February 10, 2022

Outlook 2022 – Washington D.C. Updates and Insights on Life Sciences

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Transcript

INTRODUCTION

Greg: Hello, everyone. I think we'll get started now.

We appreciate you joining our webinar today. I'm Greg Levine, chair of the life sciences regulatory and compliance practice group at Ropes & Gray, based in Washington, DC.

Today's program is part of our firm's Capital Insights series, where we provide our latest thinking on developments in the Federal government that affect our clients. Today we will be focusing on the outlook for regulatory and compliance issues in 2022, especially those of particular interest to life sciences companies. Our capital insights page is at www.ropesgray.com, and it includes alerts, analysis and podcasts. We invite you to visit that page throughout the year.

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Samantha Barrett Badlam
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Joshua Oyster
Beth P. Weinman

Moderator
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Joining me today are several of my colleagues from the DC office. In no particular order, Tom Bulleit and Margaux Hall, from our health care group, Kellie Combs, Beth Weinman, and Josh Oyster, from our life sciences regulatory and compliance group, and Samantha Barrett Badlam, with our litigation and enforcement group. Our format today will be breaking this large panel you see in front of you into three smaller panels, to talk about some discrete topics, and we do plan to try to leave some time at the end for questions.

If you have questions during the webinar, please submit them in the Q&A function at the bottom of your Zoom screen. We are going to try to get to as many of those questions as we can. One last housekeeping note: we are offering CLE credit for this webinar today, and I'll provide you with the necessary information to receive credit at the end of the webinar. There are additional supplementary materials for the content mentioned today that can be found in your confirmation email.

So with that, we have a lot to cover. We'll jump right into our first panel, which will be Kellie Combs and Josh Oyster to talk about some FDA-related developments.

PANEL 1: FDA LEADERSHIP

Greg: Kellie, why don't we start with you. Last year we did this program at this time and I embarrassed myself by predicting we'd have an FDA commissioner nominated by the end of March, and that was not even close, of course. So now we have a nominee, but tell us what's going on with this nomination, because it seems to have gotten a little more complicated than people thought. And then assuming Dr. Califf is confirmed, what kind of changes, or what might we expect under his leadership?

Kellie: Thanks, Greg, and hi everyone. So just yesterday, the AP described Califf's nomination as "stalled," and Dr. Califf of course is a cardiologist and clinical trialist who served 11 months as the FDA Commissioner at the end of the Obama administration. The confirmation hearing in the Senate health committee was all the way back in mid-December, but the full Senate hearing has not yet been scheduled. The last we're seeing in the press is the prediction of confirmation likelihood is seen as just above a toss-up. There are five key Democrats, including Senators Manchin and Sanders, who have expressed robust opposition to Califf's confirmation over his ties to industry and his prior track record with opioids. Other Democrats are just expressing more general uncertainty. Califf actually had some Republican support, a lot of Republican support in 2016; he was confirmed 89-4 back then. But now some Republicans are stating that they're concerned that Califf would become part of the Biden administration's "pro-abortion agenda," pointing to some recent changes made at FDA to allow the abortion pill to be delivered by mail following a telehealth appointment

that essentially relaxes some REMS requirements related to the drug requiring that it be dispensed in person. So what next? What are the implications of a failed vote? There's no indication yet that the White House has a backup option, or at least one that's been publicly floated. Obviously there would be an unavoidable delay, to the extent they'd need to start over with a new nominee at a time where strong FDA leadership is critical. Similar concerns have recently arisen actually in connection with the nomination of Samuel R. Bagenstos as the general counsel of HHS. That nomination also appeared to be stalled for quite some time. His committee hearing was in late October. The Senate just voted this week to allow the confirmation vote to occur for him in the whole Senate without committee actions, and we could see at least movement at the higher levels at HHS any day now.

Now, assuming that Califf gets confirmed, what will his priorities be? First, accelerated approval. So he has stated that he would take fast and strong action to hold companies accountable for providing scientific evidence required for accelerated approval products. He himself has described himself as a "fan of the process," but has expressed a lot of concern about the need for faster, better evaluation of these products once on the market. In particular, he's pointed to the creation of a real-world evidence generation system built on electronic health records, which could be leveraged more quickly to confirm risks and benefits of accelerated approval products, and in general he's a big proponent of real-world evidence. In fact, he mentioned that topic six times in his Senate confirmation hearing. Interestingly, he was previously the head of Clinical Policy and Strategy at Verily, which was formerly known as Google Life Sciences, so he's really seen as being able to bring a lot of expertise and industry perspective to the agency if he were to get confirmed. He has also expressed a lot of support for clinical trial reform, in particular, promoting increased transparency to patients as well as health care professionals, so that they can understand clinical trial outcomes and make informed treatment decisions.Finally addressing the opioid crisis was a priority for Califf during his original tenure at FDA, and is expected to be so again. He's been very firm in acknowledging that not enough has been done to stem the opioid pandemic, and he has committed himself to leading what he calls a "comprehensive review" of the opioid landscape at FDA, including a full review of product labeling.

FDA Policy Priorities

Greg: Okay, why don't we turn from FDA leadership to particular policy issues that will be of the greatest interest or highest priorities for 2022, and as part of that, maybe we can touch on how much we think the FDA will be continuing to have to focus on the pandemic, coronavirus and COVID-19 issues, versus its other work. Josh, why don't we start with you?

COVID-19

Josh: Sure, thanks Greg. I expect FDA will continue to focus in 2022 on how it can start to resume more normal operations in a world where COVID has hopefully lessened and the pandemic starts to move into the rearview. This is going to be most critical in two areas: first, how FDA deals with the inspections backlog that has resulted from COVID, and, second, how FDA manages the transition for various drugs and devices that have been marketed during the pandemic under emergency use authorizations (EUAs) and various enforcement discretion policies. With respect to inspections, in March 2020, the agency pressed "pause" on virtually all of its foreign and domestic inspection plans, and since then it's had difficulty returning to its pre-pandemic inspection cadence and volume, which has created a significant backlog in both foreign and domestic surveillance inspections. In the second half of 2021, FDA started to ramp up non-mission-critical inspections, and it looked like we were on our way to a state of normalcy. Then the Omicron surge happened, and that forced FDA in late December to again pause pretty much all non-mission-critical inspections. Most recently, FDA announced that as of February 7, this past Monday, the agency has resumed conducting domestic surveillance inspections for all product types, and the agency expects to resume prioritized foreign surveillance inspections beginning this April.

On the transition plan side for drugs and devices, in December 2021, FDA issued two draft guidance documents regarding devices that had been marketed under EUAs and enforcement discretion policies during the pandemic, and

these guidances' detail how these products will be treated once normal operations resume, meaning the end of the public health emergency (EUAs start to be terminated, guidances are withdrawn, etc.). For devices under EUAs, sponsors, if they do not wish to continue marketing their product, will need to cease distribution. If they do wish to continue marketing the product, they would need to submit an appropriate marketing application to seek clearance or approval. Or if their product was already cleared prior to the pandemic and some modification has been made, they would need to return their device to their previously cleared or approved state, as applicable. FDA stated in the EUA guidance that they would give at least 180 days' advance notice before a particular EUA declaration terminates, so they're giving some transition period there. It's a similar story and separate guidance that FDA issued on enforcement discretion policies where FDA anticipates a 180-day transition there and there are various phases to that. Unfortunately, we don't have time to get into all those details today, but there are a couple of common characteristics to be aware of from these two guidances. One was that FDA expects manufacturers of certain reusable life-supporting or life-sustaining devices, like ventilators and anesthetic gas machines, to notify FDA in advance whether or not they intend to submit a marketing application to continue distribution during normal operations. A second notable thing is that for manufacturers who are going to submit marketing submissions, FDA expects those to include what FDA describes as a "transition implementation plan," that would address already-distributed devices and what the manufacturer would plan to do in the event of a favorable decision on the marketing submission, in the the event of a negative decision on the marketing submission, and what that would mean for communications about products already in the field in distribution. It's important for manufacturers to start thinking about these things now for products covered by an EUA or guidance, because those products as a technical matter will become legally non-compliant upon a return to normal operations and the guidance being withdrawn or an EUA being terminated. Some of the expectations that they put forth in these draft guidances may be burdensome to manufacturers in that FDA may be requesting information that a manufacturer's not yet ready to provide, or a manufacturer may not yet have made the decision whether or not they intend to continue distribution. So it's important to think about these things now even though the pandemic's still going on, but hopefully we'll start to put it in the rearview and these policies will start to get effectuated. And with respect to drugs and biologics, there haven't been analogous guidances, but we have seen that vaccines and other therapeutics are moving from emergency use authorizations to full approvals as data become more available. We also saw towards the end of last year some interesting developments with respect to hand sanitizers, which had been a product where, earlier in the pandemic, there had been severe supply chain shortages. We couldn't find hand sanitizer anywhere. It was off the shelves. We couldn't find it at Costco, Target, Walmart—it was just gone. And what FDA did to try to facilitate manufacture of hand sanitizer was issue a number of enforcement policies to relax manufacturing requirements. But as supply issues have resolved and demand for hand sanitizers has somewhat returned to normal, FDA announced in October of last year that as of the end of last year, it was going to withdraw all those guidances, and so for those products that had been manufactured under those enforcement policies, FDA expects all of them to cease distribution by March 31 of this year. It's possible we'll see other policies like that for other product types. We'll of course continue to monitor those developments as the end of the public health emergency hopefully draws near.

Greg: Obviously this has been quite a disruptive event, to put it mildly, and it's unprecedented. The scope of what FDA has been doing is going to have a long tail. But hopefully FDA will, as you say, start to get more towards normal as this year goes on. Kellie, what about you? What do you think FDA will be focusing on as high-priority items?

Digital Health

Kellie: Let's start with a discussion of digital health. And I should say at the outset, we could spend an hour and a half just talking about digital health developments, so I'm just going to pick a few that I find particularly interesting.

The first is again related to real-world evidence. This is one of Califf's priorities, and as Josh will mention later, this is also a priority on Capitol Hill. And from September to December of last year, FDA issued four draft guidance documents related to real-world evidence. These guidance documents covered both general considerations, like how to support regulatory decision-making, as well as specific concerns relevant to individual data sources, like registries,

electronic health records, medical claims data, and so on. And out of those guidance documents as well as other policy development efforts, like a framework that FDA issued in 2018, there are some general themes that are emerging. The agency has highlighted the importance of collecting and using high-quality real-world data and real-world evidence that is fit for purpose, relevance and reliable. And the agency has repeatedly emphasized there is no single marker of what makes a good data set, and that it's always going to be context-dependent. So sponsors need to be thinking about how to address gaps in data, missing data, privacy issues associated with secondary use of data, and so on. The agency has also stressed the importance of not choosing analytical approaches or methods or data sets that are more likely to lead to a favorable outcome, and instead emphasize that companies should be approaching generation of real-world evidence much in a similar way as they would sort of clinical study design, with a protocol and statistical analysis plan. The guidances don't provide specific insight in the scenarios where FDA will or will not be willing to rely on or accept real-world evidence in regulatory decision-making. Instead, they emphasize repeatedly that sponsors need to be talking early and often with FDA when they're considering use of real-world data or real-world evidence to support a product application, so that they can get the agency's buy-in. More action in this space is certainly coming soon. I'm starting to hear it or have been hearing it for a long time from the clients that we work with, but FDA is also committed to progress this year. Among other things, the agency's committed to a pilot program to advance real-world evidence. The purpose of this is to identify approaches for generating real-world evidence that meet regulatory standards and also to promote consistent decision-making across various aspects of the agency and shared learning with respect to real-world evidence. I think we can certainly expect to see increased reliance on real-world evidence in product approvals with label expansions, particularly when paired with traditional trial data, as the agency has been working pretty hard to put that framework in place.

In addition to real-world evidence, the other digital health development to mention is that FDA has listed, at the top of its "A" list on the CDRH guidance agenda, the finalization of the clinical decision support software guidance, which is expected in 2022. This would finalize a draft guidance that was issued several years ago and revised just a couple of years ago. And statements by FDA officials and industry conferences suggests there's a really strong desire to provide more clarity in the final guidance, including by providing examples of what types of clinical decision support software would receive regulatory oversight, meaning full FDA review, premarket approval or 510(k) requirements vs. those that would get enforcement discretion and relaxed requirements. In particular, the agency is expected to flesh out when a tool informs or drives clinical decision-making. That's a distinction that's not clear in the draft guidance and is absolutely critical to regulatory classification. So again, as I said, lots to expect in the digital health space this year, but those are two that stand out to me.

Advertising and Promotion

Greg: What about in the area of advertising and promotion? I guess for either of you, Josh or Kellie?

Kellie: Yeah, I'll kick it off and then turn it over to Josh, because we work on a lot of these issues together. I'll start with just a brief discussion of warning and untitled letters. I think in 2022, there's nothing to suggest there will be different priorities from OPDP or APLB than what we've seen in years past. Past enforcement priorities include pre-approval promotion, minimization or omission of risk information, and false or misleading presentation of benefit information or risks, especially for products with a higher risk safety profile, like a boxed warning or a limitation of use or opioid products and so on. One of the notable untitled letters, though, that we saw last year from FDA related to a biologic/biosimilar issue. The letter was issued to a biologic manufacturer, reference product manufacturer. And FDA raised concerns in the letter with misleading comparative safety claims that FDA said might give HCPs the impression that a biosimilar was not as safe or effective as the reference product. And given FDA's focus on increasing access to generics and biosimilars, it will be interesting to see if we see more letters like this one emerge in the coming year. Josh, I know there have been some internal changes at FDA as well. Do you want to touch on those?

Josh: That's right, Kellie. In December, not too long ago, FDA announced the reorganization of the Office of Prescription Drug Promotion, OPDP. The reorganization creates a new division, the Division of Promotion Policy Research and Operations, within OPDP. FDA says that the reorganization is expected to provide enhanced support, oversight and direction to OPDP social science research program. As many of you may know, OPDP's research agenda has been very active in recent years, and we expect that will continue with the reorganization. FDA's announcement also mentioned how First Amendment jurisprudence developments in recent years are impacting the agency and explained that the reorganization will "provide additional support and increased focus on the regulatory counsel functions necessary to develop sound and legally supportable policy documents and surveillance activities."

Kellie: Speaking of the First Amendment, the other ad promo topic to touch on is the new intended use rule that FDA finalized in 2021. The final rule was the culmination of a nearly six-years-long rulemaking process, and the agency continues to assert very broad authority to consider not just promotional claims, but "any relevant source" in determining the intended use of a product. This is, of course, a concept and determination that comes up very commonly in off-label enforcement cases. Although the stated goal of the final rule was to provide clarity to industries, very significant questions remain regarding how FDA will apply the new rule in practice, particularly with respect to safe harbor communications, like scientific exchange, because there were some very concerning statements in the preamble from FDA to suggest that off-label speech, even if safe-harbored, could potentially be fair game in an intended use determination. Notably, even though industry groups had specifically urged FDA to carefully consider First Amendment impacts of revisions to the intended use rule, FDA essentially stated that the First Amendment issues were outside the scope of the rule, even though the rule does relate to speech regulation, and it doubled down on positions taken in the past, most notably in a First Amendment memo that FDA issued in 2017. Another development that's relevant both to the First Amendment and to intended use is the ongoing appeal in the First Circuit related to convictions of two former medical device executives, Facteau and Fabian, for off-label promotion. Oral argument in the First Circuit is expected in that case on March 7, so that will be one to closely watch.

Miscellaneous

Greg: Okay, I want to make sure we save a couple of minutes in this session to talk about legislative developments, because there's going to be some legislation this year for sure in the FDA area. Before we get to that, you guys want to do a quick lightning round? Any other key issues worth mentioning?

Kellie: So I'll just mention briefly, before I turn it over to Josh, action with respect to cell and gene therapy. There are a half-dozen guidance documents on CBER's guidance agenda related to cell and gene therapy, including guidance on CAR-T, gene therapy products involving genome editing, and voluntary consensus standards for regenerative medicine. FDA has also made a number of organizational changes within CBER to prepare for the influx of applications, INDs as well as BLAs, for cell and gene therapy products. So Josh, I'll let you take it over from here.

Josh: One that I'm watching—for many years now FDA has been promising to modernize and harmonize the quality system regulation for medical devices by updating the existing regulations in light of ISO 13485, which is the international consensus standard. This proposed rule is on FDA's agenda again this year.Maybe this will be the lucky year where we finally get to see it in print.

Legislative Developments

Greg: Okay, what about legislation. What are we expecting on the legislative front?

Josh: It's likely to be a very exciting year on the legislative front because FDA's key user fee programs have to be reauthorized by Congress before the end of the fiscal year/ This must-pass reauthorization has to come to fruition by the end of September. It generally becomes a Christmas tree for other FDA-related bills. They get hung like ornaments. So what can we expect this year?

The first and most likely candidate to get tacked onto user fee legislation in some form is the CURES 2.0 Act. As many of you know, the original 21st Century CURES Act was signed into law back in December 2016 and included a wide range of FDA and healthcare-related provisions. Over the past couple of years, legislators have been back at it, bouncing ideas around for a CURES 2.0. A bill was formally introduced into the House in November of last year, but has since been percolating in committee with no major movement. Among the many provisions of the CURES 2.0 Bill as proposed, it would establish new centers of excellence within FDA, including one focused on rare diseases. It would direct HHS to issue guidance on the use of real-world evidence in evaluating the safety and effectiveness of breakthrough drugs and devices and also establish a real-world evidence task force to coordinate HHS programs and activities with regard to the collection and use of real-world evidence. It would also ease post-approval study requirements for accelerated approval of products by enabling the use of real-world evidence to satisfy those requirements, and there's a plethora of other FDA and healthcare-related provisions in the proposed bill. Industry stakeholders do anticipate that this one is likely to get tacked on to user fee legislation, as I mentioned.

Another bill that may finally turn into law this year is the VALID Act that's been circulating for the last several years, which is a bill that would create a new framework for FDA oversight of laboratory-developed tests and in vitro diagnostics. It would create a new category of product called in vitro clinical tests. This is not a new bill by any stretch. It's actually the third iteration that's circulating right now, after drafts that had originally been introduced in 2018 and 2020. There's a strong sense that this might actually be the year it will pass, given the need for user-fee authorization, the impact of COVID-19 and the challenges with how FDA has regulated LDTs during COVID-19, further growth of precision medicine and then also the fact that one of the co-sponsors of the bill, Senator Richard Burr, is retiring at the end of 2022. We expect he'll want to try and get that passed before he leaves Congress. One important thing to note that came up recently in January, HHS provided technical assistance on the bill, meaning they issued a long memo with their views on the bill and support in drafting. Although they expressed a general sentiment of strong support, they raised concerns that the bill "does not strike an appropriate balance for risk-based oversight …. Key concepts that are foundational to the proposed framework have been modified in ways that raise public health concerns that may prevent the FDA from serving its mission to protect and promote public health with respect to in vitro clinical tests." While it does seem like there is movement that the VALID Act may get tacked on to user fee legislation, it's likely to be modified in some way from its current form in order to generate support from HHS. And so we'll continue to eye these as the year progresses. Congress has a lot on its plate right now with Supreme Court nominations and otherwise, but I think as we get into the summer and early fall, we'll likely see action on a lot of these initiatives.

Greg: Okay, great. Thank you Josh and Kellie. Don't go away because we have Q&A questions coming in, so we'll see what questions we get on FDA matters.

PANEL 2: DRUG PRICING & PRICE REIMBURSEMENT

Drug Pricing Reform

Greg: We're going to turn now to the second panel, Tom Bulleit and Margaux Hall. And here we'll be talking about drug pricing and device reimbursement and coverage issues and some other things as well. So Margaux, why don't we start with you. There were drug pricing provisions in the Build Back Better Act that unfortunately that legislation has come on some hard times. And so the president now has proposed to divide up that bill maybe into smaller chunks and try to move those through as opposed to the overall proposal. Do you think it's realistic that we'll see drug pricing reform by legislation this year, and if so what might that look like?

Margaux: The proverbial multi-billion dollar question is whether Build Back Better will be enacted in its current form. I think many people are cynical that will take place. I saw local trade press rebranding the bill as "Build Back Different," and that, ultimately, might be a more apt description of what we end up seeing. Most significantly from a drug pricing perspective, the current draft of Build Back Better would authorize Medicare negotiation of prices of certain high-cost Medicare Part B and Part D drugs. Legislators and regulators have explored the potential of Medicare drug price

negotiation for several years now. To date, the closest we've come to having the concept implemented was having a late-breaking regulation under the final days of the Trump administration. That regulation, the Most Favored Nation Interim Final Rule was subject to swift and fierce legal challenge by a somewhat unusual alliance of pharmaceutical manufacturers, on the one hand, and providers, on the other. If price negotiation is enacted through Build Back Better, we can expect considerable regulatory action that will be necessary in order to implement what are pretty broad, high-level contours set forth in the legislation in its current form. I expect that various stakeholders are going to closely scrutinize not only congressional action in this space, but, importantly, what happens with agency action in connection with any rulemaking, to consider potential legal challenges. We already have seen the spate of litigation that stemmed in response to the Most Favored Nation Interim Final Rule, and I would not be surprised if we had similar litigation if there is Medicare price negotiation. The other distinct possibility is Build Back Better is not enacted in its current form and we get some sort of a so-called "Build Back Different." And under that prospect, we could have certain provisions in Build Back Better remain, or else surface in other bills over the course of time. One topic that is in Build Back Better that I think has a good chance of resurfacing in some form is the concept of inflationary rebates in the Medicare program. That's a concept that has generated bipartisan support as both pharmaceutical industry "pay-for" and, seemingly, a penalty that only impacts those manufacturers that take the additional business step of increasing prices at a rate that outpaces inflation. That could be perceived as less punitive for the industry as a whole, especially in the wake of COVID-19, when we've seen the tremendous importance of innovation and not stymying incentives for robust innovation. And it could seemingly be a concept that establishes certain guard rails around drug price increases. Historically, we have seen other pharmaceutical industry "pay-fors" that surface over time in several bills and ultimately are enacted. A prime example is the lifting of the Medicare drug rebate cap that will go into effect in 2024. That was proposed in various forms for years and then ultimately was enacted as part of the omnibus COVID-19 relief bill. So could we see inflationary rebates surface in some analogous way? My magic 8-ball would say, perhaps yes.

Medicare Price Negotiation

Greg: And on the point about Medicare price negotiation, obviously that's the one that gets the really big headlines. If we assume that does not get enacted in legislation, is that the end of that, or are there other things that the administration might potentially look at doing?

Margaux: If that more sweeping drug pricing legislative reform doesn't garner that required bipartisan support, I expect there could be agency action and, specifically, demonstrations related to the concept of Medicare price negotiation. We've seen bipartisan interest in demonstrations that would test new payment models for Medicare, including the concept of the government negotiating prices. Absent legislative change, it's likely easier from a legal standpoint for the agency to pursue a demonstration in the Medicare Part B program. At the same time, we know that any agency action relating to physician-administered drugs under Medicare Part B is likely to be subject to significant scrutiny from many different stakeholders. There are real questions about the appropriate use of existing demonstration authority as its codified under statute. Can these demonstrations, for instance, be implemented on a grand nationwide basis, as was envisioned under the Most Favored Nation Interim Final Rule, or should they have a smaller scope in nature and really be about testing models and then refining them over time? And I think we might see the same alliances of pharmaceutical manufacturers and providers contesting drug price demonstrations that would altar Part B drug reimbursement, especially if they're seen as having substantive or procedural flaws.

Value Based Pricing

Greg: Great. Shifting gears a little bit, what about value based pricing? Do you anticipate significant developments in that area this year?

Margaux: CMS delayed until this summer, July 1 specifically, the implementation of the long-awaited multiple Medicaid best price proposal, given COVID-19 and operational factors. But that regulatory change, in my view, is very likely to go into effect. It's been popular; it's been less controversial. Many manufacturers seem quite eager to explore

use of that regulatory vehicle. Nonetheless, while we have a couple months until July, we still have many outstanding operational questions about how things will work. For instance, what will be the spillover impacts on other programs, like the 340B program, where pricing is reflective of the price points that are reported under the Medicaid Drug Rebate Program? What will be the impact on the Medicare Part B program and average sales price reporting there? When the rule goes into effect, it will be a pivotal moment for value-based pricing – a concept that's had various stakeholder's support for many years, but hasn't been implemented on a larger scale in the commercial market to date. And this rule alleviates some of the bigger constraints to value-based pricing that exist in the commercial market -- those have been these entrenched government price reporting issues. This addresses at least some of those issues.

Greg: Anything else? What other developments do you expect might occur this year in the drug pricing area that our clients and friends would be interested in?

Margaux: I expect we will see more regulatory and litigation action that probe the enormous complexity of the pharmaceutical supply chain in the United States. So more calls for additional transparency into rebates, into price concessions. We already have seen significant potential regulatory development in this space this year. A few weeks ago, CMS issued a proposed rule that, if finalized, would significantly redefine the way Medicare determines the so-called negotiated price under Medicare Part D. That's the price upon which patient cost sharing is based at the pharmacy counter. One thing that I find interesting and noteworthy is that many of the proposed drug pricing reforms over the past several years, if you scrutinize their details, don't have a direct nexus to patients and patient payments at the pharmacy counter and patient costsfor drugs generally. I think that's been a real deficit in many proposals that have been put forth. This proposed rule actually does have that nexus, for patients in the Medicare Part D program. It could significantly reduce patient out-of-pocket costs at the pharmacy counter. It also might result in higher premiums under Medicare Part D, so you could have shifting effects, in different directions, depending on particular patients and what their health profile is and how many drugs they're typically requiring in a given year. It's going to have diverse, pretty sweeping impacts if it's finalized: for different stakeholders – pharmacies, Part D insurers, PBMs, patients – it's an important rule. If anybody attending today hasn't checked it out, we did a deep dive into the contents of the rule. We have a client alert that we put out recently -- you can find it on our website – or if you email me I'm happy to provide a copy. The comment period is open, and definitely worth thinking about whether to weigh in and comment on that proposed rule.

I think we're also going to see litigation that necessarily has to contend with the questions about how drugs are reimbursed across the supply chain. We see examples of those questions surfacing in the federal government litigation regarding pharmacies and their usual and customary prices, as well as in the follow-on commercial litigation. Those are raising important questions about the complexity of the contractual structures that underlie pharmaceutical pricing and supply chain reimbursement. There's also dimensions of those questions that are in the active, on-going, heated litigation surrounding the 340B program and the future of contract pharmacies.

And, then, finally, not on the legal front, but market-access dynamics continue to evolve, and I think they will create calls for additional legal actions through legislation or regulation. There are three key market-access changes that I've been working on and will be closely following. I'll just touch on them, briefly. First, accumulators and maximizers and how to contemplate patient assistance programs in light of change in government price reporting obligations. What does all of this mean for patients and accessibility? Second, the advent of these so-called GPO's: Ascent, Zinc, and now Emisar, as well, and challenges and questions around contracting under those structures and government price reporting consequences. And, third, access changes that are prompted, at least, in part, by the tremendous integration and consolidation within the market, where you have payors, PBM's, specialty pharmacies as part of broad-based corporate families. We are seeing more mandatory white-bagging of specialty drugs – a shift away from buy-and-bill to white-bagging, and this shift calls for new approaches to contracting, and contemplating access strategy. These are all subjects that I've been working on, and that I'll be closely following. I expect that as those business models become commonplace, there will be more and more tension with the existing legal and regulatory structures.

Greg: Thanks, Margaux. Obviously, there's a ton going on in your area, so you will have lots and lots of things to be thinking about. Those are excellent insights for our audience. So, thank you so much.

Medical Devices

Greg: Tom, why don't we turn from the drug pricing, reimbursement, and coverage field to medical devices. You and I spent some time this year working on some of the changes that have been made in some of the Medicare coverage and innovative technology programs. You want to talk about that?

Tom: Sure. This is something that was going to be a big deal, is currently not a big deal, but is likely to become a moderately big deal, again, whether it's this year or sometime in the future. So, the MCIT program was proposal from the Trump CMS that would have allowed breakthrough medical devices to receive Medicare coverage at the point of FDA approval. The way things currently work, that doesn't happen. Historically, once a device is approved by FDA as safe and effective, it has to cross another hurdle in the Medicare world, it has to be reasonable and necessary for the treatment or diagnosis of illness or injury, or improve the functioning of a malformed body member. And, since those are different standards, the Medicare process has not historically tracked what FDA does. So, once a device is approved, it either has to be subject to a national coverage decision, which CMS does; a local coverage determination, which is done by Medicare carriers that administer the program, regionally; or, a claim-by-claim analysis: a claim goes in for a procedure that was performed with a device, and then they have to make a decision about whether they are going to pay it, because it's reasonable and necessary. And, there's, historically, reluctance in the private payor world to pay for things that Medicare is not paying for. So, there's often a couple year gap between the approval of a device and broader coverage for procedures that are preformed with that device. Over the Summer, the Biden CMS has seen this, postponed the Trump administration rule and, then, in the Fall, it finally repealed it.

So, now, we are back to the *status quo ante*: FDA approved devices still have to make reasonable and necessary showings to payors. There are several problems with that system that, historically, we've been dealing with, as lawyers for device companies for a long time, and it's probably worth mentioning that, in addition to not having access to new technology that might benefit patients, companies that try to engage in various workarounds to get their devices covered, face a number of legal challenges. We talked about this in our November podcast, but the CPT and HCPCS coding systems often have no place to go for a new device. Sometimes a device fits comfortably in a category but sometimes it doesn't. So, one hurdle is, once you get your device approved and you are looking for coverage, you also have to go to the AMA, or to the CMS division that handles HCPCS codes to find yourself a new code.

Other strategies that device companies follow have compliance issues.

So, there are evaluation devices: the AdvaMed code of ethics for interactions with healthcare professionals says you may provide a free device to a user to allow them to see if they like it for a reasonable period of time to let them evaluate it. The Sunshine law essentially defines reasonable period of time as 90 days, because that's the period during which manufacturers do not have to report that transfer of the free product as a payment or other transfer of value. But, free devices inevitably present kickback issues. That was the subject of the Olympus settlement a few years ago. And, there's also a risk that the manufacturer will get blamed for failing to report, under the Sunshine law, if they provide the evaluation device.

A couple of other strategies that companies use are warranties, which can be provided directly by the company. Or, actually, I have dealt with come clients that have worked with an insurer to provide an insured warranty for a product's performance. Or, rebates. Both of those are limited to the cost of the product, but it's a way of providing the customer with some opportunity to use a product without assuming all of the risk associated with non-coverage. There are compliance issues, there. There's guidance from the OIG, that is many years old, that companies are not allowed to provide so-called reimbursement guarantees to get customers to buy their products. And, one way of thinking about the

evaluation device or a free device is that when you are offering a non-payment rebate is that you are offering reimbursement guarantee. The contrary argument is a rebate is a rebate, and it doesn't matter if it's triggered by a non-coverage decision or not. That remains a gray area but it's one that this rule, if it were finalized, would have addressed, in some way. It would've reduced the necessity for dealing with those kinds of issues. So, I think it would've been a step in the right direction, but it wouldn't have solved all of the problems.

Greg: Well, it didn't happen. So, they repealed that ruling, and I guess industry is now back facing all these same challenges they've faced for years and years. So, is this issue dead, or is there any indication of what might happen?

Tom: Yeah, I don't think it's dead. A group of sixty Representatives sent a letter to CMS in the Fall saying they were disappointed in the result, CMS has not ignored that. They're having listing sessions on February 17th and March the 31st to get stakeholder input. And, since CMS's goal was to make sure that these devices are safe and effective for the Medicare population, which is underrepresented in clinical trials,a pathway forward here might be that the subsequent rule would allow coverage as of the time of approval but require post-approval studies to validate the approval.

Greg: Great. Anything else that you'd like to touch on that would be of interest regarding medical devices?

Tom: Yeah, just a couple of things.

The CMMI, the Center for Medicare and Medicaid Innovation, as a part of its 2022 value based design model request for applications, invited Medicare Advantage organizations to include in their bids FDA devices that don't fit into an existing category as a supplemental benefit. So, it's kind of encouraging the Medicare Advantage world to be granting coverage before Medicare Part A or Part B, grant coverage. In Medicaid plans,, Medicaid programs to do the same thing and Medicaid managed care organizations might offer coverage for devices that are not yet fully Medicare-covered.

There's also an interesting enforcement case that is specific to devices. There was a $16 million false claims and Anti-kickback Law settlement involving Arthrex, which makes orthopedic implants. The allegations were that the company's payments to a physician of royalties for intellectual property, contributions to some of its products were, in fact, kickbacks. Now, that sent a chill through the orthopedic implant industry where royalty agreements to physicians positions in exchange for their IP are commonplace. And, Arthrex got people wondering if the winds at and OIG and DOJ have changed.

Greg: Well, do you think they have?

Tom: My best guess is no. The circumstances here kind of make this an outlier. Arthrex didn't agree to any of the allegations, it just settled to move on. But, there were a couple of things that make this sound like, at least as alleged wasn't a standard IP agreement. First of all, the allegation was that the payment rate was at a higher percentage than the company's ordinary royalty practice. And, secondly, the facts were that the company had initially refused to pay royalties, and then, several years later, decided that they would. Which kind of suggests that they had made the decision that the doctor didn't deserve a royalty and then, when the doctor threatened to take his business somewhere else, they may have changed their minds. So, those are all things that might have made a difference and led to enforcement here, where it wouldn't have, in a normal royalty case. But, certainly something that we're going to be watching very closely.

Greg: That's an excellent bridge to our last topic, but we've gotten a question for Margaux that maybe we should just clear up now as opposed to later. Margaux, that question is about the definition of "white-bagging", if you could just explain, very briefly, what "white-bagging" is?

Margaux: Sure. So, white-bagging is when a drug is dispensed by a specialty pharmacy, typically sent directly from the specialty pharmacy to a provider to administer. This is in the context of position administer drugs. So, displacing

buy and bill, physicians would only bill for the cost of administration of the drug, and instead having specialty pharmacies actually dispense the drug. You know, procure and then submit for reimbursement for the drug. As a consequence of that, the drug typically shifts to the pharmacy benefit, as compared to the medical benefit, which can have implications that could go in either direction, it could be favorable or unfavorable, just depending upon benefit design. Because, patients are getting this now as a pharmacy benefit drug, even though it's a physician administered drug. And, really important business implications because any of the margin that might be available on a physician administered drug, therefore accrues to the benefit of the specialty pharmacy, as compared to a physician under buy and bill.

Greg: Okay, thanks Margaux. Now, back to where we were. We will go to our next panel, so thank you very much Margaux and Tom. We will back to you with questions, later.

PANEL 3: ANTICIPATED SHIFTS IN ENFORCEMENT PRIORITIES

FCA Enforcement

Greg: Beth and Sam, we've gone a minute over. We'll give you time back at the end, here. But why don't we get into what you two see as the government's likely enforcement priorities in the coming year, and any key issues or trends that we should be aware of.

Sam: Thanks, Greg, I'll kick us off. So, Tom mentioned that Arthrex case, which involved alleged False Claims Act violations. We expect continued robust activity in the FCA enforcement space. In fact, the Department of Justice recently released its latest False Claims Act statistics from fiscal year 2021 and approximately 90% of all FCA cases in 2021 focused on the healthcare industry, specifically pharmaceutical and medical device companies, hospitals, labs, pharmacies, and DOJ recovered approximately $5 billion in damages from these cases. I'll note that the recovery does include the $2.8 billion settlement with Purdue to resolve DOJ's criminal and civil investigations into the opioid manufacturer. While these numbers may not be that surprising because healthcare enforcement cases have been the predominant focus of FCA actions for years, this is the first time that health cases really have so thoroughly dominated the FCA enforcement landscape. And, in 2021, there were a higher number of DOJ initiated cases than previous years, with 203 out of 801 FCA cases being DOJ initiated. I think it's an open question whether DOJ can sustain this level of recovery in 2022, given the large opioid recoveries in 2021. But, the past year's focus on healthcare cases suggest that life science companies should be increasingly diligent about avoiding violations that could lead to FCA inquiries.

Anti-Kickback Statute

One area of particular concern for FCA liability is the Anti-Kickback Statute, as the government continues to read the scope of the AKS incredibly broadly to encompass a broad array of activities. Tom mentioned the Arthrex case that involved royalty payments to a surgeon, and less than two weeks ago, on January 31st, the U.S. Attorney's Office for the District of Massachusetts announced that Cardinal Health agreed to pay over $13 million to resolve a False Claims Act case based on allegations that it had violated the AKS by providing upfront discounts to its physician practice customers. Discounts to customers are a common practice, but, in this case, the government alleged that the discounts were not attributable to identifiable sales or were not tied to purported rebates customers had earned. Also, in December of last year, Flower Mound Hospital Partners, which is a partially physician owned hospital, reached an $18.2 million settlement with DOJ and the State of Texas to resolve allegations that it had violated the FCA, the Medicaid Fraud Prevention Act, the AKS, and the Physician Self-Referral Law because the hospital allegedly considered physicians' referral histories when determining who could purchase shares and the volume of shares offered in the hospitals.

In addition to examining payment arrangements, DOJ has continued, and will likely continue, to focus on incentives provided to physicians, like meals, entertainment, events, and free products and services. This area has been a focus for many years, but we're seeing a resurgence in these cases. In 2021, in particular, there was a matter that involved alleged

kickbacks in the forms of all-expense-paid invitations to sporting, recreational, and entertainment events. And, at the end of 2020, Merit Medical settled a matter for $18 million related to a local advertising program that provided free or subsidized advertising to providers.

Along the same lines, we anticipate that DOJ will continue to focus heavily on HCP engagements, specifically kickbacks related to speaker programs. As most on this call are likely aware, in November 2020, OIG issued a Special Fraud Alert on Speaker Programs, which indicated that certain speaker program characteristics are inherently suspect under the Anti-Kickback Statute. In reaction to the Special Fraud Alert, the Pharmaceutical Research and Manufacturers Association of America revised its code on interactions with HCPs, and the revised code took effect on January 1, 2022. The revised PhRMA Code does not address every concern articulated by OIG in the SFA, but it reflects a response to several key concerns that are likely to affect important aspects of how speaker programs will be run and the revisions indicate that the industry is taking the SFA seriously, which is a positive development, as this area is likely to be a focus of DOJ in 2022 and beyond.

I have a couple of quick additional points on AKS enforcement before I turn it over to Beth. With patient support services, we've seen enforcement activity related to independent charity patient assistance programs that help patients access their medicines. Those cases are really winding down, at this point, although there were some additional settlements in 2020, but we still expect DOJ to focus on benefits provided to patients as opposed to just physicians. In fact, in August of last year, Arriva Medical and its parent company agreed to pay $160 million to resolve FCA allegations based on a theory, in part, that they paid kickbacks by providing free glucometers to Medicare beneficiaries and waiving or not accepting their copayments.

One other area that also presents a kickback risk is electronic health records and digital programs. Kellie was talking about this topic earlier. In 2020, Practice Fusion, a health records technology developer, reached a $145 million settlement with DOJ for allegedly soliciting and receiving kickbacks from pharmaceutical companies in exchange for sponsoring certain clinical decision support tools that the government alleged were not consistent with best practices. In February 2021, DOJ did reiterated that misconduct relating to the EHR industry is a priority for DOJ's FCA enforcement efforts. We do expect more activity in this area as the digital health industry becomes larger and increasingly collaborates with the life sciences industry. Beth, I'll turn it over to you to discuss another FCA risk area.

Beth: Sure. Just, you know, there's a lot of different types of risks that we can be talking about in the context of FDA regulated products. But, to stay in the context of the False Claims Act, I'll just take a moment to discuss risk associated with pandemic-related products. I think for the last two years we have seen a ton of enforcement action against sort of quack COVID cures. The low-hanging fruit type easy case, but I think we are likely to see the government's sights expand to more complex cases in the coming year. With the significant sums of money the government has earmarked for and distributed for COVID-related vaccines and therapeutics and other pandemic-related products, I have no doubt the government will be looking to make sure the beneficiaries of research and development funding and significant government contracts are living up to their compliance commitments that are detailed, outlined explicitly, in those funding contracts. So, these kinds of compliance lapses can expose companies to False Claims Act liability, as well as, sort of, more standard FDCA liability. I'll just note, we have seen public disclosure of subpoenas in connection with at least two entities: one involved in manufacturing COVID treatments and another with making the drug substance used in certain COVID vaccines. And I will not be surprised if we see more investigations like this that pose both False Claims Act and other criminal enforcement risk.

Clinical Trial Fraud

I'll also take a moment to focus on another high priority area for FDA and DOJ, and that is clinical research fraud. Over the past two years, DOJ has been very busy indicting or settling criminal cases with defendants associated with contract research organizations in Florida, Ohio and Tennessee allegedly involved in data fabrication in clinical trials. The

defendants in those cases range from owners of the CROs and primary investigators, to sub-investigators, project managers, coordinators. In these cases, the charges have run the gamut, also, from conspiracy to commit mail and wire fraud, to false statements, conspiracy to defraud FDA and failure to maintain adequate records under the Federal Food Drug and Cosmetic Act. Several defendants have pled and been sentenced and those sentences have not been insignificant. I'll note that DOJ Deputy Attorney General Arun Rao made it very clear that prosecuting such cases will continue to be a priority for DOJ in a speech he gave in December, and he's promised to bring more enforcement actions in coming months. In light of DOJ's attention to fraud in clinical research and FDA's obvious concern about how such fraud impacts product submissions and approvals, I think we'll likely, we're likely to see continued cooperation in this area. And I'll note that the spotlight, to date, has been on CROs. But, I think we can expect that focus to move away from CROs, at some point, and to those who are engaging them. And these CRO cases have been criminal cases, but those engaged in federally funded research also face other risks, including False Claims Act risks. Sam, do you want to jump in with some other priority areas?

Foreign Influence

Sam: In addition to the False Claims Act risk with research misconduct, I did want to mention another area, which is foreign influence. Foreign influence cases typically arise when an investigator utilizes U.S. federal funds for their research while also maintaining undisclosed affiliations with other international institutions or universities, or when investigators inside commercial entities have undisclosed ex-U.S. affiliations that lead them to share their employer's technology without authorization. DOJ views such undisclosed relationships as problematic because they can potentially lead to investigators double-dipping by receiving both federal and foreign funds, as well as transferring to foreign institutions proprietary information funded by the U.S. and by U.S. companies. DOJ has increased its focus on foreign influence cases in recent years, including through the launch of its China Initiative in 2018 to counter economic espionage and trade secret theft by agents or operatives, specifically of the People's Republic of China. These cases can result in a number of different criminal charges against individuals, such as false statements, tax evasion, economic espionage, various customs violations, and, of course, theft of trade secrets, and they can be very burdensome for universities and companies.

FCPA

While we're talking about foreign parties, Beth, I do want to mention, briefly, FCPA enforcement. There were a number of enforcement actions involving life science companies in 2020, but 2021 was relatively quiet with respect to FCPA enforcement, which, really, is typical during a change in administration. But, importantly, the Biden Administration has announced that countering corruption is a "core United States national security interest," and DOJ has signaled that corporate criminal enforcement is a top priority. With the backdrop of COVID-19, which brings inherent fraud risk as governments make large purchases from private companies, and the global and highly regulated nature of the life sciences industry, life sciences companies are likely to be a target for the increased anti-corruption efforts of the Biden Administration.

FDA Inspections

Beth: I'll take a moment now to talk about two more topics. One is sort of standard, traditional FDA regulatory enforcement. As Josh noted, there has been a real pause in FDA inspections until this week domestically. And, for that reason, GMP regulatory enforcement, in terms of warning letters and the like, has been down over the past two years. But I think as FDA resumes inspections, we are likely to see more 483s, more warning letters, and potentially more judicial enforcement – injunctions and criminal prosecutions – flowing from that. I also note that DOJ has never stopped bringing criminal cases that rely on underlying FDA regulatory violations. So, while we may be prioritizing, and I'll talk in a moment about the focus still being on opioids and we may be focusing on clinical trial fraud and there may be a sort of issues du jour, there is always a likelihood that, if there is a sexy FDA regulatory case that can be brought criminally, or through the False Claims Act, DOJ will do that, whether that is due to GMP violations, reporting lapses, products that

are misleadingly labelled. I think what really turns a straight-up regulatory case into a criminal case has to do with transparency or lack thereof; whether there is a lack of transparency during inspections, or in submissions, or with respect to product labeling and transparency with consumers. That is really what brings an ordinary, run-of-the-mill regulatory case into a potentially criminal one. So, I think firms should keep in mind the critical nature of transparency.

Opioids

And, I think the last topic I'll talk about is, and maybe could have been the first, is opioids. Right, I mean… This is clearly still a significant DOJ priority. We are still very much in the throes of the opioid crisis and the government is still looking to take enforcement action against anyone they believe is permitting highly addictive prescription drugs to be diverted into the hands of abusers. The government has been extremely aggressive in this area and I think is likely to grow even more aggressive, building on recent successes. I'll note one recent case. Just about a week ago, the former CEO of Rochester Drug Cooperative, a major opioid distributor, was convicted at trial in the Southern District of NY of narcotics conspiracy based on allegations that he conspired with others to ship large amounts of opioids to those he allegedly knew were dispensing them to dealers and addicts. And he was also convicted of conspiring to defraud DEA based on decisions he allegedly made not to investigate or monitor, or report to the DEA pharmacy, customers that he and others knew were diverting controlled substances for illegitimate use. This case was touted by the prosecution team as a first-of-its-kind prosecution where a corporate CEO was prosecuted on charges that are typically reserved for street-level drug dealers. And based arguably on underlying regulatory violations, so this marks, I think, a big change, and I don't think that will be the last time we will see these charges brought against a corporate executive.

I will also note that DOJ has been aggressively pursuing health care providers in connection with inappropriate prescribing, and the Supreme Court is about to hear two consolidated cases brought against physicians with respect to prescribing outside of the usual course of medical practice in violation of the Controlled Substances Act and applicable DEA regulations. Those cases are consolidated US v. Kahn and US v. Ruan, and they are slated for oral argument in March. They raise the question of the state of mind required for a jury to convict a prescriber under these provisions,whether or not a good faith defense is available and would negate the required intent, and what the contours of such a defense should be. And you know, how the Supreme Court rules in these cases, I think, will be very important to future charging strategies both against providers as well as corporate employers of providers, so a decision in this matter is really one to watch, and it will be a decision that is important for HCPs to study. That case is also very important to DOJ's massive civil monetary penalties action against Walmart, which is currently on hold until the Supreme Court decides Kahn and Ruan. That case is based on allegations around pharmacists knowingly filling prescriptions not issued for a legitimate medical purpose, in addition to failures to file suspicious order reports. So, Sam, I am going to turn things back over to you.

Cybersecurity

Sam: We have covered some of the highlights, and the one we didn't talk about was cyber security. DOJ did announce a new civil cyber fraud initiative, using the False Claims Act to pursue cyber security related fraud by government contractors and grant recipients. But I think in the interest of time, I will turn it back over to you Greg.

DOJ Policy

Greg: Why don't we talk about whether there have been policy changes at DOJ that would be of interest to our clients, anything folks should be aware of?

Sam: It's a great question. Deputy Attorney General, Lisa Monaco gave a speech in October 2021 in which she announced important changes to DOJ's corporate criminal enforcement policies and I would like to mention two of these in particular. The first change in policy relates to individual accountability and cooperation credit. In her speech Deputy AG Monaco affirmed DOJs focus on individual accountability, emphasizing that it is DOJs first priority in corporate

criminal matters to prosecute the individuals who commit and profit from corporate wrongdoing. Consistent with prioritizing individual accountability, she directed DOJ to restore previous guidance, making clear that to be eligible for corporation credit companies must provide DOJ with all non-privileged information related to individuals involved in or responsible for the misconduct at issue, regardless of that person's position, status or seniority. This represents a change from the previous policy which gave companies some discretion to limit disclosures to individuals they found to be substantially involved in the relevant misconduct. The second policy change that I would like to mention relates to consideration of a company's history when determining an appropriate resolution of a corporate enforcement action. She announced that all prior misconduct needs to be evaluated when determining the proper resolution with a company regardless of whether the misconduct is similar to the conduct of issue in a particular investigation. To elaborate on this, Monaco directed that prosecutors should consider the full criminal, civil and regulatory record of a company when deciding how to resolve a criminal investigation and not just a narrower subset of similar misconduct. So now prosecutors will take a department-wide view of misconduct and will also look at whether a company has been prosecuted by another Country or State and whether it has a history of involvement with regulators. I think it remains to be seen how prosecutors will put these policies into practice, but these announcements in October 2021 suggest that companies should expect more aggressive investigations, prosecutions and punishment of corporate crime.

Beth: I'll just talk about one more, maybe not as sort of earth shattering as some of those recent policy changes, but one that I think could have a meaningful impact on life sciences companies, and that is a July 2021 memo that Attorney General Garland issued that reversed prior policies of former AG Jeff Sessions and former Associate Attorney General Rachel Brand regarding the issuance and use of agency guidance, both within DOJ and as part of enforcement actions. These policies had precluded DOJ from issuing binding guidance documents without undergoing a notice and comment rule-making process, and maybe more importantly for our purposes, it strictly limited the use of regulatory agency guidance in enforcement actions. And while we all know enforcement based solely on non-binding agency guidance is never appropriate, the Garland memo makes it clear that there is potentially a role for guidance in enforcement actions and that the government and the prosecutors can rely on such guidance when, you know, it makes sense to do so in enforcement actions; when such guidance may be entitled to deference or persuasive weight with respect to the meaning of an applicable legal requirement, and when such guidance documents might be relevant to claims or defenses in a litigation. So, I think we should expect to see greater use of guidance in enforcement actions in the future.

Prosecution Strategies

Greg: I think we have just a couple of minutes left and I know you guys had some thoughts, perhaps, either on prosecution strategies we should be aware of or best practice tips for companies. You have the last couple of minutes however you prefer to use them, Sam and Beth.

Sam: I would just say that companies need to be diligent in their compliance with all federal statutes, as prosecutors can bring charges like mail fraud, wire fraud, tax invasion, and false statement charges, even when they may not be able to charge the underlying problem. A good example is in August of last year, DOJ brought one of the largest Medicare fraud cases in its history, alleging that the owner of a telemedicine company orchestrated a healthcare fraud scheme that involved submitting over $784 million in false claims to Medicare. The defendant was initially charged with conspiracy and kickback charges, however, the grand jury later issued a superseding indictment charging the defendant with a count of conspiracy to commit healthcare fraud and wire fraud, and then also four counts of income tax evasion. So my advice is that companies consider other federal statues that may be implicated by the conduct that may not be potentially obvious from the face of the conduct.

Beth: I will just note that conspiracy charges are a big risk for highly regulated companies. I mean, we see all the time there seems to be a favorite strategy of DOJ, to pull regulatory violations into a narrative of conspiracy, whether that is conspiracy to commit the underlying regulatory violation, like a Food, Drug, and Cosmetic Act violation or a conspiracy to defraud an agency or deprive it of its regulatory authority, and we see that all the time. We saw that in the Doud case,

we saw that in the NECC cases, Vascular Solutions, in Facteau and in many, many other cases. We see this kind of strategy, and, you know, it's a question why we keep seeing this, and I think it is a theory of choice for many reasons: the inclusion of allegations that can be highlighted as overt acts when they couldn't be charged on their own. Conspiracies allow the government to try and reach back and involve conduct beyond the statute of limitations; they provide for venue flexibility, evidentiary advantages and also in terms of the burden of proof when charging a conspiracy. The government doesn't have to show the conspiracy was successfully executed or anyone was actually defrauded, but just needs to show the conspirators agreed to undertake the offensive conduct and took some steps to effectuate the goals of the conspiracy. So, you know, it becomes, you know, really a theory of choice, and certainly a big risk for regulated companies.

Greg: Thank you very much Sam and Beth. This concludes the panel portion of the program today. We are going to turn to questions. We are more or less on time, so we have a few minutes.

Q&A

Greg: We have questions that we received both live during the meeting today, and also we have some questions that we received in advance of the meeting. So, one we actually have gotten a couple of different questions on relates to reimbursement trends for digital health products and coverage of diagnostic apps. I don't know if anyone wants to speak to that issue.

Margaux: Well I am happy to generally weigh in and say, you know, one thing that we are seeing is, and Tom touched on this briefly with regard to Medicare Advantage organizations, that where there is not a clear, independent coverage or reimbursement pathway for a digital app, there is increasing flexibility in managed care for either managed care organizations or Medicaid managed care plans to cover additional services as so called "value added services." There are a couple of different pathways to do that, both within Medicaid and then also in Medicare Advantage, where they would be structured as supplemental benefits. We are seeing an uptake in managed care organizations taking advantage of these flexibilities – that is true in some state Medicaid programs. We were seeing managed care organizations either substitute out otherwise-covered Medicaid benefits for "in lieu of" benefits, or add on top of the full suite of Medicaid covered benefits additional benefits, and there is a host of potential implications and potential opportunities and challenges around that.

Tom: One thing I would add is that it does seem related to the whole telehealth expansion that happened as a result of COVID because some apps obviously make it possible to communicate with your health care professional either in real time or in some other manner, and coverage for those things certainly increased. Generally speaking, we expect that the Telehealth expansions that have happened in the last two years are going to dial back some, but not go away altogether, so it may well be that additional coverage of procedures and visits that are enhanced by digital technology will continue.

Greg: Another question we got was about the timing of implementation of the new CMS rule on VBPs. I know, Margaux, you talked about this rule before. Tom, did you have further comment on that topic?

Tom: Oh, on value-based payments, is there a specific question on that?

Margaux: I am happy to reemphasize what is happening on the regulatory front with regard to the multiple best price proposals. The implementation of that final rule that will give manufactures the opportunity to report multiple best prices, that has been delayed until July 1. Apart from the actual rule delay, I think there are a tremendous number of implementation challenges, and CMS has said one of several reasons underlying the delay of that rule was that states needed to have appropriate infrastructure to potentially operationalize the multiple best price proposal on their end. Additionally, CMS recently launched a whole new Medicaid drug rebate program price-reporting interface and system, so that will have to be capacious enough to be able to accommodate reporting multiple best prices for the same potential product. CMS, in delaying the implementation of that rule, kicked the can in various regards and said, give us more

time, we need to sort through these nuances and complexities. I expect in the months leading up to July 1, we are going to need to see additional guidance from the agency in order for manufacturers and States to be able to appropriately prepare to hit the ground running on July 1 or any date thereafter. The other question, Tom, that I think you know would be helpful if you could weigh in on is the availability of the anti-kickback statute's value-based agreement safe harbors and whether those safe harbors are available in order to enable manufacturers as they structure value-based agreements.

Tom: Yeah I was thinking of that as you were talking about the drug piece. The short answer is they're not available for drug and device manufacturers. There is a sort of minor pathway for some device companies to, um, participate in value-based enterprises by providing free digital health technology to value-based enterprise participants, which could include their customers, and that is for the purpose of coordinating and managing care, things like remote patient monitoring and telehealth. There is some pathway there, for some device makers, but in general, the value-based safe harbors that were inactive at the beginning of 2021 are just not available at this point for drug and device makers. That was a deliberate policy decision. I think the OIG is simply not, at this point, convinced that those things can be done without what it considers to be risks of fraud and abuse, so there will continue to be lobbying about that, and those rules might change in the future, but right now, it is very limited for the drug and device space.

Greg: Another question we received is whether we are seeing any False Claims Act trends relating to incentive and loyalty programs. I don't know if anyone feels they want to take that one on.

Sam: Yeah, I can talk about that. I mean, I think we covered a number of these cases when we were talking about the trends and enforcement actions, especially from last year, and I think the bottom line is that when you are talking about payment arrangements with your prescribers, you need to take a hard look at how those are structured to make sure that they are not structured in a way that could be interpreted that there is content to induce prescribing of your product, because the way that the government views the kickback statute is that, if one purpose of a particular arrangement is to induce a prescriber to choose your product, then that could be a kickback violation, so any incentive and loyalty programs just really need to be examined carefully from an AKS perspective. It doesn't mean that you can't do them, you just really need to take a close look at them, and I do think they are going to be continually scrutinized by DOJ.

Tom: I guess I would add that the usual pathway to what I think the questioner is asking about, is discounts for increased use of product from market share use of product, There was a 2019 advisory opinion that approved a loyalty program for one of the drug stores that could be applied to prescription drugs as well as to other products, so, you know, if Walmart issues a loyalty card, it says you get a discount if you buy a certain amount of product, OIG said we are not worried about that also being applied to some prescription drug products. That was kind of at the consumer level, and certainly market share in value and requirements in purchasing agreements, but hospital and other health care providers can be permissible as long as they are structured to meet the discount safe harbor. Those are the things that come to mind for me.

Greg: I think we have time for one more In the FDA area, we have a question about whether we are seeing the beginnings of a renaissance in OPDP (the Office of Prescription Drug Promotion), given the posting of Untitled Letter close-outs, establishment of new policy in the research division, and some greater visibility. They have been putting out a monthly newsletter, so Kellie and/or Josh, do you guys want to tackle this in the next 120 seconds? I think that will take us to our conclusion.

Kellie: I am happy to kick it off. As we mentioned during the program, we are not necessarily expecting there to be a shift in priorities with respect to OPDP enforcement actions. But there have been a number of developments, including some of the organizational changes that Josh mentioned, as well as some pretty aggressive language in the Federal Register preamble accompanying the intended use rule last fall, to suggest that maybe there is some sort of renaissance at OPDP. It's certainly going to be a hot area to watch in the first part of this year, especially in light of the fact the Facteau and Fabian case will have oral argument next month. Over to Josh, if you have any additional thoughts?

Josh: I agree with that. The ground is ripe, and maybe we are going to see some further developments on the OPDP side or more aggressive enforcement, but it hasn't manifested itself in an increased volume of letters or an increase in the breadth of those letters yet. We will just have to wait and see.

Kellie: One more thing with respect to priorities before I turn it back over to Greg. So, since we have been speaking, there has been an important development with respect to the Califf confirmations. Senator Schumer this morning filed cloture, which means that the Califf nomination could go to a full vote in the Senate as early as next week. That suggests, but does not necessarily indicate with any certainty, that Schumer thinks he may have the votes to confirm Dr. Califf next week.

CONCLUSION

Greg: Thanks Kellie, there is never a dull moment in this business. You go 90 minutes, there is going to be some breaking news. Also in parallel, there is a big FDA advisory committee meeting going on today about the acceptance of clinical trial data for studies conducted solely in China. It's actually a pretty momentous meeting, and we've gotten some questions in the chat or in the Q&A about that, but it is too complicated a topic to take on right now.

I would just like to thank everyone, and this is all the time we are going to have for today. But thank you very much for joining us. As I mentioned at the outset, we are offering CLE credit for this conference. For those seeking CLE credit, you need to fill out the attorney information form that is included in the registration confirmation email you received yesterday. The CLE confirmation code for this program is 6744, that's 6744. Please email the completed form to professionaldevelopment@ropesgray.com, or fax it to 617-235-9606, within 48 hours. We will continue to provide additional news and analysis about regulatory enforcement issues emerging from the federal government throughout 2022. Once again, you can access that information by accessing our capital insights page on our main web page, www.ropesgray.com. Thank you all for your attention and I wish you a good day.