition that's ultimately going to lower their drug span. I think they need to take the long view year.

The captive health plans seem to do that. You look at Intermountain Health and Kaiser, they've done a better job of introducing these products because they had more control over utilization. So they've had a better -- done a better job of capturing the opportunities and the savings than some of the private health plans. But the whole notion of having PBMs in health plans is supposed to be to manage utilization. So if they can't do

this, I'm not sure what they're doing.

MS. EDNEY: So when is your last day?

COMMISSIONER GOTTLIEB: It looks like I'm going to stay to testify before Congress on April 3rd, so I'll probably make that Friday, April 5th, my last day.

MS. EDNEY: Okay. That's on the budget you'll be testifying?

COMMISSIONER GOTTLIEB: I'm going to testify on the budget before the House and the Senate. There's no one else who wanted to do it. (Laughter)

MS. EDNEY: So there was a Tweet that you did on January 3rd that you heard from friends contacted by an online pharma news pub that's preparing a story speculating that I'm leaving. I want to be very clear, I'm not leaving. And then two months later, we heard a very different story. What happened?

COMMISSIONER GOTTLIEB: Well, that was this article that was going to run saying I'm leaving, I'm going to announce my resignation within a week. And this was during the shutdown. I certainly wasn't going to do that.

Look, this has been a very difficult decision. And, you know, I've been going through a week of speculation about what the real reason I left is because you can't possibly just leave for personal reasons and because you miss your family and you're not seeing them. But there really wasn't more intrigue to the story than what was there.

You know, if you asked me back in January what my goals were, it would be to probably stay to the two-year mark and try to get into the summer. That got increasingly difficult. I didn't think I was going to be able to stay till August.

I was literally at the point where I would come home Friday night, get home 10:00, spend part of Saturday with my kids, you know, go out to dinner with my wife on Saturday night, spend all day Sunday reviewing documents, writing documents, working, and then be back on the train Sunday night. This was two years, two years of doing this with young kids. I didn't think it would be as hard as it got. If I had to do it over again, in retrospect, I probably would have looked to move my family down here rather than try to

commute between Westport, Connecticut, and Washington, D.C. But I can't do it over again and it got difficult.

This is very hard to walk away from the job. This is the best job I'll ever have and we felt good at it. We were doing great. But I think the FDA will continue to be great. There's a great team left behind. I think there's a lot of policy that's laid out, there's a lot of policy that's going to continue to roll out. I feel very good about the inflexion point that FDA's at right now, stepping away from that. And if I didn't, I wouldn't have done it.

We're finalizing a lot of stuff that's important to me. We're going to continue to finalize certain things this month. There's other things that are going to roll out that are highly meaningful. And the other policies are either on a good trajectory or are longer term enough that I was never going to be able to bring them over the finish line in any reasonable period of time that I was going to be able to be affiliated with the FDA.

MS. EDNEY: Do you think under this current administration that the FDA will have a permanent FDA commissioner?

COMMISSIONER GOTTLIEB: I mean, I don't think it's a question of under the administration. I think it's really looking at the Senate calendar. I hope so.

You know, I've made no secret that I'm a big fan of Ned Sharpless and I think he's going to do an outstanding job. He's very public health-minded. I think he's got a great ethic for the agency. I think he's going to be embraced by the professional staff. He's coming out to the campus. He's met with a lot of the folks already. You know, I've met with him a few times. So I feel very confident about his leadership of the agency. Obviously, it's up to the Secretary and ultimately the President what they do with that slot.

MS. EDNEY: What's next for you? Anything fun on the horizon? Where do you want to go to work?

COMMISSIONER GOTTLIEB: Well, so I got the week off after I leave the job and then the next week is my girls' Spring Break, and so I outsourced my vacation plans to them, so they picked Disney World, of course. I'm one of the few people who could say

I'm going to Disney World after I'm done. (Laughter) But I'm really going to Disney World between -- you know, that April 15th week. And so I'll see what comes next. As you know, I can't look for a job while I'm in this job, and I really haven't given a lot of thought to it.

MS. EDNEY: Okay. I know I want to keep time for audience questions, so we can move on to that. Wherever you see anyone.

MR. YOCHAM: Hi. Thank you for sharing your thoughts. My name is Matthias Jochum. I work at the Austrian Embassy.

My question concerns the intersection of regulation and international trade. There is a possibility that in EU-U.S. trade talks horticultural and food products will be included, which might entail a certain degree of regulatory convergence. Do you have any thoughts on the types of difficulties might be encountered in that process? Thank you.

COMMISSIONER GOTTLIEB: Well, I think the broader challenge when you look at harmonization across EU and the U.S. on food policy is that I think EU in many respects has adopted a precautionary principle when it comes to some of the technology that we readily embrace here because we think they provide public health value, whether you're looking at genetically modified animals or genetically modified crops. And so I've always, from a policy standpoint, people talk about harmonization across our portfolio, I think that we have more ability to harmonize on the medical products side than we do on some of the regulation on the food side because of some of the positions that the EU has adopted.

Where we see opportunities to create more harmonization is around things like inspections on food products and produce, some of the more bread-and-butter regulatory work, where we have, in fact, entered into mutual recognition with certain European regulatory authorities where we can borrow from their inspectional work and they can do it with us, as well. We're currently in discussions I think with the U.K. We've done it with New Zealand. I forget the countries that we've harmonized with on produce inspections and some of the inspectional work under FSMA.

MS. KLASMEIER: Hi, I'm Coleen Klasmeier presently (inaudible; off mic).

Dr. Gottlieb, you are, without a doubt, the most prolific communicator out of all of the commissioners that FDA has had. And it's hard to imagine any successor being able to keep up with the complexity of the agency's portfolio and the need for -- and the expectations that in some sense you've created among external stakeholders as to transparency. Do you think now is a good time for policymakers to start thinking about a three-person commission format for the agency? Do you think it's a good time to think about FDA as an independent agency given the complexity of the relationships between FDA and HHS?

You've written about FDA from a management perspective before. Has your thinking evolved on any of those structural issues as a result of the past two years?

COMMISSIONER GOTTLIEB: Well, I think FDA's still manageable by a single commissioner. I mean, if you ask me what the single biggest difference is between the agency during my three sort of stints at the agency it's the complexity and the scope of the portfolio, which has grown enormously over a period of time if you look at new authorities that we have and the whole new centers. But I still think it's manageable with the right structure and the right team and I feel like we've managed the agency and been able to pay attention across the entire breadth of the portfolio and make policy within every aspect of the agency.

But when you come into that position, you do need to make a conscious effort to staff yourself in a way that you can maintain involvement with all of the components of the agency. And the first thing I did when I got there was to move the reporting of the center directors to me directly. Previously, they reported through deputy commissioners. I think having that direct contact with all the center directors, I met with them on a weekly basis, was exceedingly important to not just being able to advance policy, but maintaining a perspective on what was going on and help the centers solve their problems.

As far as an independent agency, I'll reserve my judgment for that for about two and a half weeks, and then I'll opine on that. But, you know, the agency, I think the

portfolio of FDA is so unique in many respects that it's hard for folks who have never worked or don't work there to fully understand the breadth of the issues at FDA, whether it's HHS or the White House or the other components, because you're dealing with very complex, scientific, regulatory matters. So there is a very unique aspect to the work that FDA does.

MS. CALLAHAN: Hi, Noelle Callahan with the White Coat Waste Project. And I just wanted to thank you for your leadership and for ending some nicotine testing experiments on monkeys last year and sending monkeys to sanctuary or decreasing some of these with dogs at the agency, as well. And I'm just curious what motivated you to make those historic announcements.

COMMISSIONER GOTTLIEB: Well, you know, what happened to the monkeys in our possession, in our trust was tragic in that experiment in NCTR. And it was hard to justify what happened to the monkeys relative to what our expected gains were from continuing that experiment, so I made the decision to shut it down and reserve capital to move them to a sanctuary and paid for their safekeeping in that sanctuary.

I think when animals are entrusted to our care and when we're conducting experiments under our stewardship or directing the conduct of experiments, it needs to be done with great care and with a very clear understanding that there's an overwhelming public health purpose to the experimentation. And I think across our portfolio we've looked for opportunities to use modern technology's better predicted toxicology as a way to supplant the use of animals in studies. And that's a long-term goal of the agency.

With respect to the dog study that we were doing, what we're seeking to do there is to provide a sort of model, develop a model for how dogs metabolize drugs. And so that if we can have a rigorous model that predicts the metabolism of drugs in dogs, we wouldn't need to use dogs in future studies. And so you can supplant that model for all future studies where you might involved dogs and save literally hundreds, if not thousands, of dogs from future clinical trials.

And in that study in particular we've taken great care to make sure that

there's not going to be a lot of, you know, intrusion. They're going to get blood draws, but that's it. They're going to be -- you know, the circumstances of the studies themselves, I think we're going to provide very good care of these dogs who are in the hands and the custody of the Center for Veterinary Medicine, who will love these animals. And then we're going to put them up for adoption.

And there's a lot of work going on in FDA because I think if we can sort of get legal clearance, the dogs will be fully adopted by FDA staff. (Laughter) Because there's like a real desire -- they're beagles and there's a real desire, everyone wants one, and we have to make a legal determination whether we can adopt federal property, so we're actually going through that process right now. We're spending a good amount of legal time on that question. But I feel very good about that, too, because if we can develop what we hope to develop in that context, that could have a lasting legacy in terms of reducing, if not eliminating, the need to subject other dogs to experimentation in the future.

MR. PORZECANSKI: My name is Arturo Porzecanski and I'm a rare disease patient advocate. I wanted to ask you about the implementation of the 21st Century Cures Act. If I had an existing FDA-approved medication that can be repurposed and so it needed approval for a new indication from the FDA to be used on label, would I notice a difference between going through the grind now versus a couple years ago?

COMMISSIONER GOTTLIEB: Well, I would hope so. I think that there's been a lot of, when it comes to rare diseases in particular, there's been a lot of innovations that we've introduced with respect to the overall development process, whether it's different kinds of clinical trial designs where we're looking at, you know, enriched trial designs, we're looking at non-placebo trials where we used natural history models. Part of the money that we got in the 2019 budget that we asked Congress for was $20 million to develop natural history models that we can use in lieu of placebo arms in rare disease trails. We've allocated a lot of resources to that ourselves and made that a real focus.

We've promulgated frameworks for things like basket trials and master

protocols to make it easier to conduct studies in rare diseases where you could allow the same patient population, if you have a small patient population. You don't have to constantly recreate new protocols, but you could have a master protocol where you have patients that are able to enroll in multiple clinical trials and test multiple different drugs in different clinical trial settings.

So there's been a lot of innovations in clinical trial designs that I think have facilitated a much more efficient process for drugs targeted to rare diseases. And I think it's having a tangible impact. Whether it's going to impact one specific disease or not, it's hard to judge. But I think overall it's had a tangible impact. And I think it's evidenced by a record number of approvals last year: 59 novel drug approvals, a majority of which were targeted to rare diseases.

MR. BLAIR: Paul Blair with Americans for Tax Reform. Earlier you mentioned Europe's standard overview regarding the precautionary principles, so I wanted to ask you about one of your Tweets from this past weekend where you said that whatever the redeeming public health value this category of pod-based products, talking about e-cigarettes, may have for adult smokers, the potential benefit would be fully offset by youth use.

Given the fact that more than 35 million American adults still smoke cigarettes, what is the regulatory standard for review at the FDA or I guess beyond your tenure as commissioner for approving current products, for example, IQOS, or making determinations on how PMTAs will be approved moving forward given the fact there still are not guidelines on how a manufacturer is supposed to bring a product to market or keep a product on the market beyond 2021? Thank you.

COMMISSIONER GOTTLIEB: Well, there's guidance out right now on the PMTA process and there'll be additional guidance coming out very shortly that's going to lay out more of the rules of the road. We've received PMTA applications from sponsors and I think there is a demonstration that you can successfully adjudicate the PMTA process.

I've said publicly before we haven't received a single PMTA application from an e-cigarette manufacturer. I don't know what they're waiting for and I don't know why they're not further along on the PMTA process, but they're at the point of filing applications. These products have been on the market for a very long period of time now.

So the FDA is open for business. And it's giving a lot of direct feedback to a lot of sponsors, including some e-cigarette manufacturers, around the application process. I think the onus is obviously on the e-cigarette manufacturers to file PMTA applications. You know, if they had gotten underway a couple of years ago, they'd probably be pretty close to the finish line right now, potentially, certainly with the PMTA process.

Obviously the MRTP and demonstrating that as a modified risk tobacco product we can make a claim around is a higher hurdle and a different standard. But the PMTA standard could potentially be met. I don't want to prejudge the outcome of the process, but it could potentially be met by certain e-cigarettes that marketed in a certain way or flavored in a certain way, where you can demonstrate that you're going to help adult smokers transition off of combustible tobacco and position them in a way that you're not going to allow for youth initiation. And there's ways to do that with heightened age verification and other measures that some of these manufacturers could be taking; some are taking, but some are not.

MR. GITCHELL: Hi, Joe Gitchell with Pinney Associates. And we consult for the pharmaceutical and consumer healthcare industry, and this is a question about nicotine. And we're consultants for Reynolds American on their non-combustible nicotine products, not on their combustible ones.

I wanted to ask a question about the comprehensive framework that I think hasn't gotten a lot of attention. That is the public's misperceptions about nicotine still referenced in the web page about the plan. Two related questions. Any comments about the public's misperceptions? And does FDA have any plans to start to address those misperceptions? Thank you.

COMMISSIONER GOTTLIEB: No, we speak to this. I think that this is a challenge because there's a perception that nicotine is what causes cancer by some people, and nicotine in and of itself is a very harmful substance. And while nicotine isn't a benign substance, nicotine isn't what causes all the death and diseases associated with tobacco use. It's the products of combustion, and we've been clear on that. So we don't want to discourage currently addicted adult smokers from transitioning to other nicotine delivery vehicles.

And nicotine's a legal substance. There's going to be adults who want to enjoy nicotine. There's going to be adults who have to enjoy nicotine, who have derived some, you know, potential value from it.

But we've been clear on that, you know, that we believe nicotine exists on a continuum of risk. And I think what we did in that summer of 2017 announcement was put nicotine at the center of our regulatory efforts and talk about tobacco regulation really as regulation of nicotine existing on a continuum of risk with the combustible products being the most harmful and the medicinal products being the least harmful with other products in the middle.

What I think changed our policymaking was the explosion in the use of nicotine by children. And I think that the comments from the e-cigarette community have been overly dismissive of that risk. And I think that the positions that they've taken have created an existential threat to the entire category because I think that they have been insufficient in terms of their earnestness and seriousness about addressing that problem.

I mean, the idea that, well, the kids are only using it on weekends, so it's not a big deal, we're capturing an exploding epidemic right now. And so, of course, the new users that we're capturing, and that's who we're surveying, aren't going to be using it every single day. When you look at the nature of any epidemic and the evolution of an epidemic, people become occasionally users before they become regular users.

You look at the evolution of the opioid epidemic. It started with people

becoming medically addicted with medicinal products. They started to use it recreationally. They started to then crush pills, snort pills, inject pills, and then they migrated on to heroin. There was an evolution, not for everyone, but for a lot of people.

You're going to see occasional use by children before you see regular use and before you see a progression onto cigarettes. But we have enough evidence now to know that that's going to happen. And so that's where our concerns have been raised around nicotine. It's not necessarily around nicotine with adults. We recognize, again, not a completely benign substance, but certainly not what causes the death and diseases associated with tobacco use.

MS. KODJAK: Hi, Scott. Alison Kodjak with NPR. You've made a big push to streamline approvals of generics and biosimilars, but I've been hearing on Capitol Hill a little bit of agita over the 12-year market exclusivity for biologics. Do you think that's too long and should be reduced?

COMMISSIONER GOTTLIEB: You know, I haven't looked at that question closely in a while. I think that trying to divine what the sort of right period of time is for exclusivity in order to create the incentives to attract sufficient investment to have the kind of robust innovation that we have is a very difficult science.

All I know is what I see, which is that we have very robust investment in the pharmaceutical sector. We are in a period of unprecedented innovation and opportunity in medical science. Whatever we did, we did the right thing in terms of getting tremendous opportunity for patients. And so we got a lot of things right.

You know, there are still problems of affordability with patients being able to -- having a difficult time accessing medicines. But I think that a lot of the problems and market failures aren't related to sort of patent terms, which over time have actually come down. If you look at the average patent life of a drug, and outside the biologics context where you have sort of a guaranteed data exclusivity, patent terms have actually come down.

And as you probably know, when you look at the biologics, most of them, their exclusivity extends beyond 12 years because they have other patents around those. The 12 years really isn't the floor for a lot of those products -- a ceiling, it's sort of a floor.

But I think the challenges are we don't always have the product competition that we expect. When we have the product competition we expect, we don't always have the pricing mechanisms in the marketplace that allow that competition to actually deliver savings, so I'm think particularly of Part B where you don't have a competitively bid system. Medicare's a price-taker in the Part B context, so we don't bid those drugs out like we do with Part D. But then when you actually do have price competition, so when you have product competition and then you actually have price competition, sorry, the discounts come in the form rebates that don't accrue to the patient. So those are the three failures that I see.

Lack of product competition, we've talked a lot about that at FDA, you know, lack of competition with complex generics, people gaming the system to prevent the entry of generic drugs. Then lack of price competition in certain areas of the market when you do have products, multiple products, that could be competing against each other. And then when you finally have product competition and price competition, the discountings in the form of back-ended rebates that don't benefit the consumer who's out of pocket for the medicine. Those are the three failures. That's where I'd be focusing my time. That's where I am focusing my time.

MS. EDNEY: I think we have time for one more.

MS. GREENBERGER: Dr. Gottlieb.

COMMISSIONER GOTTLIEB: Hey, how are you?

MS. GREENBERGER: I'm not going to surprise you. You've been terrific about --

MS. EDNEY: Want to grab the microphone?

MS. GREENBERGER: Sorry. Phyllis Greenberger, Healthy Women. Dr. Gottlieb and I have worked for years together.

You've been terrific on women's health issues. As you know, the director of the office retired in January and made her announcement in October. There's still a vacancy for the director. Will you be able in the time you have left to pick someone to head that office? I'm concerned about that.

COMMISSIONER GOTTLIEB: Yeah, I mean, I don't know that in the next two weeks we're going to be able to name a permanent director of that office, but I feel like we're leaving that office in very good leadership with the acting director who's there, who's outstanding, who came over from the Office of Medical Policy and was a reviewer in the Endocrinology Division. She's a physician. I met with her probably about a week ago and she's got a lot of interesting ideas in terms of what she wants to try to advance to promote women's health. She's going to be working very closely with Amy Abernethy, the new principle deputy commissioner, who's very engaged in these issues.

So I feel very good about where that office is right now, the leadership of that office, obviously on an acting basis, and the relationship of the office not just to the Commissioner's Office because it reports directly to the commissioner, but also under the sort of guidance of the principle deputy commissioner, as well.

MS. EDNEY: Okay, I'm told we can do one more. Get in the back there.

MS. RIEMENSCHNEIDER: And mine's a pretty short one, so this is good. I'm Jenna Riemenschneider with the Asthma and Allergy Foundation. And we were really pleased last October when you put out the RFI for a sesame allergen and the potential for labeling it. And I was just wondering could you comment on the status of that possible regulatory action, labeling sesame as the ninth major allergen?

COMMISSIONER GOTTLIEB: Yeah, so we're still going through comments that we received. I think that without sort of prejudging the outcome, I think that we're concerned about both the incidence of allergies and the severity of the allergies associated with sesame. And it certainly appears, based on the information we have now, that it meets the sort of objective criteria of the eighth allergen, and so both in terms of the incidence of it

and how severe some of the reactions are. So I think that there's sufficient concern that FDA's going to continue to move forward what that process. It's obviously a rulemaking process, so it would take some time to declare it the ninth allergen.

But I've been concerned about it. I've had a lot of discussions with the center about it and we've obviously received a lot of input from patient groups, others, clinicians, Capitol Hill, as well. So I'm confident it's going to continue to go forward. I don't want to sort of prejudge the outcome other than to say that it seems to meet the threshold of where the eighth allergen sits, if not in some respects exceeded, in terms of the severity.

MS. EDNEY: Thank you, Dr. Gottlieb.

COMMISSIONER GOTTLIEB: Thanks a lot.

MR. WESSEL: Before you go, Scott, there's a demand on Twitter for you to explain if there's any significance to your socks. I don't recognize any complex molecules there. Is there anything?

COMMISSIONER GOTTLIEB: No, they're skeletons. You know, I just liked them and I ended up buying a bunch of pairs of them.

MR. WESSEL: Skeletons?

COMMISSIONER GOTTLIEB: Yeah. These were the socks that I was in the Rose Garden the day that they announced the drug pricing blueprint and the New York Times took a close-up of these socks and published the picture on their editorial page, so they objectified me.

MR. WESSEL: With that, please join me in thanking Scott Gottlieb and Anna Edney. (Applause) And if there's papers or coffee cups at your feet it would be nice if you took them to the back of the room where there are wastebaskets.

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I, Carleton J. Anderson, III do hereby certify that the forgoing electronic file when originally transmitted was reduced to text at my direction; that said transcript is a true record of the proceedings therein referenced; that I am neither counsel for, related to, nor employed by any of the parties to the action in which these proceedings were taken; and, furthermore, that I am neither a relative or employee of any attorney or counsel employed by the parties hereto, nor financially or otherwise interested in the outcome of this action.

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