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Outlook 2021: Washington, D.C. Updates and Insights on Life Sciences and Health Care

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INTRODUCTION

Speakers:
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Stephanie Webster

Al: Hello, and thank you for joining our webinar this afternoon. I am Al Cacozza, a partner in the Washington, D.C. office of Ropes & Gray, and a member of the firm's Life Sciences Compliance and Regulatory practice group. This webinar is part of our ongoing Capital Insights series where we are capturing our latest thinking on developments from the federal government that might affect our clients. Today's webinar focuses on regulatory and compliance issues in 2021 of particular interest to life sciences and health care companies. Our Capital Insights page at www.ropesgray.com includes alerts, analyses and podcasts, and we invite you to continue to visit that page throughout 2021.

Joining me today over the next hour and a half are several of my colleagues. We are going to have two panels. Our first panel will feature Greg Levine, Kellie Combs and Beth Weinman and will focus on issues relating to the U.S. Food and Drug Administration and the changes that might occur under the Biden Administration. The topics we will touch on are issues around FDA leadership changes, agency policy priorities and legislative policy initiatives, real world evidence, digital health issues and anticipated shifts in FDA's enforcement focus. Also joining me today, for the second part of our program, are my health care colleagues Christina Bergeron, from our Boston office, Tom Bulleit, Margaux Hall and Alex Talley, who are in D.C. and will be a part of our HHS-focused panel that will be moderated by my partner, Stephanie Webster. This panel is going to be discussing changes in HHS, CMS, and OIG in terms of priorities for 2021. We are going to look at the future of the Affordable Care Act, drug pricing prospects including the Most Favored Nation rule, Congressional Review Act possibilities and provider relief fund auditing activities, which promise to be very active.

We do plan to save time at the end of each panel to address questions from our listeners. If you have questions during the teleconference, please submit them through the Q&A function and we will try to get to as many as we can. One further note: we are offering CLE credit for this teleconference. We will provide you with the necessary information to receive such credit during the program. And additional supplementary materials for content mentioned today can also be found in your confirmation email.

PANEL 1: FOCUS ON FDA

Al: With that introduction, let's get started. So we can focus first on FDA, and let's talk to Greg Levine.

New FDA Leadership

Greg: Thank you, Al. According to the trade press, the leading contenders appear to be Janet Woodcock herself, who's currently in the Acting role, as you mentioned, and she's a 40 year FDA veteran. The other leading candidate seems to be Joshua Sharfstein. He's currently Vice Dean and a professor at Johns Hopkins School of Public Health, and he formerly was a Deputy Commissioner to Commissioner Hamburg during the Obama administration. There have been others mentioned as well, including Dr. Hamburg herself, and Amy Abernethy, Deputy Commissioner at the FDA. But Drs. Woodcock and Sharfstein have been the most frequently mentioned. Like Former Commissioner Hahn, both Dr. Woodcock and Dr. Sharfstein are MDs, but unlike Dr. Hahn, they both have significant experience working at the FDA and navigating FDA politics. And I think we all observed, as Commissioner Hahn unfortunately learned the hard way, that the FDA

Commissioner role is highly visible, and the politics can be extremely harsh and challenging. So I think, regardless of who is ultimately chosen here, I think they'll be looking for someone who has not only the technical background and capabilities to do the job, but also someone who has got the political and sort of public-facing experience and demonstrated ability as well. As far as Dr. Woodcock and Dr. Sharfstein, we've got sort of a pitched battle going on between their proponents and detractors of each. Now we'll see what happens. On the timing you asked about, Al, at this point, we don't even have a confirmed Secretary of HHS, the department of which FDA is a component. The nominee there, Xavier Becerra, has been having his hearings this week in the Senate, and so he may want to weigh in on that decision. Maybe he'll have other ideas for candidates as well. In the meantime, with Dr. Woodcock at the helm, I think the feeling is there's not an urgent situation here, and the FDA's going about its job and seems to be handling its business fine. On the other hand, with the COVID 19 pandemic in particular and also this priority of kind of restoring the FDA's reputation to some extent, I think the administration will want to name a permanent commissioner sooner rather than later, so I'd be surprised if we didn't see someone named before the end of March.

FDA Priorities

Al: Thanks, Greg. So let's turn from personnel, which is obviously very important, to issues. What do you see as the highest priority issues for 2021 for the FDA under the Biden Administration? Do you think the focus will solely be on the pandemic? Or are there other issues that will rise to the top of their agenda?

Greg: The first thing is really this sort of reputational issue, I think. I don't want to overly emphasize that, but I think their reputation did take a hit as a result of, what appeared to be at least, the FDA caving to pressure from the White House in the last administration. For example, the authorization on an emergency basis of the use of hydroxychloroquine as a COVID 19 treatment. Also there was a press conference where the commissioner stood by the president and overstated, vastly overstated, the benefits of convalescent plasma. We have had HHS overruling FDA and saying the FDA doesn't have legal authority in certain areas such as requiring emergency use authorizations for laboratory developed tests. So I think a big part of this job is going to be on the optics. Sorry to use that word, but I think we'll see major emphasis in sort of the theater of it. Just stating and demonstrating repeatedly and publicly that the FDA makes its decision solely based on science. As far as the substance of what the FDA will be doing, I do think in 2021 a lot of the focus will continue to be on COVID 19. So, we've got the issues now with the variants of the virus that are particularly concerning, the SARS CoV 2 virus. So we saw the FDA even this week issuing guidance on how vaccines and therapeutics manufacturers can sort of nimbly and flexibly address those variants. I think FDA will be continuing to focus on promoting faster and cheaper and more convenient diagnostic testing for COVID 19 and also trying to look at genomic sequencing to identify variants and follow them. And then the FDA will be continuing to monitor for shortages of key equipment like PPE. Eventually, hopefully, at some point this calendar year, FDA will be looking towards unwinding some of the emergency measures that it has taken for the COVID 19 pandemic, such as perhaps ending or limiting some of the emergency use authorizations it has issued or its enforcement discretion policies where those are no longer required by the circumstances. So for example that could be for certain types of PPE, maybe some things on the hand sanitizers, those kind of products. And then also FDA is going to have to figure out what to do with some of these products that it has authorized that are out there on the market and that are durable, like ventilators. You know there have been ventilators on the market where modifications have been made or didn't go through normal FDA process and so forth. There are going to be a number of issues that FDA is going to have to deal with there. But then I think beyond that, the FDA will be looking at what lessons it learned from this experience, and I think that's going to have to be important work to do there. They'll have this inspection backlog. I saw some numbers just today. Between March and October

of 2020, FDA conducted only three foreign inspections, whereas sort of a normal benchmark for that time period would be 600. And domestically they did 52 inspections whereas normally in that same timeframe you expect them to do 400. So they obviously have a huge inspection backlog, but also through this experience they've gotten more experience in doing some things remotely, whether it's just reviewing documents remotely, or relying on inspection reports from foreign regulators, like the MDSAP program for medical devices, and reliance on EU regulators' reports for pharmaceuticals, those kind of things. So you know it will be interesting as what kind of long-term lessons the FDA takes from that. I don't think FDA in person inspections will ever be replaced, but it may that be some fusion of these techniques will be used increasingly over time. There's the issue of the supply chain fragility that we've seen and sort of a lot of talk now about on shoring of manufacturing of certain critical components. They've had some executive orders issued on that topic just in the last few days. Some important issues about diagnostic tests in a pandemic. Obviously that rollout didn't go very well here, and sort of what lessons can be learned from that. And I guess lastly, the FDA's going to want to get back to doing its normal business as much as it can. Some of the key public health issues that the FDA was focusing on before the pandemic, vaping, tobacco products, a lot of device safety issues particularly involving women's health devices. FDA's been taking some steps, but clearly the focus has been on COVID. Digital health, I think Kellie will talk a little more, and then just this broader issue about regulation of lab developed tests, not just for pandemics or epidemics but these kind of diagnostics which are key to the future of precision medicine, and this issue has been lingering since the Obama Administration. So I think all of those things and more the FDA is going to have on its agenda.

Prospects for FDA-Related Legislation

Al: Let's broaden the lens a little bit, Greg, to talk about legislation. Do you see any FDA-related legislation in 2021? And if so, what topics do you think will be the focus of that legislation?

Greg: Yeah, I mean, it may be challenging in 2021 if we just think about all Congress is going to have on its plate, and the new administration is going to have on its plate trying to push through major legislation in a lot of areas. Now we know the user fee statutes for drugs and for medical devices, they will need to be reauthorized next fall, so fall of 2022. And so I would say that would be the outside date for some major FDA reform legislation because typically those happen every five years, and generally they get lit up like Christmas trees with everybody putting their ornaments on them. So generally those turn out to be pretty substantial bills. If there were some things that might move sooner than that potentially, I do think that this legislation that's been out for some time, I think we've talked about it maybe three or four years running on these Outlook teleconferences that we do, the Valid Act is a bill that would create a comprehensive system for FDA regulation of in vitro clinical diagnostic tests. That would include tests that are developed by labs as well as tests that are developed by your traditional IVD manufacturers to try to bring some more coherence to that whole system. There are a lot of details that still need to be worked out, but I think the broad frameworks of that legislation have pretty broad bipartisan support. So I could see potentially some legislation there that could proceed, maybe preceding the user fee statute. I think this issue about the "on-shoring" of medical product manufacturing is one that's going to get a lot of attention, already is getting a lot of attention, and there have been legislative proposals on the subject before. For example, Representative Frank Pallone, who's the Democratic chair of the House Energy and Commerce Committee, along with a Republican member of that committee, had introduced a bill that would create a national centers for excellence in continuous pharmaceutical manufacturing. And I think this whole area of what things should we be producing domestically—how do we get better prepared for pandemics and epidemics? And just, the supply chain: how do we have a less fragile supply chain for medical products? I could see some legislation there sooner. The

last area maybe would be digital health. In the 21st Century Cures Act that was enacted at the end of 2016, there were some important provisions there. In particular, one section of that law removed a number of device software functions from the definition of a medical device, but there's still a lot of open questions about the boundaries of some of these things, particularly in what's called "clinical decision support software." And then, there's other things FDA's been working on, this precertification process for software, that probably would require legislation to really implement in a robust way. So maybe that would be a last area, but we'll see again if Congress has bandwidth for any of this before 2022.

Al: Thanks, Greg, and on the consumer front, I think there may well be some push in the CBD regulatory area because Congress has been eager to get that behind them, and FDA has been trying to solve that issue. We will have to see if there is any push for that at all. Thanks, Greg.

Let's turn now to Kellie Combs to talk about a number of issues about digital health, advertising and promotion, and some real-world evidence issues. Kellie is not only a partner in our Life Sciences Regulatory Compliance group, she's also the co-chair of our Digital Health initiative, which is obviously a very hot area and an area that is only going to continue to grow.

Real-World Evidence

Al: Kellie, can you describe the impact that the pandemic—I guess all questions relate back to the pandemic at some point—has had on the generation and use of real world evidence, and what this might mean for FDA policy developments and industry practices in the coming year?

Kellie: Sure, Al. Thanks, and hi, everybody. So real world data and real world evidence have both been steadily gaining visibility and prominence in recent years but were really given a boost in 2016 with the passage of 21st Century Cures Act, as Greg mentioned. Cures required FDA to establish a program to evaluate the potential use of real world evidence to support approval of a new indication for drugs and to help satisfy certain post approval requirements. Cures has also required FDA to issue a draft proposed framework for real world evidence, which the agency accomplished in 2018, and to issue guidance addressing standards, methodologies and circumstances in which companies could rely on real world evidence. Real world evidence approaches have been used pretty frequently on the device side, but uptake has been significantly slower with drugs, where real world evidence still to this day is most commonly used post approval, for example in the form of registry studies, claims database analyses, and so on. FDA has expressed some concern with real world evidence approaches over the years, particularly when it comes to establishing effectiveness for an initial approval decision. The agency continues to say that really significant efforts are needed to understand what data sets may be available as well as how they can be used with confidence and how to address the gaps or quality issues in real world evidence and various data sets. In addition, the agency has long been trying to determine how to consider real world evidence in its totality when considered in conjunction with, for example, traditional clinical studies, and how all of that information should be factored into a regulatory decision. During the COVID 19 emergency, not surprisingly, both FDA and industry have been forced to rely heavily on real world evidence to understand the virus and to assess potential treatment options. Just to give a few examples, FDA last year established a partnership with Aetion focused on real world evidence to study the use of COVID 19 diagnostics and medications and also to seek information about risk factors for COVID-related complications. FDA's also been using its Sentinel system to assess COVID drug use and shortages and to conduct treatment impact studies, and then finally, the agency's been encouraging health care professionals to use the agency's Cure ID platform to share learnings about how to treat COVID 19 in various patient

populations. Real world evidence has also played a pretty central role in FDA decision-making in the Emergency Use Authorization, or EUA, context, and it's expected to do so as companies pursue full approval. For example, FDA issued the EUA for convalescent plasma based in large part on a real world evidence study of 70,000 patients that was conducted by the Mayo Clinic. Most recently, top-line results from a real world evidence study, also conducted by Mayo, demonstrated that with the Pfizer and Moderna vaccines in 60,000 patients that had their first dose were showing comparable efficacy to what was seen in the clinical studies. So what does this mean for the future, and in particular beyond the COVID 19 context? FDA officials, including former Commissioner Hahn, as well as Principal Deputy Commissioner Amy Abernethy, have emphasized the importance of real world evidence. They've noted that innovations and learnings taken from FDA over the last year or so will be considered in standard agency procedures post COVID, to the extent appropriate. FDA officials have also made clear that FDA's grown increasingly comfortable with the use of real-world evidence to support regulatory decisions. So what should we be looking out for this year? I mean, I think for one thing we'll see additional EUA, and, ultimately, approval decisions that incorporate certain elements of real-world evidence. And those precedents should be really valuable for those of us who are watching this space. In addition, FDA is planning to issue a few guidance documents specific to real-world evidence, including guidance on how electronic health records and prescription claims data can be used to support regulatory decisions for drugs and biologics. On the whole, I think it's certainly fair to say this will be a big year for real-world evidence.

Digital Health, Including Artificial Intelligence

Al: Thanks, Kellie. Now let's turn to digital health more generally. FDA obviously is interested in this area, and, in fact, before the Biden Administration was sworn in on January 12th, FDA issued the Action Plan for Artificial Intelligence and Machine Based Learning Devices. What are the key takeaways from that Action Plan, and what other digital health developments are on the horizon?

Kellie: So creating and honing the regulatory framework for digital health technology has long been a priority for FDA, and they've taken a number of steps in recent years. Right before the Action Plan came out, FDA established what it calls the Digital Health Center of Excellence, which is really meant to spearhead digital health regulation. The Action Plan, though, focuses on artificial intelligence, and machine learning based software as a medical device. This is a broad category of medical devices that are able to take data generated during the real-world use of and experience with the device, and learn from and act on that data. Software developers can use machine learning to create an algorithm that's locked, so that its function doesn't change, or to create an adaptive algorithm so behavior can change over time based on new data. Some examples of AI and ML based technologies that we've seen include an imaging system that uses algorithms to give diagnostic information for skin cancer in patients, as well as a smart sensor device that estimates the probability of a heart attack. Given their adaptive nature, these technologies raise some really unique regulatory concerns. And in the Action Plan, FDA outlines five actions it believes will advance the policy making effort and practical oversight of these devices moving forward. Now, we actually just did a deeper dive on the action plan that will release soon as part of our Non Binding Guidance podcast series, but I'm just going to hit the highlights here. The key elements are updating a prior proposed framework that FDA issued in 2019, including through issuance of draft guidance on some of the elements the FDA would expect to see in submissions for AI and ML based software. FDA also plans to encourage harmonization of good machine-learning practice development, and to hold public workshops on how device labeling can support transparency to users of devices, and also enhance trust in these types of products. The agency also plans to support regulatory science efforts to develop methodology for the evaluation, and improvement of, machine learning algorithms. So, this

is an issue that's gotten a lot of attention, particularly as it relates to the identification in elimination of bias in existing data sets, and for the promotion of algorithm robustness. Finally, the agency plans to work with stakeholders who are piloting these sorts of products. Because FDA believes it's really important to see how real-world data collection and monitoring can help manufacturers understand how their products are being used, so that they can identify opportunities for improvement, but also to be able to respond practically and efficiently to safety concerns. So I think 2021, with the action plan, we should really start to see FDA policy as these sort of devices take shape.

Aside from AI and machine learning, there are a number of other digital health issues that we expect to see FDA grapple with this year. Greg already mentioned clinical decision support, or CDS, software. We have seen draft and also revised guidance on this topic, but it is highly complex and it's also an evolving area, both in technology and regulation. There are a lot of open questions and additional opportunities for FDA to clarify. Among other things, there's a threshold question of whether the software "informs or drives" a clinical decision, and I know just from my practice advising clients on these sorts of issues that the distinction tends to be very difficult to assess, so we're hoping for better guidance from FDA there. We also expect to see additional guidance from FDA on its risk categories for software as a medical device. FDA has historically used a risk based framework to determine the extent to which it will exercise regulatory oversight over certain digital health technologies, so additional clarity there will also be welcome. And then finally, as Greg alluded to earlier, we can expect to see some guidance on a transition plan for products that are currently distributed under EUAs. A lot of these EUAs include products relating to digital health technology, like remote patient monitoring, wearable patient devices and screening systems, so certainly a lot to watch out for this year, Al.

Advertising and Promotion

Al: Thanks, Kellie. Let's finally turn to an area I know you have been monitoring very closely, and that's with the change in administration, do you expect there to be a shift in how FDA approaches advertising and promotion in terms of policy development or even enforcement?

Kellie: The short answer here is it's too early to tell, but I'm sure that you and many others want a little more from me than that, so let's talk about a few key developments. In October 2020, Tom Abrams retired after 20 years as the director of OPDP, the Office of Prescription Drug Promotion and its predecessor, DDMAC. Katherine Gray was named as the acting director, and she is a long-standing FDA employee, previously serving as an OPDP staff director and director of the Division of Prescription Drug Promotion, among other roles. As she described at an FDLI conference in November, current OPDP priorities include public health issues like the opioid crisis and COVID 19, products approved under a REMS program, products whose labeling includes box warnings, and products that have been a subject of a previous compliance letter. Now if that sounds familiar to you, it's because that's generally consistent with the priorities we've seen from OPDP over the last number of years, and the first two letters that we've seen in 2021 are very consistent with those priorities. On the device side, we don't have such a clear description of priorities, though in general, we continue to see emphasis on omission of risk information for restricted devices, as well as broadening the indication in some of the more recent letters coming out of CRDH. I know Beth will have a lot to say about enforcement more generally, so I'll just wrap up with a quick update on the intended use rulemaking. In September of 2020, FDA issued a Proposed Rule clarifying what the government may consider relevant to its determination of the intended use of product. There's a long and really convoluted regulatory history, as FDA had initially proposed a revised rule back in September 2015. In the interest of time, I'll cut to the chase and just focus on the most recent step. The agency's purported objective here was to make clear that the

government would not consider a manufacturer's knowledge of off label use—without more—as sufficient to support this determination that the manufacturer had intended product for use for the new intended off label use. That's a helpful clarification, and certainly welcome and consistent with what the agency had proposed back in September 2015. FDA also indicated in the preamble to the proposed rule, but importantly not in the text of the proposed regulation, that the government would not consider speech within established safe harbors like distribution of off label reprints or responses to unsolicited requests as evidence of a new intended use. That's also a helpful clarification, but certainly not optimal. For one thing, I think as many of us know, the boundaries for these safe harbors have never been clear, and there's a lot of ambiguity even among those of us who practice in this area when something, for example, constitutes scientific exchange or promotion. Given that there's a lack of clear boundaries, it's hard to say whether what a company thinks it's doing to fit within a safe harbor will be the view shared by the government. And then, of course, this clarification comes in the preamble to the proposed rule—not in the proposed regulatory text—so it doesn't really provide that much protection. Other than the changes described, the approach by FDA in the intended use rule is generally consistent with what the agency has been doing for many years, advancing this very broad interpretation of intended use, where the government can consider essentially anything in determining intended use, not just marketing claims but also internal company documents, other circumstances surrounding distribution. Now, there's nothing to say or suggest that an FDA in the Biden administration would approach intended use any differently, and we also don't know how this fits in with the agency's broader policy making priorities. Given the extensive public comment submitted, though, including on very important First and Fifth Amendment issues, it's reasonable to expect to take some time for FDA to finalize it.

Key Areas of FDA Enforcement in 2020

Al: Thank you, Kellie, and, as you predicted, we are now going to turn to Beth Weinman, to talk about enforcement issues, and discuss FDA's enforcement policy going into 2021. But before we do that, Beth, let's look back at 2020 and see what the key areas of enforcement were back in the previous year.

Beth: Sure. I think it's important to look back, because, unfortunately, priorities, especially in the public heath context, don't change on a dime; or really, they're not really motivated typically by politics. They arise out of context, and the harm that we see being caused by misconduct. While the aggressiveness of enforcement may change, I don't think we're really going to be seeing a major change in priorities in the coming year. So let's look back. Undoubtedly, COVID fraud was the number one enforcement priority this year for FDA, for DOJ, and also for other enforcement agencies as well, which we are not used to seeing in this space. For example, U.S. Customs and Immigration Enforcement has initiated Operation Stolen Promise 2.0 to identify and prevent the production, sale, and distribution of unapproved and unauthorized COVID products, including drugs and vaccines. So across government, not just in typical enforcement actors, we are seeing attention through COVID-related products. In the past year, FDA and FDC together have issued more than 150 warning letters for unapproved, adulterated, misbranded medical products intended for COVID 19 uses. FDA has issued safety alerts for products it views as unsafe.

Al: In addition to the COVID fraud issues, in 2020, obviously there were major enforcement actions related to opioids. That is still obviously a huge impetus of the government, and there were two global settlements: Purdue Pharma and Indivior. They also launched a 120 day pilot program with the Department of Commerce's national telecommunications information administration to target unapproved opioids illegally sold online. The other major area in 2020 was groundbreaking food safety cases. There were issues around public safety and involved household names: Chipotle and Blue Bell Creamery. Those really are not politically based, as

the FDA's mission is to protect the public, and so when they had issues around food safety, the FDA continued to follow its mission to engage in normal enforcement activity.

The next step is what's going to happen in 2021. And in terms of that, I think, as Beth noted, these are not necessarily politically driven, although there are some enforcement priorities and some of that is going to be a function of who the eventual FDA commissioner turns out to be, and also what the priority is in the Department of Justice, once Attorney General nominee Merrick Garland gets in place. It is no surprise that COVID fraud is going to remain front and center. We are talking about billions of dollars, billions of federal dollars going out to a range of contractors. It should be no surprise that there is some element of fraud and abuse, even if it is a small percentage. Fraud and abuse are going to be front and center. The other thing, which is somewhat unique, but again it is all pandemic-related, is around issues of companies billing outside of the scope of their EUA authorizations. An EUA is not an approval; it's an authorization, and the question is are they going outside of the bounds of what they are authorized to do.

Beth, before turning to a preview of 2021, do you want to expand on anything, related to either opioids or food safety from 2020?

Beth: I want to talk about two precedent setting Opioid settlements that took place in 2020; the Purdue case and the Indivior case, and we will talk about how we will continue to see opioids as a priority in 2021. Also, I don't want to move forward to 2021 without talking about some ground-breaking food safety cases we saw last year. One of those was Chipotle, which is a case that was resolved with a deferred prosecution agreement in April of 2020. To avoid criminal indictment, Chipotle agreed to an enhanced food safety program and to pay a twenty-five million dollar criminal fine. And this case is really different from cases we've seen in the food safety contest in the past, because this involved the alleged adulteration of food while held for sale at Chipotle storefronts. And, you know, the charges stem from incidents arising at store level employees' failure to follow company food safety protocols. In particular, good hygiene and sanitation procedures. And again, there were policies in place preventing the employees from working when they were sick, but there are reports in this case of employees being pressured to work while sick, and there were outbreaks connected to food purchased from Chipotle that led to around eleven hundred illnesses. So typically, we think of restaurants as regulated by local authorities to inspect, and sometimes shut down restaurants when they fail to abide by these hygiene practices. But here we see FDA and DOJ asserting authority under the Food, Drug, and Cosmetic Act, and I think this is a fact pattern we may see again connected to national food chains. Here we have food ingredients that travelled interstate commerce, that are sent to these storefronts, where you have employees that aren't following protocols, and leads to the contamination of that food product, which is then sold. That's squarely within FDA's jurisdiction in the form of a 331-K charge. So, that's what we saw in that case, which I think is really important to keep our eyes on for similar cases in the future. And then there was another more traditional food safety case involving Texas-based Blue Bell Creamery, an ice cream manufacturer, which involved a guilty plea to two counts of introducing adulterated food into interstate commerce that was connected to contaminated ice cream linked to a 2015 listeria outbreak, and that also had a very large fine for food safety case. Seventeen million dollars; second, I think, only to Chipotle. So that's all I'll say about last year's enforcement.

2021 FDA Enforcement Priorities

Al: Let's jump to this year's highlights. I already mentioned that COVID fraud is going to continue to take front and center, and I was just talking about EUA overreach. So if you want to pick up there.

Beth: Yeah, for sure. I mean the easy cases, obviously, the low-hanging fruit are the clear fraud. You know the counterfeit products and products that aren't approved or authorized. But I think it's possible that we will start to see enforcement around products that do have a market to use authorization, but are used outside their conditions of use, or maybe authorizations that were based on fraudulent data. I think we'll see these cases to the extent problems arise. So if products aren't performing as labeled, if they're marked beyond the scope of what's permissible, and we see harm, that is where I think we are likely to see enforcement. I think that companies that have received significant federal money to scale up production with federal contracts are likely to be the highest priority targets in this space. I think there is likely to be a continued focus on products and conduct that threaten public safety and health in a material way. In more traditional areas of FDA enforcement: I think we will see more food safety; I think we'll see continued emphasis on opioids. Greg mentioned that inspections were way down this year because of the pandemic. As inspections resume, and FDA is able to see inside companies for the first time, I think we are likely to see increased enforcement in the G & P context. We are starting to see warning letters pick up. We just had a plea in a data integrity case that was an old one related to the destruction of documents in advance of an FDA inspection. It's possible we see more cases like that, I think as FDA inspects companies that had to, had deviations to their typical manufacturing processes and protocol because of the pandemic. I think FDA is going to be looking at how those were handled. Were products that could have been impacted appropriately quarantined? Was appropriate testing done to make sure those products were safe to enter the market? And were deviations appropriately recorded and investigated? I think another area we should keep our eyes on is regenerative medicine. There are two cases in litigation, two injunction cases: the U.S. stem cell case, and stem cell treatment of in America. I think there's a question to whether or not FDA and DOJ can win these cases based on existing rules governing HTCPs. If the government is successful, I think we will see similar enforcement actions in the future. I mean, we've seen plenty of warning letters. We haven't seen criminal enforcement, but I think we could be if these cases are successful. If the government loses, potentially we will see rule making enabling FDA to take enforcement action in this area. I think FDA is very interested in seeing real science based regenerative medicine products come to market, but there's a lot of fraud in this area. And I think the fraud is disincentive to companies who would otherwise be inclined to get to market legally. I think we've seen a growing number of clinical trial form cases. This needs to be a priority for the consumer protection branch. It's obviously critically important that FDA is able to rely on the data that's submitted, so I think this may be a trend that we continue to see, and it's a trend that impacts doctors, CROs, manufacturers. One note I'll just say on promotion, and you know Kellie talked for a little bit about promotion and the new intended use rule, I think companies need to continue to tread carefully in this space, because it does not appear that off label cases are dead. We continue to see off label promotion as a focus in false claims act cases. The First Amendment has yet to preclude enforcement under the FCDA. You know earlier this year, the District of Massachusetts upheld misbranding and adulteration convictions of two former device executives based largely on evidence of off label promotion. The cases are on appeal to the First Circuit. They may eventually land in the Supreme Court. It remains to be seen whether the government will have a pathway to prosecute companies that promote their products outside of their approved and clear uses when a case is prosecuted carefully, so that promotion is the evidence of the crime rather than the crime itself. So, you know, those are cases to watch. And in the meantime, I think, companies should be careful to stick to their labels and to promote consistent with those labels.

Al: Thank you, Beth. We have one question, which I will present to the panel. But before we do that, and before we move to the next panel – for those seeking CLE credit, you will need to fill out the attorney affirmation form that was included in your registration/confirmation email you should have received yesterday.

The CLE course code for this program is 6073. Again, that is 6073. Please email the completed form to professionaldevelopment@ropesgray.com. Again, professionaldevelopment, all one word, @ropesgray.com, or fax it to 617 235 9606, 617 235 9606, within 48 hours. I think we have one quick question, and we can hopefully answer it before we turn to the next panel. And that is: does anyone have any thoughts on the likelihood of FDA declaring an end to the COVID public health emergency? And, if so, what would be the implications of that declaration?

Greg: Well I'll start with that. The FDA doesn't, itself, have the authority to declare the end to the emergency. There are a couple different emergency declarations. The one that affects FDA is the one that allows FDA to issue emergency use authorizations, and so if the HHS secretary were to declare the emergency to be over, then that would certainly have an FDA. I think it's more likely that we're not going to see like a hard stop, you know, the emergency is over, everything is back to normal, at least anytime soon. But as I mentioned before, I do think, and we know, I think Kellie mentioned, I think the FDA has said they're working on a plan that where they're going to start phasing out some of the EUAs and some of the core transgression policies and things like that. So I think what we're likely to see is more of a wind down, rather than a hard stop for the emergency, at least anytime in the foreseeable future.

Al: That makes sense. So obviously the answer is, 'Stay tuned.' With that, people who have questions for the FDA panel, at the end you can still submit them in the Q&A, and we will try to get to them if we have time. With that, I want to turn over the program to my health care partner, Stephanie Webster, who will lead the panel on a discussion of issues related to HHS, CMS, and OIG. Stephanie?

PANEL 2: FOCUS ON HHS

Stephanie: Thanks very much, Al, and thanks to all of you for joining us this afternoon. And also, thanks to the panel for all of their insights on how the Biden FDA may look different from the Trump FDA. My name again, Stephanie Webster; I'm the partner in the health care group of Ropes and Gray in Washington, D.C. My practice focuses on litigation against the federal government. Our next panel is going to discuss likely changes the Biden administration may bring on other issues regulated by other key parts of HHS, especially the Centers for Medicare and Medicaid Services, and the Office of the Inspector General, or OIG. We're going to hear from Margaux Hall on drug pricing, Alex Talley on the wave of rules that came about at the tail end of the Trump administration, Christina Bergeron is going to talk a bit about compliance and enforcement relating to COVID 19 relief funds. But before all of that, we're going to hear from Tom Bulleit on a variety of hot topics. So, Tom to kick things off, last year at the Outlook 2020 teleconference, you discussed the Supreme Court postponing a decision on the Affordable Care Act until after the election. So we're after the election now. Where do things stand?

Affordable Care Act

Tom: Thanks, Stephanie. The smart money is that the ACA survives. As probably everybody who follows the ACA knows, the suit currently pending before the Supreme Court is *California v. Texas*, which was brought by Republican attorneys general to declare the Act unconstitutional because of the Congress having zeroed out the tax penalty for the individual mandate. The Trump administration joined that lawsuit. Based on comments at oral argument, it seems pretty clear that the Court is prepared to uphold the ACA, even if it decides that the individual mandate itself can't survive without a tax, because it will conclude that that provision is severable from the rest of the ACA. So most of what we've gotten used to as the ACA will continue: the exchanges, the subsidies for exchange coverage, Medicaid expansion, no restrictions on pre

existing conditions, no lifetime limits, children on their parents policies till age 26, and a host of other provisions, like the demonstration projects run by the Center for Medicare and Medicaid Innovation. But the Biden administration is likely to take a different approach to many of these issues than the Trump administration did.

Medicaid Expansion

Stephanie: Thanks for all of that, Tom. It would be great if you could expand a little bit more on what Congress and the Biden administration are likely to do with respect to Medicaid expansion.

Tom: You may recall that the ACA originally required states to expand Medicaid coverage to people with higher incomes that would be 95% paid by the federal match. It's dropped each year since 2017. It's now at 90%. But some states objected, and the Supreme Court decided that it was optional at the state level whether they were going to expand Medicaid or not. Currently 38 states and the District of Columbia have expanded programs. There's been speculation that Biden will work with Congress to increase federal matching funds again, and the COVID 19 package currently in the house would bring the percentage back to 95%. It's possible that red state governors could pressure Senate Republicans to go along. And there's also a possibility that this could be deemed budget related, in which case it would only take 51 votes, and therefore would pass the Senate without any Republican votes.

Medicaid Waivers

Stephanie: Tom, I know there are also some Medicaid waivers that have been controversial that the Trump administration granted. What is the sense on those?

Block grants

Tom: Right. For example: in January, the Trump administration approved Tennessee's Section 1115 waiver to allow an annual block grant. Block grants are a long time Republican Medicaid reform proposal, the idea being to give the states a fixed amount of money every year in exchange for fewer federal restrictions on how it's spent. This waiver will almost certainly be re examined under a Biden executive order, which, in part, calls on federal agencies to reexamine current policies, demonstrations, and waivers that may reduce coverage or undermine the ACA or Medicaid. And it seems likely that the Biden HHS will try to rescind that block grant.

Work requirements

They're also likely to target similarly controversial Medicaid waivers. For example, just this week the Biden DOJ reversed the prior administration's position on the Medicaid work requirement waivers previously granted to Arkansas and New Hampshire, and asked the Supreme Court to return those matters to HHS for reconsideration. Lower courts had found the waivers unlawful under the Medicaid law. The states appealed and the Trump administration sided with the states. The Biden administration has already changed position there. Whatever the result in these current cases, this is a strong signal that the Biden HHS is likely to rescind the work requirement waivers if they can, and won't be granting any more.

Rescinding waivers

The process for rescission of previously granted waivers is somewhat uncertain. While many waivers contemplate agency withdrawal of approval within their express terms, the agency rarely if ever invokes that

authority. Stakeholders have raised questions regarding the agency's authority and timing for withdrawing its approval of a waiver. The outgoing administration also took quite deliberate action to try to tie the new administration's hands, by signing so-called "letter agreements" with several waiver states, including Tennessee, to agree to a nine-month administrative process for withdrawal. Others, led by Senate Finance Chair Ron Wyden, believe that the letters are not binding, and that rescinding the waivers can be accomplished unilaterally by HHS. What seems clear is that if states resist a federal effort to rescind approval of a waiver, this may end up in court, in which case the short term will be dictated by whether the states win an injunction on enforcement of the rescission.

Affordable Care Act Exchanges

Stephanie: He got a taste of a lot of the hard issues, there were a lot of questions on the vaping and e-cigarettes, also issues like drug shortages, drug pricing, opioids, antimicrobial resistance, rare disease, CBD, OTC monograph reform. A pretty wide range.

Al: Do you think we learned anything from his answers to those questions?

Availability/Cost of Plans

Short-term and Association Health Plans

Stephanie: Okay, so let's turn to the availability and cost of health plans, Tom, if you don't mind. What does the new administration have in store for those ACA non compliant plans that received subsidies under the Trump administration?

Tom: In the long run, the Biden administration is likely to use the rule making process to reverse Trump policies that supported such plans. But as the pandemic continues, I'm betting that the process won't be a priority. There were two specific kinds of plans the Trump administration made eligible for ACA subsidies, though they don't have to meet the comprehensive "essential health benefits" coverage requirements. For short term, limited duration plans, the Trump administration issued a final rule in 2018 extending the term for these plans for a year, and allowing them to be renewable for up to three years. The other kind of plans are Association Health Plans, which are ERISA plans not regulated under state law; that historically were available only to members of associations, like an association of freelance writers, that had some commonality of interest other than that they wanted a cheap health plan. The Trump administration issued another final rule that many would say allows pretty much anybody to form an association for the purpose of getting cheap health insurance. In 2019, after the Trump administration released those two rules, the Congressional Budget Office estimated that roughly 5 million more people would be enrolled in an Association or a short term plan and that about a million of those would, otherwise, be otherwise uninsured over the next decade. Because these plans are not required to cover all ACA "essential health benefits," the new administration has already taken steps to scale that back. But I'm thinking that because of the pandemic, I don't think the Biden administration will be aggressive about trying to withdraw these plans in the short term, and may just wait to let the court challenges play out.

Premium Support Expansion

Stephanie: What about the cost of these plans, Tom? Do you see the Biden administration having specific plans either to bring down premiums, or at least slow down the increase in premiums?

Tom: Not much here, I'm afraid. One of the rules of health insurance is that premiums seem to go up every year. Biden's American Rescue Plan includes money to lower premiums by expanding premium tax credits to apply to costs of up to 8.5% of income, down from 10% currently. It looks like that will be part of the COVID relief package, and therefore could pass with just 51 votes in the senate.

AKS Safe Harbor/Stark Exceptions Changes

Effects on Drug and Device Makers

Stephanie: Okay, we now want to switch to AKS Safe Harbor/Stark Exceptions. The stated purpose is to allow a freer exchange of funds between health care industry players to facilitate so called "value based care." Tom, any ideas that you would like to share about how profound these changes may be? Perhaps starting first on the Life Sciences front?

Tom: Sure. There were two final rules issued at the end of last year; one for the Stark law, and one for the anti kickback law, both of which were designed to improve the ability to allow financial relationships that pay for quality, instead of quantity, of health care services provided. With respect to Life Sciences companies, these won't be of much help, because they specifically don't apply to drug and device companies.[1] There are other changes that have already been in process, such as Louisiana's subscription based model for purchasing Hepatitis C drugs. Even without those changes, that will probably continue. And there are changes that broaden the personal services safe harbor that'll facilitate agreements between Life Sciences companies, and physicians, and hospitals, and recent expansions of the warranties exception that will allow more of those relationships. But the big news probably would be in the area of health care providers, rather than drug and device makers.

Effects on Providers (e.g., Doctors, Hospitals)

Stephanie: Tom, could you talk a bit about providers and hospital doctor relationships in particular?

Tom: Here it is widely expected that these rules will make it easier for providers and hospitals to operate. That's because value based care probably defines what most providers are trying to do already: pay for outcomes, pay for results, rather than pay for the number of procedures that are performed. For example: the long standing practice of gain sharing, where hospitals share the financial benefits of reduced costs with doctors who perform procedures at the hospital, following certain protocols and using specific products, should now be freed up and may even expand because doctors who take post discharge responsibility and, thus, prevent re hospitalization, could conceivably be paid for such services in a safer way than they have been before. And the industry has been worried about gain sharing, as reflected in the several HHS advisory opinions over the years. So this is a real positive development for hospitals and doctors.

[1] Note: Drug and device makers are generally ineligible for protection under the new value-based safe harbors. However, certain device makers (that don't have reportable ownership under the Sunshine regulations, 42 CFR 403.906) are eligible to participate in a limited way as "limited technology participants" (includes device manufacturers that are "VBE participants," meaning they engage in value-based activities as part of a value-based enterprise–VBE participants can be all types of individuals and entities, but not patients) and provide "digital health technology" (no money, but hardware, software, services that electronically capture, transmit, aggregate, or analyze data and that are used for the purpose of coordinating and managing care, i.e., remote patient monitoring and telehealth) to VBE participants or VBEs. Also, drug or device makers could participate indirectly in value-based arrangements through wholly owned that qualify as value-based enterprise participants (85 Fed. Reg. 77684, 77716 (Dec. 2, 2020).

Stephanie: Thank you very much, Tom. Now we're going to turn to a different panelist, Margaux Hall, to discuss what actions might be taken on the prescription drug pricing front, which of course has gotten a lot of attention lately.

Prospects for Drug Pricing Legislative or Regulatory Actions Under Biden Administration

Stephanie: Thanks for joining, Margaux. First question: We saw a flurry of midnight drug pricing rulemaking under the Trump Administration, including some policy changes that would really dramatically alter the drug pricing landscape. Where do things stand now under the new Administration, Margaux?

Margaux: Sure. Thanks, Stephanie. And hi, everyone. It has been an exceedingly busy past five months when it comes to drug pricing regulatory reforms. There were several big changes that took many of us by surprise in the waning days of the Trump administration. And I'll talk about three, each of which has at least a somewhat uncertain future under the new Biden administration.

1. Most Favored Nation Drug Pricing

First, Most Favored Nation: in November 2020 the Trump administration released an interim Final Rule that intended to launch, as of January 1, a Most Favored Nation program that would tie the reimbursement rates for various drugs under the Medicare Part B program to lower prices paid in a fairly large set of foreign reference countries. That Interim Final Rule created alliances that are rarely seen when it comes to issues of drug pricing. Providers, patient advocacy groups, hospitals, health systems and pharmaceutical manufacturers aligned in expressing extreme opposition to the regulatory program. Four lawsuits were filed within weeks of the issuance of the Interim Final Rule challenging the Most Favored Nation program on procedural and substantive grounds. HHS was enjoined from implementing the Rule in multiple courts, with the parties in one case agreeing to stay the litigation until a Final Rule, based on that Interim Final Rule, is published in the Federal Register. So the fate of this Most Favored Nation program very much lies in the hands of the Biden Administration.

2. AKS Safe Harbor Reforms

Second, also in November, the Trump administration issued a Final Rule that would eliminate certain Anti Kickback Statute safe harbor protections for rebates negotiated with PBMs in connection with the Medicare Part D program. The PBM industry challenged that rule, which was slated to go into effect January 1, 2022. And under that lawsuit, implementation is delayed until January 1, 2023, pending HHS review. The court gave the Biden Administration until April 1 to decide whether it wants to defend the rebate rule in court. These reforms have generated a wide variety of questions among stakeholders, not the least of which are: what are the costs to the government and the Medicare program at large? And what are the potential costs to Medicare enrollees (with many individuals believing that this Final Rule, if put into effect, would result in higher premiums within the Medicare Part D market)? So, certainly, I expect that the Biden administration is going to revisit those actuarial and economic analyses as part of its rule review. And, at a minimum, we can expect to know by April 1st whether the administration intends to defend this Final Rule in court.

3. 340B ADR Process

And then last, but certainly not least, the 340B program has had more than its share of regulatory changes and, presently, regulatory uncertainty. In December, the agency finalized a rule to establish a long awaited alternative dispute resolution process for covered entities and manufacturers under the 340B process. To say

that that Rule was long awaited is really an understatement. HHS was required to establish and implement this ADR process pursuant to the Affordable Care Act, with a deadline of September 2010. HRSA did issue an Advance Notice of Proposed Rulemaking in September 2010, but the Proposed Rule didn't come out until six years later in 2016, and then, of course, we didn't see this Final Rule until this past December—more than 10 years past the statutory deadline.

So after that protracted history, the Final Rule arrived, but it did at the same time that multiple lawsuits were brought across the country, seeking to compel the agency to take action against drug manufacturers that limit 340B pricing for therapies that are dispensed through hospital affiliated contract pharmacy arrangements. At this stage, multiple lawsuits have been dismissed or stayed, as courts have instructed providers to first pursue their disputes through this new ADR process.

At the same time, from the other side, you have multiple pharmaceutical manufacturers that have filed lawsuits challenging an advisory opinion that contended that manufacturers must extend the 340B program discounts to these contract pharmacy arrangements. So, a lot of moving parts here. We can't be certain how the new Administration is going to view these multi faceted disputes. At least for now, though, it seems that the ADR process is going to be a gateway to certain types of disputes between covered entities and manufacturers.

Attorney General Becerra, Biden's nominee for HHS secretary, was part of a coalition of attorney generals that issued a letter to HHS asking the agency to address manufacturers' refusal to provide discounts to contract pharmacies. It's not clear to me whether that letter reflects his personal opinion. He artfully navigated around questions about contract pharmacy policy during his nomination hearing earlier this week. So, we'll have to wait and see. With so many lawsuits and this nascent ADR process, there are certain to be many more developments in the 340B space.

The Future of International Reference Pricing?

Stephanie: Thanks for all of those insights, Margaux. With the uncertainty of the Most Favored Nation program of the Trump Administration that you talked about; what approaches to international reference pricing are you envisioning as we move forward in 2021 under the new administration?

Margaux: I expect that we are going to have to contend with international reference pricing in some form under the Biden administration for a few reasons. First, the Biden administration is forced to deal with this head on as the Most Favored Nation program has been challenged in court, and it has to decide whether to defend that program. Second, international reference pricing was part of the presidential platform. The Biden campaign endorsed creating a review board that would use international reference prices to help establish the prices for newly launched specialty drugs. And Democrats, of course, have pursued their own version of international reference pricing in the Medicare program through legislative proposals over the past few years. So it's certainly a concept that has generated a lot of attention, both within Biden's immediate administration, and the Democratic party across the board. Finally, now that Democrats hold control of the Senate, President Biden can pursue more ambitious drug pricing policy on the whole, including with regard to international reference pricing. There is a caveat—that with the narrow margin that the Democrats hold, Democrats still are going to need to pursue policy approaches that have at least some level of bipartisan support in order to be able to overcome filibuster. I think it is very possible that there could be bipartisan agreement on a topic like international reference pricing. The topic has drawn interest in different forms from both sides of the aisle. But, even in the absence of legislation, executive orders and regulatory action remain on the table, within the

confines of the law. And I wouldn't underestimate those tools in Washington D.C. As those of us in this city know, with partisan politics and ongoing gridlock, agencies have become very powerful, and in some instances, even more powerful than Congress when it comes to critical policy making.

The Future of Supply Chain Intermediaries Like PBMs

Stephanie: Margaux, switching gears a little bit: what changes do you anticipate with respect to supply chain intermediaries, like pharmacy benefit managers?

Beth: Well, if the Final Rule that amends the Anti Kickback Statute safe harbors ultimately goes into effect, it will portend dramatic changes when it comes to PBM contracting in connection with the Part D program, and a fundamental realignment of certain portions of the pharmaceutical supply chain for Part D. The assumption of the Trump administration had been that those Part D program changes would have spillover effects to the commercial market, and would create potential downward pressure on prices and additional incentives to pass rebates through to patients at the point of sale. So, certainly something to watch there.

But in the meantime, the PBM industry is nimble and creative, and it continues to evolve in ways that potentially mitigate the impact of that rule, if it does go into effect, and/or preserve other revenue streams for PBMs and other entities within the PBM corporate families. There are evolving approaches that merit close business and legal attention by all actors in the supply chain – whether pharmaceutical manufacturers, payors or providers. And I'll give two examples.

First, we have seen the emergence of new intermediaries that are corporate siblings of PBMs – framed as group purchasing organizations, or other types of supply change intermediaries. There are live questions about those intermediaries' business model, and how that business model fits into the contracting landscape and the legal framework for drug pricing. Second, PBMs increasingly are pursuing white-bagging and brown-bagging through specialty pharmacies. This practice is disrupting the long-standing "buy and bill" practice for reimbursement of physician-administered drugs, and is creating living tension over who gets the margin when it comes to specialty drugs. So I think we'll see more developments, and more tension, around those types of issues.

Other Potential Drug Pricing Issues

Stephanie: Thank you, Margaux. As your time draws to a close, are there any other issues that you're tracking that you want to flag for our participants today?

Margaux: Sure. I'll briefly list four that have drawn attention, including, in some instances, during this week's confirmation hearings. First, I expect that there will be closer scrutiny of pharmaceutical manufacturers' competitive market practices, including potential increased antitrust enforcement activity. Second, there might be increased discussion about the potential use of march-in rights under the Bayh Dole Act, and compulsory licensing of drug products that are developed with government funding, and as part of that, questions about potential legal limits on those types of actions. Third, I'm closely watching the potential lifting of the Medicaid drug rebate cap under the COVID 19 relief bill that's moving through Congress. We've seen versions of the lifting of the rebate cap in other legislative instruments, but, given the procedural posture of that bill and the urgency around the COVID 19 relief measures within it, this is certainly a bill and a bill provision to watch. And fourth, lingering in the background is the Medicaid Drug Rebate program Final Rule from late last year that materially changes manufacturer obligations, including with regard to which drugs

qualify as line extensions, and how accumulator programs intersect with the price reporting exclusions for patient benefit programs. Those are all on my watch list, and I'm sure as time goes on, there will be many more to add.

Stephanie: Thanks again, so very much, Margaux. And now we're going to shift over to Alex Talley, also of the Health Care Practice here in DC, to discuss how the new administration and Congress can potentially undo Rules that were issued in the waning of the days of the Trump administration. Alex, tell us about that, please.

Congressional Review Act

Alex: Of course. Thanks Stephanie. And I think a lot of this piggybacks on some things Margaux just spoke about. I'll be talking specifically in the time I have about the Congressional Review Act, which is a law enacted in 1996 as a way for Congress to have a little more oversight over these rules from the various agencies that get issued. Generally, it requires that agencies submit rules to Congress prior to becoming effective, so that Congress can review them. And it also provides a mechanism by which Congress can actually introduce a bill or something called a "joint resolution of disapproval" that can ultimately overturn a particular rule. And the CRA takes a very broad definition of rules—not just those published in the Federal Register. It also looks at the core of what the policy is that the agency is doing, and whether it walks and talks and acts like a rule. Which can be important, particularly given the things that happened at the tail end of the last administration. But, procedurally, upon receipt of a Final Rule in Congress, it starts a clock which any member of Congress can introduce a joint resolution of disapproval. The time for which Congress has to review a rule: they get 60 days. If they did not get a full 60 days before the end of the session, the clock restarts when the new session starts. We had a new session start in January. And when they introduce a joint resolution of disapproval, it goes to the President for signature before it can overturn a rule. So normally this isn't used because a President in theory would never overturn his own regulation. But when you get this change of administration, you have the ability of a new administration with a Congress of his or her party, that has the ability to come back over top, and undo a regulation that was passed by the previous administration, and that's where we are now. This provision was used very sparingly in the first 15 years. I think it was only used once before, until early 2017, at which point the Republican led Congress, with the new Trump administration, overturned 16 different regulations that had been passed by the tail end of the Obama administration. Now we have the exact opposite situation. We have a Democratically controlled Congress, a Democratic President where we're seeing a lot of rules that came out of the Trump administration that they now have the ability to overturn through this mechanism.

Stephanie: So Alex, what HHS rules then could potentially be undone by the CRA? I wonder if you could just give us a little bit more detail on that?

Alex: Certainly. Just last week, actually, the tail end of last week, the Congressional Research Service came out and said that based on their math, it's any rule issued on or after August 21, 2020, which will touch on a bunch of different rules that Margaux and Tom both mentioned earlier. On the health care front, there's a lot issued in that kind of four to five months towards the end of the year. The first one that kind of comes to my mind, based on our practice, is that it includes the bigger annual Medicare Rulemaking Rules, such as Inpatient Prospective Payment System, which included a requirement that hospitals now have to report on their annual cost reports their negotiated charges with the Medicare Advantage plans, something the hospitals have been very upset about, obviously. But it's not just the Inpatient Prospective Payment, also included is the Outpatient Prospective Payment System, the home health system, the Physician Fee Schedule and the ESRD plan, just to

name a few that came out during that time frame. Another one, a separate, stand-alone rule is the Transparency in Coverage Rule, that requires group health plans and insurers similarly to make publicly available their negotiated rates, including an estimate of the particular individual's out of pocket costs. A lot of these too, now, I'm not saying any of these are likely or this is how the administration will go, but many of the ones that Margaux mentioned, the Most Favored Nation for Part D drug payments, anti kickback safe harbors for the Medicaid Drug Rebate, and the Alternative Dispute Resolution for 340B disputes, are all in this time frame. Another example is a rule that relaxed the requirements for group health plans and insurers to be deemed grandfathered under the Affordable Care Act. The last one I'll mention is, HHS issued something called the Good Guidance Practice. This attempted to consolidate all of its informal guidance documents and create a process by which interested parties could challenge those and say that they should actually have been regulations that went through notice and comment rulemaking, which falls within that time frame as well.

On the timing front: also, the Congressional Research Service—all of this is based on session dates, so it's a little fuzzy math, because it's not completely certain right now, but it believes that a member of Congress would have until early April as the calendar looks right now, in which to introduce a joint resolution of disapproval of any one of those various rules that came out of the agency.

Stephanie: So, Alex, talk to us a bit about what happens if Congress actually were to pass one of those joint resolutions of disapproval. Then what happens?

Alex: So, it only requires a simple majority in both chambers, which makes it a lot easier to pass, and then it would be like any other law, which I kind of mentioned earlier. Interestingly the legislation could be sent to the President only to be vetoed. But this would be a coordinated effort, that they wouldn't pass anything if the President wouldn't also sign. The agencies are also prevented from enacting a similar rule going forward that would, that there would be some wiggle room on what that means, if it was to go through and be overturned by the CRA. And finally, the CRA has a very broad preclusion of judicial review provision that prevents the actions of Congress being challenged by the courts, and it has been interpreted pretty broadly by a number of courts.

Stephanie: Well, that's unfortunate, Alex. But, anyway—I don't like those preclusion and review provisions. Thank you, Alex. He was cutting out a bit. I'm sure if you have questions about anything that he said, you could follow up with him afterwards. We are going to shift to our last speaker, Christina Bergeron, who is a newly minted partner in the health care group out of the Boston office who is going to talk about COVID relief-related compliance and enforcement activity. Christina, do you—How will the new administration's approach to enforcement on the provider relief front be similar to enforcement with respect to the paycheck protection program? Please share your thoughts.

Provider Relief Fund

Christina: Enforcement of the Provider Relief Fund is likely to focus on compliance with the terms and conditions of the program that each recipient attested to in order to retain the funds. Mainly three things: one, were the funds spent on COVID 19-related eligible expenses? Two, were the funds appropriately applied to losses related to patient care revenue? And three, were funds returned that could not be used appropriately? Now, importantly, unlike PPP round one, recipients haven't yet reported to the government regarding how they've used funds, and whether they need to return any of the funds. The first reporting period was supposed to be at the end of this month, and it's been delayed, to be determined. So, I think that enforcement is likely to

pick up after those reporting periods, and after the government has received that information. To give you an example, there is only one enforcement action related to PRF compliance that we currently know of, and DOJ brought—it was kind of an extreme case—DOJ brought criminal charges against a Michigan resident who received funds for a home health agency that actually [was] not operational during the pandemic. And instead of returning the funds, that individual used them for personal benefit. And so again, I think that, I think that it really will pick up in sort of the way that the PPP enforcement has once that reporting occurs. With respect to PPP enforcement—given how much farther along that program is, I mean, a lot of folks have already received forgiveness under that program. We've seen a lot more enforcement. I mean, to date, DOJ attorneys have prosecuted more than a hundred defendants in seventy criminal cases, seized more than sixty million in proceeds related to fraudulent use of PPP funds. You know, importantly and personally, given how close I am to both programs, I do think there is more room for fraud and abuse under the PPP program. The rules are a lot more strict on how the funds can be spent, and the sort of scope of who could apply was a little bit gray in the beginning, there were a lot of moving parts. So I do think that we are going to see a lot of focus in that program. And we will for PRF, as well, but I don't know if to the same extent, if you will, just because the eligible uses of the PRF funds are a lot broader; but to be determined. In the recent HHS/OIG work plans, PRF enforcement is listed as a priority to make sure funds were used appropriately, so I do think that we will see an uptick in enforcement after the first and second reporting periods, which likely will occur this year, if not early next.

Stephanie: Christina, I sense a lot frustration with the ever changing guidance on the Provider Relief Fund, and I wondered if you could speak to that, and, you know, offer any advice as to how folks are complying with that ever changing regulatory landscape.

Christina: Sure, I mean part of the frustration is that the new guidance typically comes out on Friday evening, so there are a lot of weekends spent catching up. I would say from a compliance standpoint, there are really some things you can do that will be key with respect to this program, and the ever changing guidance. Now, even though reporting hasn't occurred yet; because of financial reporting deadlines, companies have had to make some tough decisions without additional guidance as to how to use the funds, whether to return funds, et cetera. And so, what we have told clients is make sure you document very specifically for your file which FAQ you're relying on, whom you spoke to from outside counsel. Get emails from outside counsel regarding an outline of their advice, save that advice, along with the accountants you're working with, just to make sure you have a record of the position you took, and why. And I think that that's going to go a long way to sort of a good faith intent in trying to use the funds appropriately, and report on them appropriately. I also think it is very imperative to work closely with the accounting and finance departments in the organization to make sure things are being tracked appropriately. So how are we going to report ineligible expenses? How are we looking at losses related to patient care revenue, and if we have to provide documentation related to this, what are we showing? And making sure before the eleventh hour, if you will, that you sort of have that lined up because, internally, that can take some time to work through, and so that's what we're advising people. I will say, I do think the government's expectation will be that folks do keep up with the FAQs, if they receive these funds. In a way, keeping up with the guidance is part of ensuring you comply with the terms and conditions (which links back to enforcement risk). So I would say absolutely "head in the sand" is not the best approach with any of this. Keep an eye on the FAQs; especially as we get closer to reporting or you have to make a big decision from a financial reporting standpoint so that you will be in the know, and we've been advising a lot of clients on this. We're happy to answer any questions. We've been very much keeping up with it. Again, if

you call the hotline to confirm something—another thing that is good to document. They'll give you their name and last initial—write that down, when you called, exactly what was said, et cetera.

Stephanie: Christina–Go ahead.

Christina: I would say the three biggest issues I see with PRF in terms of enforcement are going to be: one, making sure that you apply the requirement of reimbursed from other sources correctly, especially as it relates to other government funding received. You know, a lot of folks who have received PRF funding have also received either FEMA funding, or PPP monies, or funding from somewhere else. And the government has made it clear that you can't double-dip with respect to eligible expenses. So that's going to be really key to make sure that you're doing correctly. Two: if you have an expense that doesn't fit one of the broad categories in the current guidance, I'd be careful about, you know, applying PRF funds towards that. The categories are quite broad in terms of what expenses, incremental expenses the government is defining as attributable to COVID, and so if you're not seeing an expense fits, I'd tread carefully, or get some guidance from either counsel or accountants, and sort of their interpretation and what they're seeing. And then, third: there's a lot of confusion right now about, if you're anticipating not being able to use all of the funds, what do you do? Do you return money now? Do you return money after reporting? Et cetera. You know, most of our clients are waiting until the final reporting period to make that call, which I think makes sense under the terms of the program. But I would say definitely keep that top of mind in terms of when you do that final reporting what the latest guidance is, and making sure you go through that process accordingly.

Stephanie: Thank you very much Christina.

CONCLUSION

Stephanie: It does look like that is all the time we have today. Some of you have sent in questions, and I would encourage you all to follow up with the speakers with your specific questions. I want to thank all of you for joining us today, and thank you to all of my Ropes & Gray colleagues in the FDA and health care group at Ropes & Gray. As Al mentioned at the outset of the webinar, we are offering CLE credit for this teleconference. For those seeking CLE credit, you will need to fill out the Attorney Affirmation form that was included in the registration confirmation email that you received yesterday. The CLE course code for this program is 6073. Again, that number is 6073. Please email the completed form to professionaldevelopment@ropesgray.com or fax it to 617 235 9606 within 48 hours. We will, collectively, of course, continue to provide additional news and analysis about regulatory and enforcement issues emerging from the new Biden administration throughout 2021. You can access that information by visiting our Capitol Insights page at www.ropesgray.com, and again, thanks very much and we hope you all enjoy the rest of the day.