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SIDLEY UPDATE

Life Science Innovators Tackle COVID-19: Developing Pathways to Diagnose, Prevent and Treat the Virus

April 2020

Life sciences companies are rushing to find ways to diagnose, prevent and treat the COVID-19 virus. They face legal challenges, from regulatory oversight to supply chain disruption and product liability. What are the opportunities in trying to solve the COVID-19 virus puzzle? And how do these global innovators handle the risks? Our latest episode of *The Sidley Podcast* grapples with those questions and many others. Join host and Sidley partner **Sam Gandhi** as he speaks with two of Sidley's thought leaders on the critical issues that life sciences companies face—**Becky Wood**, who leads Sidley's FDA regulatory practice, and **Doro Schramm**, an international arbitration partner in the firm's Geneva, Switzerland office. Together, they address what businesses can do in anticipation of the challenges ahead.

Executive Producer: John Metaxas, WallStreetNorth Communications, Inc.

Life Science Innovators Tackle COVID-19: Developing Pathways to Diagnose, Prevent and Treat the Virus

Sam Gandhi, Rebecca Wood and Dorothee Schramm
April 2020

Sam Gandhi:
As COVID-19 sweeps across the earth, life sciences companies are rushing to find ways to diagnose, prevent and treat the virus. They face legal challenges—from regulatory oversight to supply chain disruption and product liability. How do these global innovators handle their legal risks as they rush to solve this puzzle? We'll find out in today's podcast.

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Sam Gandhi:
From the international law firm Sidley Austin, this is *The Sidley Podcast*, where we tackle cutting-edge issues in the law and put them in perspective for businesspeople today. I'm Sam Gandhi.

Hello, and welcome to this special edition of *The Sidley Podcast*, part of Sidley's ongoing efforts to help you stay on top of legal developments in the coronavirus crisis. You can find more information on our COVID-19 Resource Center at sidley.com.

Today, we focus on companies that are developing pathways to diagnose, prevent and treat COVID-19 and the opportunities and risks of producing these products.

I'm joined by Sidley partners Becky Wood and Doro Schramm. Becky's a partner in our Washington, D.C. office and leads Sidley's FDA regulatory practice. She recently served at the FDA as chief counsel under former commissioner Scott Gottlieb. Becky has been counseling clients as they navigate their COVID-19 strategy, including those accustomed to FDA regulation and those entering the space for the first time.

Doro is an international arbitration partner in our Geneva, Switzerland, office. She is primarily a contract troubleshooter, and she helps clients resolve commercial disputes, either as counsel representing companies or as an arbitrator in deciding such disputes. Doro's been counseling clients recently on managing a wide range of COVID-19-related risks and on preventing and efficiently resolving disputes.

Becky joins us from Washington, D.C., and Doro joins us from our Geneva office. Becky and Doro, thanks for joining us today.

Becky Wood:
Great to be with you, Sam.

Doro Schramm:
I'm happy I can join you across the pond.

Sam Gandhi:
Neither of you have gotten a lot of sleep lately. I know that you've been busy helping clients in what's really on the frontlines of this crisis.

Becky, if I can just start with you, there is a race right now all over the world for companies that are getting into the production of personal protective equipment, or PPEs, that historically didn't produce that equipment. Companies are trying to find a cure, a way of detecting the virus, a vaccine and an effective treatment. What are you seeing from your clients?

Becky Wood:
That's exactly right, Sam. Over the last few weeks, we have really seen an incredible mobilization of private industry, academic labs, individuals with amazing ideas, and despite all of the negative headlines, I think there is also great cause for hope.

We certainly see established biopharmaceutical companies and medical device companies rushing the zone, but we also see companies that have never been FDA regulated before who want to be part of the solution. We've heard from fabric companies. We've heard from groups of seamstresses who want to use idle time that they have right now to fashion masks, to at least provide some protection to people who are walking the streets. We've heard from industrial companies that had to let some of their workforce go but want to repurpose the facilities that they have, almost like a war-like production, to go forward and try to be part of the solution in terms of providing medical supplies to hospitals —ventilators, respirators. It's been a real outpouring, and the FDA has reported quite recently that there is progress.

So the dream of a vaccine, obviously, which public health officials have warned us could be as much as 18 months away under normal schedules, FDA has said there's some 20 vaccine studies under way right now racing to try to find a vaccine that all of us could benefit from.

In terms of new diagnostics so that people can find out whether they have coronavirus, whether they have the antibodies, FDA has reported more than 220 test developers have already told the agency that they're seeking EUAs [Emergency Use Authorizations]. We know 23 EUAs as of the date that we taped this broadcast have been issued for diagnostics, and more than 100 labs have begun testing.

And we know that the career professionals at FDA are working around the clock. We have very experienced center leadership in Drs. Woodcock, Sherman and Marks in the various medical product centers.

And agencies recently created what it calls CTAP, the Corona Treatment Acceleration Program, and reassigning staff to try to get back to […] sponsors who want to submit a regulatory solution within one day.

So we're seeing more speed, more flexibility, and FDA has an array of existing methods to try to make it easier for people who are both accustomed to being part of FDA regulation and those who are new coming into the system.

Sam Gandhi:
So, Doro, what are you seeing from your clients in Europe in terms of how they're being part of the solution and the concerns that they have about jumping into this fray?

Doro Schramm:
Now, here in Europe, I see things mainly from a commercial perspective rather than from a strictly regulatory perspective. And obviously, people are focused on finding a solution to the problem—and obviously, finding a solution for COVID-19 will be a glorious moment for all of us, for humanity.

And on the human level, this cannot be really measured in money. But obviously, life sciences companies are commercial enterprises, and on the commercial level, there's no doubt that offering solutions promises to be very profitable. And that is absolutely necessary in order to cover the development cost of the solutions and of other potential solutions that do not work.

So, the situation here is that people have to work fast at a time when a lot of the world is in lockdown, while, of course, protecting human health and avoiding the toxic issues that can poison future profitability. And that is a balancing act that is not easy, but if you have a good team around you, you can do it right.

So in terms of the toxic issues that companies here are concerned about, it's basically they fall into four different buckets. First is getting the regulatory authorizations quickly enough, and that is an issue that Becky has addressed.

The second is securing supplies and avoiding reputational risks and liability that come from supply problems. The third bucket would be producing really enough of the quantities that are needed while securing the quality—that's particularly if you produce PPEs even though your company hasn't done it before.

And the […] fourth bucket of issues that is not top of people's mind but that nevertheless has a big impact on profitability in the future is the IP protection that you have to put in place while you're developing your solutions.

Sam Gandhi:
Becky, what's the FDA's role in the COVID-19 response?

Becky Wood:
Well, I think, as everyone knows, FDA regulates the marketing of medical devices, biopharmaceutical products and food products here in the United States, and for many people who've never been regulated by FDA, they may be surprised at how broad FDA's reach is.

And so, essentially with respect to a device or a drug, if you're intending to diagnose or treat or protect

from disease, chances are, FDA's starting place is going to be that you are an FDA-regulated drug or device. And so, it's been very interesting with all of the recent discussion around personal protective equipment. The starting place for FDA, by and large, is that those things are regulated, and normally, they would come into the system through a mechanism called 510(k) that can take 180 days. Obviously, that is, from a public health and emergency perspective, a non-starter given the circumstance that a lot of hospitals, a lot of people, are facing with respect to shortages.

And so, one place that FDA has given a little bit of leeway in recent days, in what is called enforcement discretion, is taking a risk-based approach and issuing very quick guidance letting folks know where it's going to have more flexibility in terms of allowing people to get into that space more easily through what's called an Emergency Use Authorization, which is a much faster process.

It also has freed up in guidance and given some guidance around the individual use. It said explicitly now, as of a few days ago, that FDA recognizes that when alternatives such as FDA-cleared masks or respirators are not available, individuals, including healthcare professionals, might improvise. And in those circumstances, FDA does not intend to object to individuals' distribution or use of improvised PPE with no alternative such as the FDA-cleared or approved versions […] available.

There's also been, I think, a lot of interest in donating. People may want to go out and buy a bunch of masks or surgical gowns and donate them to their local hospitals. They may have their own supplies; they may want to craft them.

So we've been seeing a lot of interest in those sorts of questions, and as I said, as a general matter, the agency takes a risk-based approach to those things. So in normal days, a lot of those products would have to come into a longer process in the system, but given the realities that are out there right now in hospitals, and the desperate situations, FDA has signaled a more relaxed approach to how it's going to regulate and enforce in that space.

Sam Gandhi:
So what's your message to a company that, say, is an industrial company or a retail company; they're not in the medical equipment industry but they want to help, they think they can retool their machines or their people to try to create PPEs, and they're worried about the risks?

Becky Wood:
Yeah, so there's a lot of people in that circumstance right now, who either want to change their line of work or want to get into the charity and donation business, to meet a really compelling need in their own community oftentimes.

And so, FDA in the last week or so has issued an extraordinary amount of very particular guidance in response to a lot of specific requests that it's been getting from people who want to know the rules of the road in a very transparent and clear way. And I think the agency's been very fast and very transparent in the last week or so in getting that kind of information out, and so there's more guidelines.

I know sometimes people will call and say, "I want to make a mask" or "I want to make a respirator. How

do I do it?" And the devil is really in the detail of: What kind of a mask is it? What is it being used for? Who is it being used by?

Those are all jurisdictional questions that FDA takes very seriously and that can lead to a different answer, so you really have to look closely at that guidance, talk with your regulatory consultant or counsel about it. But there are more pathways to get into the system more quickly than ever before.

Sam Gandhi:
It sounds like the landscape has changed, that the time frame that the FDA is using to consider and even approve some of these procedures, practices, etc. [has] accelerated. How do you advise clients on effectively interacting with the FDA in this environment?

Becky Wood:
I think you have to be really prepared. You have to do your homework. There is a lot of information that is available for companies that want to come into the system to put together their package of what they want to do in terms of their product or their donation.

So, the agency is trying, I think, to make itself more available than ever. There are people that you can talk with at the agency, or counsel can talk with them at the agency.

Also, downtown at HHS [Health and Human Services], something called BARDA [Biomedical Advanced Research and Development Authority], which is essentially sort of a SWAT team to try to navigate really good, new ideas for bringing solutions—what are called covered countermeasures—to market. And people are also obviously working with other government authorities, with their local governors, with their local hospitals, to try to figure out what the need is and put all of those pieces together.

Sam Gandhi:
Even before COVID-19, the workload at the FDA was immeasurable. What's the impact of COVID-19 on FDA's regular non-COVID-related work?

Becky Wood:
We get that question a lot, and in many cases the regular freight of the agency is moving ahead—if not full steam ahead, at least quickly ahead. Before COVID hit, I think as everyone may know, FDA had had a number of landmark years in terms of successfully bringing record numbers of new therapies to market as part of the 21st Century Cures [Act] environment, where it had increased accelerated-approval mechanisms that were increasingly successfully used, also bringing more generics to market. And so that's sort of the background run of work that the agency was doing in addition to all of its other priorities.

And so, certainly the agency is well equipped to prioritize and deal with crises. […] The agency has been through tough times in the past through the Ebola years, through the AIDS years, through different hurricanes and natural disasters that took out medical supply lines to some extent.

Obviously, COVID is unprecedented, and so far, the agency has been ramping up. It has been creating a number of different task forces and expedited mechanisms and has indicated publicly that it is trying

to keep on track a lot of the regular work of the business. But I think it's starting to signal more and more that there's only so many hours in a day, there's only so many resources. And I think we may see increasing signals from the agency around postponing certain meetings, certain deadlines.

We've already seen a little bit of that. We've seen the agency file papers for extensions in some circumstances because of oppressive work. We've seen the agency have to cancel meetings, have to do tele-meetings, and so forth.

And so, I think the big question on everybody's mind is whether there will more of a massive, across-the-board delay, for example, of PDUFA [Prescription Drug User Fee Act] … dates, and we're watching that very closely.

Sam Gandhi:
Doro, what should a company that's developing ways to try to counteract the virus do to protect its future profitability and ensure that they can continue to perform?

Doro Schramm:
Well, if you're at the stage of developing a medication or a vaccine or a cure, then your future profitability will be largely driven by the strength of your IP. And even though this is not something that you might be thinking of right now, you should still set your patent lawyers into motion—in order to file for patent protection, for example—if you can.

Now, my perspective is more that of a contract lawyer, so I'm now looking into how contracts can help you protect your profitability. And a lot of the work that we see on COVID-19-related countermeasures, be it PPE or vaccines or other drugs, is done typically jointly with other partners. And here, […] contracts are vital to protect your own investments and to avoid unnecessary risks, and here are maybe three tips I can share with you in that regard.

So the first would be that you should make sure that your contracts say clearly, and without too much legalese, […] who shall have ownership of the results of your development work and who has the right to use them.

As a second point, it's also important to protect the know-how that's coming out of the joint development, because there is no uniform trade-secret law across the globe. So therefore you have to make sure that you cover the confidentiality obligations for the know-how that results from the development work. And oftentimes, contracts only address confidentiality of your background knowledge.

And then also, if you collaborate with your competitors because the situation demands it, you should still seek the advice of an antitrust lawyer—for example, if you intend to later jointly commercialize the results or if the products that you're developing may not be solely used to treat COVID-19.

Now obviously, the focus of any company at the moment is to get the results as quickly as they can, but this should not prevent their contract lawyers […] from doing a good job ensuring that the contracts protect the future profitability of the company.

In that regard, maybe let me add a word of caution. As we all know, currently we are in the situation of shortage, so any company wants to avoid being perceived as using any IP rights to prevent others from fighting the pandemic. That could really turn into a PR disaster. But that doesn't mean that you shouldn't protect your IP, but you could address the pitfall […] through other measures. For example, you could consider offering free licenses that are limited in terms of time and purpose.

Now, when you've done your development and you're ready to launch, then these other risks I talked about earlier—the first, obviously, is getting the regulatory authorizations, and Becky spoke to that.

The second is: you have to find suppliers and secure those supplies. And we will talk about this in more detail later on, but at this stage, let me just say that you should address the uncertainties of whether the suppliers will really be able to supply already in your contracts now in order to avoid big liability risks.

And then, you have to produce required quantities. That's not obvious, because a lot of our production, of […] mass production, is done in China, and even though factories there might be up and running again, there are still a lot of problems with transportation from China to the rest of the world. So you have to actually really find local production, and that is not easy for a lot of companies.

And then you have to get the quality right in those production facilities, because if you don't, then you're at risk of damaging your brand reputation, and of course, you might run into a lot of liability. So, while we will address the product liability aspect here a little bit later, but already your contracts should reflect that this is a situation in which you have more interest than ever to appropriately limit your liability.

Sam Gandhi:
You're listening to The Sidley Podcast. We're speaking with Sidley partners Becky Wood and Doro Schramm about opportunities and risks companies face developing medicinal solutions for COVID-19.

Becky recently served as chief counsel at the FDA, and she leads Sidley's FDA regulatory practice. Doro counsels clients on managing COVID-19-related risks and on preventing and efficiently resolving related disputes, and she's an international arbitration partner in Sidley's Geneva office.

Becky, I want to come back to something that Doro just mentioned. Even in ordinary times, much less in the case of a pandemic, the production of medicine and medical supplies is challenging, and shortages in supply chain disruptions are going to happen. How should companies working on COVID-19 countermeasures address these issues with the FDA?

Becky Wood:
There are a couple of things that we're seeing. First, with respect to sponsors of drugs and devices, they already have background obligations, if there are going to be shortages in the system, to report those into the agency with certain frequency.

What we're seeing now from the agency is a call for a voluntary heads-up even more quickly. We're

also seeing people who have medicines and devices that have nothing to do with COVID being a little more proactive in how they interact with shortage staff, understanding even though FDA has amazing career professionals on their shortage staff, it's a small office. And so there's a need, if you are experiencing a shortage outside of the COVID setting, to really make sure that you are communicating with them as clearly and efficiently as possible given all of the pulls on their time.

The other big issue with respect to shortages has been, in the last couple of weeks, one that we've talked about a little bit already, which is personal protective equipment, PPE. Given the incredible shortages that have come, that's a place where the agency has really tried to loosen the reins a little bit and give more discretion for companies just to kind of flood that space in a way they've never done before, while trying to make sure that they still exercise appropriate oversight over the more risk-prone devices.

Sam Gandhi:
And Doro, let me follow up with you on that. How do you address supply chain disruptions on a contract basis?

Doro Schramm:
The question that we hear most often from clients is whether any supply disruptions are excused because COVID-19 is *force majeure*. Now, there's no doubt that COVID-19 is an event beyond anyone's control, but that does not mean necessarily that it excuses the supplier's failure to deliver the products on time.

So, think about it. In both sides here, both the supplier and the customer are not responsible for the pandemic, so it's not obvious why one and not the other should bear the damage that is caused by the pandemic.

So what you need to look at is the contract and also the governing law to find out how this risk of a pandemic is allocated between the two partners. If, for example, you have a *force majeure* clause in the contract that says that a party is excused if it can't perform due to a pandemic, well, then the supplier obviously has very good chances of being excused. But still, […] they can't just rely on that. They still have to give the required notices, and they also must check very carefully what is owed under the contract. Because if the supplier doesn't own goods or, you know, like ingredients or components specifically from its own production, then it can typically only invoke *force majeure* if it's not able to procure them from other sources.

So that means: despite the *force majeure* clause in the contract, the supplier in that case still must make real efforts to get the goods from somewhere else. Now, if that doesn't work or if, let's say, a company can't honor its contracts because its own supplier doesn't supply it, that's another big question that we get very often—situations where a client is sandwiched in the middle between a supplier that doesn't supply and the customer that's waiting for the client's goods.

So this is really a very uncomfortable position, and if you're in the middle of that sandwich, you really have to look at each of the two contracts separately. So, you look into the contract with your upstream supplier, and you check whether the upstream supplier is excused under a *force majeure* clause or the

applicable law. But you must also look into the contract with a customer, and check whether you can either invoke *force majeure* or whether you bear the procurement risk under that contract.

And oftentimes it will come down to looking again exactly at what is owed under the contract—so whether, you know, these ingredients or components from the supplier has to specifically come from your supplier's own production or whether you can and must procure them from somewhere else.

And so, depending on how these two contracts play together and how they allocate the risk, you might find yourself in the comfortable position that you are excused under your contract with a customer. But you can also find yourself in the very undesirable position that you're not excused under the contract with a customer but that your supplier is excused under its own contract.

Now, as I said before, none of the three parties in this are really responsible for the pandemic, and in this scenario, the company in the middle would be kind of holding the hot potato of bearing the risk and being liable for damages.

Sam Gandhi:
Doro, what can companies do to proactively manage their supply chain disruptions?

Doro Schramm:
The first thing you can do is try to minimize the risk of supply chain disruptions happening, and there are maybe three things you should be thinking about doing. The first is, know your supply chain. So, you should really get to know all of the suppliers and subsuppliers in order to be able to identify the weak points in your supply chain.

It's also a good idea to regularly call your key suppliers and also your key customers. Not only does that strengthen your bond with them in the current situation, but you also will get to hear problems early on and can already start developing solutions with them.

The second tip would be to actually support your supply chain. So, if you have good arguments why your products and why your supplier's products are essential, then this is something you should share with your suppliers in order to support them to overcome lockdowns, for example. So, if you get an exception, that is something you could pass onto your suppliers and help them get an exception for their own products as well.

And then last but not least, you should know your Plan B, which is: prepare a list of alternative suppliers, if you have key ingredients or key components, and keep that list updated. So if something goes wrong with any of your ingredients that you're getting, then you know who to call to get it from elsewhere.

Now, at the same time while you're trying to minimize the risk, you should also prepare for the time when you get a *force majeure* declaration from your supplier, and there's a number of steps you can take in order to get really prepared for that, as well.

The first would be for you to get the data. So you should really get your hands on all your supply and

customer contracts, have a look at the *force majeure* provisions that are in there, and maybe at the laws that are governing your key contracts, to get a sense of what is the situation in case of *force majeure*.

On that basis, you should also then prepare instructions to your purchasing teams and your commercial teams—what they should do if they are facing a *force majeure* declaration from either the supplier or the customer. Because you don't want your commercial team to run off and do things that in hindsight will be very counterproductive if you later have to worry about who's going to pay the bill.

And then, at the same time, you can also start preparing certain templates—template *force majeure* notices, template responses to *force majeure* notices—so that if and when it hits, you are ready to roll and you know what to send back.

Sam Gandhi:
Customers that are distributing products that help fight the pandemic, they face unique risks in terms of liability given how fast everything is moving. Becky, what are some of those liabilities, and are companies protected? Are there immunities under these new fast-track rules and new ways of doing business as we fight the virus?

Becky Wood:
So, under American tort-law principles, there is a duty of care with respect to any issue around biopharmaceutical or medical device development and distribution. The devil's in the detail, but as a general matter, one has a duty of care with respect to the design and manufacturing and labeling and warning with respect to these devices and drugs.

And so, one thing that Secretary Alex Azar at HHS did a couple of weeks ago was sign a declaration under the PREP Act [Public Readiness and Emergency Preparedness Act] which purports to give immunity from suit and liability for so-called covered countermeasures.

Courts have not interpreted the PREP Act very frequently—it hasn't been invoked very frequently—but as a general matter, when a product is in the FDA system, if it's cleared or approved or if it's subject to one of these Emergency Use Authorizations, there would be an argument under the PREP Act, if certain circumstances applied, that you would get immunity.

The purpose of all of this, of course, is to encourage people to responsibly go into the system and responsibly flood the zone with new products, old products, that can be used as part of a countermeasure when there's a state of emergency, which depends on the nuances of how those states of emergency have been declared in the relevant jurisdiction. In practice, this certainly provides some degree of protection, some degree of solace, to people who want to get into the space. But because it, ultimately, like any potential immunity or pre-emption event, would have to be interpreted by a court, there still is question about how it might apply in a particular case.

There's still question about how it may apply in circumstances where the agency has exercised what it calls enforcement discretion, where it says, For purposes of this emergency, we're not going to object to certain products being marketed even if they haven't undergone traditional FDA clearance or

approval or authorization.

And so it will be an open legal question how the courts will deal with all of those array of products.

Sam Gandhi:
And Doro, do you think the liability protection in the U.S. under PREP and others will actually apply in cross-border sales or distribution contracts?

Doro Schramm:
I wouldn't count on it. The U.S. Health Department says on its website that immunity from liability is not available for foreign claims where the U.S. has no jurisdiction. Now, there are certain, maybe, exceptions where you might still be able to invoke that immunity, but in most cases, it would be very difficult.

Now, on the product liability and tort level, it's important that your liability risks in Europe are a lot more limited than in the U.S.—that's why it's not so much of an issue here as it is in the U.S. So, at the moment, most European countries do not know U.S.-style class actions, and there are also no punitive damages, so that already limits your risk quite significantly.

So any damages that you […] might be ordered to pay are limited, and if you have marketing authorization for your drug or a CE mark for your medical device, the threshold of being held liable is generally high. So overall, there is less liability risk for you in Europe than there is in the U.S.

Sam Gandhi:
The stories that we've heard of companies and individuals stepping up to do whatever they can to try to fight the virus—there's some truly heroic stories. Unfortunately, there are also invariably in these crisis situations […] fakers and there are fakes, and those who market products with fraudulent diagnostic, prevention and treatment claims.

Becky, in this environment, how does the FDA fight those fakes? Does the agency have time and do they have the priority to try to fight those in this environment?

Becky Wood:
Quite clearly, yes. So, from the beginning of this coronavirus situation, the agency announced that it did have an enforcement priority to go after people who would be promoting a particular product that hadn't gone through the system or was not appropriately labeled, particularly where it was claiming that it would potentially cure or diagnose COVID when there wasn't data for that and where it hadn't been appropriately in the FDA system.

And FDA's made good on that word. It has issued a number of what it calls warning letters. I think, as you know, FDA, under the Food, Drug, and Cosmetic Act, has a variety of civil, and potentially criminal, enforcement capabilities. It has the ability, among other things, to issue what's called a warning letter, which is a shot across the bow, where the agency says in a public way to a company, We see that this is what you've said about your product, we think it's false and misleading, we think it violates the FDCA, and if you don't clean it up, we're going to take additional action with the Department of Justice to go

after you.

The agency has already issued a number of those types of warning letters in this situation. We're also aware of circumstances where competitors are policing the market, calling in claims. All of this happens outside of the COVID scenario. This is background FDA enforcement protocol in some sense, and FDA always looks to take a risk-based approach. And certainly the risk of giving people a supposed cure that doesn't actually work, or a diagnostic that doesn't actually work, is quite high. And so it's something the agency is taking very seriously and getting a number of calls about.

One way that this comes up is if a company wants to start saying something potentially—in the agency's view—prematurely about what it's developing. There's very careful promotional rules that FDA expects companies to abide by.

Sam Gandhi:
And Doro, how do you fight the fakes on a private contract level?

Doro Schramm:
Now, in the U.S., the False Claims Act gives private citizens the possibility to file suit on behalf of the government against fraudsters, but Becky and my other U.S. colleagues are much better suited to talk about that. If we're talking on the pure private-law level, you obviously have contractual remedies if you happen to have a contract with a fraudulent company, but my suspicion is that this would be a very rare occasion that this happens. So, competitors might also have claims and remedies under national unfair-competition acts or the EU's Unfair Commercial Practices Directives, which each EU member state has implemented in its own way. But that being said, in my view, the actions available to the FDA and its foreign counterparts are in my view your best bet, and the most effective way to fight fakers is to report them to the regulatory authorities.

Sam Gandhi:
We've been speaking with Sidley partners Becky Wood and Doro Schramm about the opportunities and risks in developing countermeasures for COVID-19. Becky, Doro, the whole world is watching these companies as they try to save us from the crisis. Thanks for sharing your insights today.

Becky Wood:
Great to be with you, Sam.

Doro Schramm:
It was my pleasure, Sam.

Sam Gandhi:
Before we wrap up, a word about Sidley Insights, the content section of our website. We've set up a special page for the COVID-19 Resource Center. You can read articles related to various legal issues impacted by the coronavirus crisis, including the effects on mergers and acquisitions, securities disclosure, environmental law and contract disputes, and we're going to be posting more in the coming days, and we're planning future podcasts, too.

You can find our COVID-19 Resource Center by going to sidley.com.

You've been listening to *The Sidley Podcast*. I'm Sam Gandhi. Our executive producer is John Metaxas. You can hear more episodes at sidley.com/sidleypodcast, or subscribe on Apple Podcast or wherever you get your podcasts.

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