

**Can Private Businesses Mandate COVID-19 Vaccinations?**

Wendy Lazerson and Rebecca Wood

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**Sam Gandhi:**

Hello. I'm Sam Gandhi and welcome to *The Sidley Podcast*.

In this edition, we present my talk with Sidley partners Wendy Lazerson and Rebecca Wood about COVID-19 vaccines and the implications for employers who may consider mandating vaccinations for their employees.

Of course, events move quickly in the world of COVID.

And since we recorded this podcast, one of the three manufacturers with emergency use authorization for its COVID-19 vaccine applied for full approval from the FDA. The same manufacturer also received emergency use authorization for its vaccine to be given to children ages 12 to 15.

As you'll hear, these developments come as no surprise to Wendy and Becky. Enjoy the podcast.

**Sam Gandhi:**

Three COVID vaccines are now authorized for use in the United States, and more than half of all U.S. adults have received at least one shot. The push for vaccinations is raising ethical and legal questions. Can private employers mandate their workers get vaccinated and what are the ramifications if they do? How should businesses navigate federal and state requirements? We'll find out in today's podcast.

**Rebecca Wood:**

Things are changing quickly all the time, every day, in the COVID world. So, we have to always keep our minds on what is happening. What is the science showing? As you know there's not an automatic mechanism for turning an EUA into an FDA approval.

**Sam Gandhi:**

Is litigation just inevitably on the horizon here?

**Wendy Lazerson:**

Well, I think it is inevitable and I also think there is going to be some chaos within the workplace between those who want everybody vaccinated and those who don't want to get the vaccine. Employers like certainty and right now they aren't going to get certainty.

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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 edition of the Sidley podcast, episode number 20. Today we focus on the COVID-19 vaccines and their implications for employers. Whether private businesses can mandate their workers to be vaccinated. I'm joined by Sidley partners Wendy Lazerson and Rebecca Wood.

Wendy is the co-chair of Sidley's Labor and Employment practice and a partner in the firm's San Francisco and Palo Alto offices. She also serves on the firm's COVID-19 Task Force. She represents employers in their workplace disputes, including jury trials and arbitrations. She also advises employers on workplace issues and conducts workplace investigations. Becky serves on the firm's Global Life Sciences Leadership Council and leads our Washington, DC Healthcare and FDA group. She was a founding member of the firm's COVID-19 Task Force and advises FDA regulated clients on a range of COVID response efforts. Becky recently served at the FDA as Chief Counsel, the General Counsel row under former commissioner, Scott Gottlieb. Wendy, Becky, thanks for coming back on the podcast.

**Becky Wood:**

Thanks for having me, Sam.

**Wendy Lazerson:**

Great to be with you, Sam.

00:02:57

**Sam Gandhi:**

President Joe Biden announced that he had shattered his revised and upgraded goal of administering 200,000,000 COVID shots in his first 100 days of office that just passed. Becky, let's talk about the availability of vaccines. How do these vaccines even come to be authorized in this breakneck time, by the FDA, and how does this compare to the agency's standard process?

**Becky Wood:**

Well, I think you're right to start by acknowledging the really extraordinary effort by innovators, regulators, clinicians, clinical trial participants to bring these products to market so quickly. It has been a really a herculean effort and does laps around the normal review and time to bring product to market, and it really gives, I think, extraordinary hope for what can be accomplished across a host of different vaccine disease states.

You're also right to emphasize that these vaccines enjoy authorization, but not yet approval from FDA, and that's really important to our discussion. To understand that FDA regulatory context.

We often hear people talk colloquially about FDA approved COVID vaccines, but in fact there is no FDA approved vaccine at this point. Rather, the COVID vaccines currently available in the U.S. have received emergency use authorizations (EUA) from Food and Drug Administration, and that discussion matters to what we're going to talk about today.

One place I want to ground us is in the Food, Drug, and Cosmetic Act. So, Section 564 of the EUA gives the EUA authority. This is a special marketing authority for the use of unapproved products or for unapproved uses of approved products during an emergency declaration and of course as you know HHS, the Department of Health and Human Services, declared a public health emergency with respect to COVID last year, in February of 2020, and in March of 2020, the Secretary of HHS declared that the circumstances existed to allow the authorization of the emergency use of drugs and biologics during the COVID outbreak. So, that set the stage to allow these EUAs for vaccines, and an EUA in a particular case

turns on whether the known and potential benefits outweigh the known and potential risks.

One very important aspect of that statute of 564 E is that it states that patients are to be informed of the option to accept or refuse the administration of a product that is being marketed subject to EUA, and you'll see that option language reflected in the COVID vaccine sheet that healthcare providers and patients get when they get vaccinated. So, healthcare provider factsheets say the recipient, or their caretaker, has the option to accept or refuse the vaccine, and the patient factsheet has questions and answers. So, one of the questions is what if I decide not to get the vaccine? Answer. It's your choice to receive or not receive the vaccine. So, that's the FDA language that will accompany vaccines as they are being distributed.

Now, it's really interesting, as part of this discussion, to note that there's a totally different statutory provision, 10 U.S. Code 1107a, which discusses emergency use for the armed forces, and unlike EUAs generally, that provides a provision that the President of the United States can waive that option language if he or she chooses to, and so that's come up historically where there have been discussions. For example, in the setting of anthrax, of whether or not there should be a mandate for personnel to receive it. But there's not a provision like that outside of the military context and were not aware that the President has invoked that, even in COVID, for the military context.

It's also important to recognize that when the EUAs were being decided at FDA during the advisory committee meetings, the Chief Medical Officer for the National Center of Immunization and Respiratory Disease also said the federal government cannot mandate vaccines. Vaccines have been shown to increase coverage in some settings, but the federal government would not be mandating the use of these vaccines, and they recognize that hospitals and organizations like that may have the capacity to ask their workers to get the vaccine, but in the setting of an EUA, patients and individuals will have the right to refuse the vaccine.

So, that's what the federal government has said about it. Also, I think significant is your thinking about the issue of mandates to ask yourself, "why would somebody not want a COVID vaccine?" As you point out, Sam,

you know more than half of Americans have already signed up and gotten at least one shot. There is a small one number of people for whom the COVID-19 vaccine would be contraindicated. So, the FDA approved language says COVID-19 vaccines are contraindicated in patients with a known history of severe allergic reaction to any of the components of the vaccine, and so the physician EUA labeling says do not administer for such patients.

There's also some very significant questions about the use of COVID vaccine in pregnant and breastfeeding women. As is typical of clinical trials, the vaccine trials did not include pregnant women, and FDA has said while there's no specific studies in these groups, there's no contraindication for women who are pregnant or breastfeeding, and the advice has been that women should discuss it with their doctors. We know that CDC is following about 30,000 pregnant women who have gotten the vaccine to see how that is going, and it's interesting even in the last few months, the tone from the federal government has migrated a little bit from discuss with your doctor to saying that vaccines should be made available to pregnant women as more data has unfolded, but I think there's still some uncertainty about how comfortable women who are pregnant or may become pregnant will be in getting the vaccine.

And then finally, we should just acknowledge the very real aspect of vaccine hesitancy. We know that there has been an enormous public education campaign and community outreach campaign to get people comfortable with receiving the COVID vaccine, but there still may be some large pockets of the population who have some reluctance to get the vaccine.

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**Sam Gandhi:**

Yeah, we saw over the weekend that Dr. Fauci basically said that the hope is unlikely that we're going to get to herd immunity, but that there's more efforts to try to get more people to use the vaccine.

Are there anything in the FDA regulations that prohibit the government from even strongly encouraging the vaccine?

**Becky Wood:**

Well, I think that optionality language that's based into the statute is one important limiting principle, but at the end of the day, a lot of work should be done with education, getting the facts to people.

You know even though this is an emergency use authorization, there has been an enormous study, and for the vast majority of people, it appears that the potential risks associated with the vaccine and its newness are far outweighed by the potential benefit of not getting COVID. Or if you get COVID having a reduced seriousness of it. You know they're finding that even people who got the vaccine and got COVID, which is a very small number to begin with, you know those people are much less likely to experience the worst side effects of COVID itself, and so I think that overall picture of the public health pros and cons is getting out there and the focus so far has really been on education and persuasion.

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**Sam Gandhi:**

So given the proliferation of vaccinations, more people are headed to the office. They're back, and employers want to ensure a safe transition, and they may want to know whether their employees have taken one of the vaccines, and President Biden also recently announced a tax credit for employers offering COVID vaccine related paid leave.

So, Wendy, when is it okay for a private employer to encourage that people get vaccinated, and if I'm an employer, how do I start that dialogue and how do you frame it?

**Wendy Lazerson:**

Well, Sam, we should really keep in mind all of the things that Becky has talked about in terms of the significance of the emergency use authorization only. Just in terms of the general vaccine discussion, in the employment arena, I think it's safe to say that employers can always encourage employees to be vaccinated and to act as ambassadors for the vaccine. To explain it in the context of the desire to have a safe workplace. Safe not only for an individual employee, but for all employees, and to go about talking about the science and the statistics which we are now seeing that there is clear evidence that when people are vaccinated, they do have

an immunity and that they can't give the disease to others in the workplace and other places.

So, therefore, you know now that we've got some history behind us with the vaccine and people getting vaccinated employers can talk about the science and what we've seen. The danger, I think, is when encouragement leads to requirement, and that's where there is a lot of confusion, still.

Many people seized on the EEOC's guidance that came out several months ago that said, if an employer mandates the vaccine, then they must do certain things such as accommodate people with sincerely held religious beliefs and accommodate people with medical conditions that make it difficult for them to have the vaccine and require reasonable accommodation. People seized upon that to assume that meant employers can mandate vaccines, but again, the language was if, and as Becky pointed out, we don't have authority in our history of our country for mandatory vaccines where it is subject to only an emergency use authorization.

So, what we're seeing is employers are educating, encouraging, incentivizing, by for example giving personal paid time off to go get the vaccine. Time to recover, obviously. Some employees are using gift cards and other tokens, but there is that tension between encouraging and mandating, and I think we need to be sensitive to that.

Things are changing quickly all the time, every day, in the COVID world. So, we have to always keep our minds on what is happening, what is the science showing, and how does that, from a practical standpoint, impact employers and what they can do?

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**Sam Gandhi:**

Ever since the FDA granted the EUA for vaccines, employers, schools, and other organizations have grappled with whether to require those COVID vaccinations. So, Wendy, I want to come back to something you said earlier. What are the inherent challenges in trying to mandate COVID-19 vaccinations in schools and workplaces?

**Wendy Lazerson:**

Well, Sam, here we have to be careful because one size does not fit all. Schools are not the same thing as a workplace. A private employer may not be the same as a public employer, and movie theaters, stadiums, there may be different rules for all kinds of venues.

So, is work a privilege? Is going to a baseball game the same thing? So, for somebody who is not going to be able to go to a baseball game, it may be lower consequences than somebody who can't go to work if they don't want to get the vaccine, and an employer is attempting to mandate it. So, we have to think about that. We can't talk about these in one big giant blanket way.

The EEOC guidance has said if an employer is going to mandate, so, presuming that it could mandate, then you'd have to make reasonable accommodations for employees with disabilities that prevent them from being vaccinated, and they go on to say that even if you can't find a reasonable accommodation, you can't terminate somebody. So, here we are back to square one of, can employers really mandate if you can't fire somebody?

So, what would a reasonable accommodation look like? Who are the people who would get them? What's reasonable? What's a disability? Now we have employers getting in the business of having to come up with some kind of administrative system to evaluate each of these requests for a reasonable accommodation, or if it's a sincerely religious held belief, they have to get into the business of understanding what is a sincerely held religious belief and what is one that is not sincerely held.

What's going to happen to that information once employers have it? Is it private information to ask somebody to get a vaccine? And they say no, I'm not going to get it and then you have to get a doctor's note. Where do I store that?

Is the very fact of whether or not somebody is vaccinated a medical question? Medical information that requires privacy, and the fact of the matter is, it is. At least under federal law, and under the law of certain states. So, if employers are going to get in the business of mandating, whether or not they can, they are going to have to have these



systems in place, and they're going to be some practical headaches because it is quite certain that employees will ask for, in certain cases, accommodations on a wide variety of issues, and then you're going to have people who may feel discriminated against. So, for example, Becky mentioned that pregnant women other than some different recommendations in the beginning for pregnant women not to get vaccinated, and now there's been certain recommendations that they can be. If pregnant women decide that they're uncomfortable getting the vaccine or have this increased risk for severe illness, are all pregnant women then going to feel that are subject to discrimination because even if they're allowed to work at home, is there some advantage to coming into the workplace and having face time where there are people who now are back in the workplace? So, I think all of these issues are going to be very present in the coming months for employers.

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**Sam Gandhi:**

Let me ask you both, is this a particularly a U.S. thing because if you look at the case in Israel, almost everybody in the country has been vaccinated. A number of people hold extremely strong religious beliefs, yet you're seeing almost everybody being vaccinated in Israel. In Asia historically, in India, people/everybody's got a mark on their arm because they've all received vaccinations as children. Do you think this is uniquely a U.S. thing?

**Wendy Lazerson:**

I think there's a couple of aspects that might be unique and maybe some not. I did see a survey recently of vaccine hesitancy among a number of different countries and the U.S. was actually somewhere in the middle. I think at that time, Russia and France were showing a population that even had increased vaccine hesitancy, which was sort of surprising. You know, France being the place where Louis Pasteur invented vaccination. So, I think you know it may vary from country to country, and perhaps the piece that's a bit different in the U.S. is that a number of trusted regulators internationally have a different system, and so they've actually granted their version of a full marketing approval for their vaccines, whereas we have this EUA vehicle which just I think does introduce a bit of a special legal analysis into the equation.

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**Sam Gandhi:**

So, let's talk about the status of where we are in terms of EUA, and the transition to potentially a permanent approval. Becky, vaccine manufacturers are now in the process of collecting data to support a full FDA approval. So, what's the ramifications of that transition under federal law?

**Becky Wood:**

Yeah, so probably the most significant change would be that if there is a full approval for a vaccine, you're no longer going to be marketed under the EUA, which has the special optionality language that we talked about. That you would be under the normal rules for drug approval, and so the precedent that we have that informs when various entities can mandate a vaccine that has approval from FDA would then be triggered, and this question of when the COVID vaccines may migrate from EUAs to approval is a really interesting one.

As you know, there's not an automatic mechanism for turning an EUA into an FDA approval. Instead, the manufacturer has to submit a biologics license application (a BLA) to FDA for review, and FDA of course wants to encourage continued study of the BLA submission, and it says it needs at least six months of follow-up data for a COVID-19 vaccine BLA submission to be accepted. We know that the makers of the authorized vaccines in the U.S. have said that they plan to submit their BLAs to FDA in 2021, and of course it's unknown whether some of the recent headlines suggesting some side effects from vaccines in certain limited populations will affect how those BLA submission go in, and the timelines. In recent years, just as a sort of general benchmark for BLA approval, it's generally taken something like 8 to 12 months following submission, but of course here people are hoping that there may be some possibility of expediting that, given the extraordinary circumstances of COVID, and given the fact that the FDA is already deeply familiar with the safety and efficacy profile of these vaccines.

So, if you had to guess, probably unlikely that we would see a BLA approval before the end of this year, but of course this situation is very fluid and that could change, and we also should say, of course, FDA may change its approach to how it wants to engage in approval and could

provide more guidance, and more different timetables, as we go forward, but as the process unfolds, we may also see a hybrid environment in which we have some available vaccines marketed under EUA and others under BLA so that could potentially further complicate the approach to mandating.

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**Sam Gandhi:**

You're listening to *The Sidley Podcast* and were joined by Sidley partners Wendy Lazerson and Becky Wood. We're discussing COVID-19 vaccinations and their implications for the workplace. Let me take you all back to kind of some recent events here.

Last Tuesday, Montana's legislature passed a bill. It would prohibit employers from requiring any vaccine as a condition of employment, and it's a measure that could block Great Falls Health Systems from requiring its employees to have COVID vaccines. On the other hand, we've seen now that the Houston Methodist Hospital is requiring all of its employees to receive the COVID vaccine or be subject to termination. So, Wendy, beyond the federal ramifications we just discussed there are these individual state laws to consider, and what are you seeing taking shape as employers around the country navigate this?

**Wendy Lazerson:**

This is a very interesting phenomenon. We're seeing a lot of variation. A lot of states are introducing these bills. Many have failed, a few have passed, and there been some executive orders also prohibiting employers from requiring vaccines in exchange for the right to come to work, and some of these bills have also not only applied to the right to go into the workplace, but also the right to get goods and services, and each state has its own variation on this theme, and I think we've got to keep in mind whether these apply to employers that get state funding. Whether the state can do this. There's a lot right now up in the air on this, but this has become something of a political debate, and you can see when you look at the states that are enacting the legislation, and the ones that are not, and who it's coming from within the state, you can actually, you know, just kind of see the political lines, unfortunately, where many of these bills are not so much based on the science, but based more on peoples' politically held beliefs.

So, I think it's too early to know where these are going to end up. I'm certain they're going to be challenges to many of these laws, both on the federal level and also, you know, within the state. So, I think this is one of those "stay tuned, it's too early". We're going to have to see where these end up in the courts.

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**Sam Gandhi:**

Well, let's talk about that a little bit. Becky, you said before mandatory vaccinations are not necessarily new. All of us who have school children who have filled out those forms and taken them to the doctors and mandatory vaccinations. So, do you think that this is going to evolve with the COVID-19 vaccine the same way that the mumps vaccine and other vaccines did? Parents who didn't want to vaccinate their kids lost to the schools as we saw in the last couple years. Specifically, here in New York where it was pretty much every school district that was subject to suit, and most of the parents in those cases lost.

**Becky Wood:**

Yeah, it's really interesting and you're pointing out the setting of schoolchildren and even some colleges where there is more of a history of mandating in the setting of vaccines that have received approval from the FDA. I think here, it may be a question of time.

At this point in time, as you know, there is no FDA EUA for children that are younger than 16. The current EUAs are for people 16 or 18 years of age or older, depending on which one you're speaking about? That study is ongoing. The FDA said just a few weeks ago that it has plans to decide quickly whether to extend one of those EUAs to children in the tween group, ages 12 to 15, and it's also been reported that the COVID vaccine trials are underway in children and in infants as young as six months old.

So, you certainly could see, in the coming months, a circumstance in which one or more of those EUAs extended to pediatric, to teens, at younger and younger age groups, and then overtime, as you see approvals, that full approvals would also be extended to those age groups. Then as you point out, Sam, I think in that case you do have something of a well-trod path, or at least more precedent, for how those vaccines in the setting of schools and colleges will play out.

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**Sam Gandhi:**

There's a new survey from New Eagle Hill Consulting and was conducted by IPSOS that found U.S. workers that they surveyed were almost evenly split on employer mandated vaccination proof and the management of unvaccinated workers.

So, Wendy, is litigation just inevitably on the horizon here that's potentially brought by workers who don't want the vaccine or those, on the other hand, who want it mandated in the workplace?

**Wendy Lazerson:**

Sam, I think it is inevitable, and I also think there's going to be some chaos within the workplace short of litigation between the two camps of those who want everybody vaccinated and those who don't want to get the vaccine, but, with regard to litigation, I think in the union context we're going to see that unions and the collective bargaining agreements are going to come into play here and the implications of those.

We're going to see lawsuits that challenge the right to privacy, and employers should not be asking the medical question of whether or not somebody has a vaccine, and then if they do, who gets to know that and where does that information get stored? I think we're going to see litigation in the area of failure to provide a safe workplace under OSHA for those or not mandating the vaccine. Some employees will feel unsafe. I think that we're going to see challenges on the discrimination front as to whether or not mandatory vaccine discriminates against those who have a condition and/or hold a sincere religious belief, and even if there is no mandatory vaccine, there could be still some lawsuits that are claiming that because people know that they didn't get a vaccine, for example, even though it wasn't mandated, they were treated differently in the workplace. So, there can be litigation there as well. So, yes, I do think we will have a very busy time with this, and it will be interesting as the science develops, whether we see development in the FDA and we see developments in the legislatures of these states. It'll be interesting to see where this all plays out as well. So, stand by.

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**Sam Gandhi:**

As we wrap up, I want to end with a question of what are you both seeing as the next steps here. Becky, let me start with you. How do you I think things will change if the FDA finally approves the vaccines on a permanent basis.

**Becky Wood:**

Yeah, it's a great question, Sam, and I think on the one hand, if you migrate from EUAs to full FDA approvals, you do get rid of the one complexity we started this conversation with, that mandated options language that's in the EUA statute and in the information that patients and their healthcare givers get when they are considering whether to get the vaccine. So, that will eliminate part of the complexity in the analysis of whether or not to mandate at this particular period of time, but I think as this discussion illustrates, it's by no means the end of the conversation because there continued to be a number of these different issues that will have to be weighed in determining whether an employer ought to mandate, and you know somewhat different considerations of whether schools and other places of entertainment and so forth ought to mandate different considerations. The courts, inevitably, I think are going to be called on to help interpret that as we go forward in time.

**Sam Gandhi:**

And Wendy, what are clients telling you and what are their greatest challenges going forward about reentering the workplace?

**Wendy Lazerson:**

I think employers are very worried about the administrative burdens of all of this, given the fact that they're going to need to address these issues of reasonable accommodation and sincerely held religious beliefs. They're concerned that employees won't feel safe in the workplace and what's that going to do to worker productivity. I think they're concerned about the culture in the office and whether it's going to be divisive between the pro-vaxxers and the anti-vaxxers, and what's that going to mean? What's the implication going to be on environments that were previously collegial, and I think people are just generally waiting to see what the state legislatures do and what's the implication on them and then will those laws be upheld?

So, there's a lot of moving parts, and as we know, employers like certainty, and right now, they're not going to get certainty. So, I think there's just going to be a lot of standing by and doing the best that they can. I think for that reason many employers are saying we're not going to rush back to the workplace. It's just too uncertain, right now. We've been doing fine with remote work, and let's just see if we can wait a little longer and hopefully herd immunity will happen, and this will be all or none issue. So, I think everybody's crossing their fingers there.

**Sam Gandhi:**

We've been speaking with Sidley partners Wendy Lazerson and Becky Wood about COVID-19 vaccines and their implications for employers. Wendy and Becky, thanks. This has been a great look at the landscape and the exciting future that we hold in terms of vaccines. Thanks for sharing your insights.

**Wendy Lazerson:**

Sam, thanks for having me.

**Becky Wood:**

Great to be with you guys.

**Sam Gandhi:**

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