

Speaker 1: Well, hello and welcome to another episode of getting through the Greenberg Traurig podcast for environmental concerns during the pandemic. I'm your host Bernadette [00:00:30] wrap hold. Um, today we have a special episode for you, uh, called before men, before making pandemic response products, consider environmental regulations. I'm joined today by my friends and colleagues, uh, Jillian Kern and candy wild Jillian, why don't you introduce yourself?

Speaker 2: Thanks, Bern. Um, hi everyone. My name is Jillian Kern. I am a shareholder in the Philadelphia office of Greenberg Traurig. Um, and I'm an environmental specialist [00:01:00] doing a little bit of litigation, transactional work and regulatory compliance counseling. And I'm delighted to be here today.

Speaker 1: Well, thank you, Jillian and candy. Would you say a few words about yourself please?

Speaker 3: Sure. I am an associate in the Philadelphia office specializing in environmental law like Jillian. I also do a variety of things, including regulatory compliance litigation and some transactional [00:01:30] work.

Speaker 1: Thanks candy. Well, let's get into it. Um, the COVID-19 pandemic, as we've all seen as Kermit created a big demand for medical supplies and products, there have been shortages and Julian I'll turn to you first. Can you describe how companies are addressing this need and this demand?

Speaker 2: Yeah, of course burn, um, you know, [00:02:00] really appended business as usual throughout not only the United States, but the world. And, you know, at the, at the beginning of coronavirus hitting the U S we saw an increased demand for hand sanitizer. Um, there was, you know, a lot of pivoting from making alcohol or perfume to trying to make hand sanitizer. One of my clients actually, who an electric generating company started making their own hand sanitizer to address the internal need within their company. And then you've also [00:02:30] seen other companies try to, um, change their processes in order to make personal protective equipment, uh, medical gowns, or ventilators for patients. And I think the supply has improved as time has gone on. Um, but it's still low, particularly in certain strategic areas. And so this, uh, this change in manufacturing really continued.

Speaker 1: So what are the key compliance requirements that companies are making [00:03:00] these kinds of transitions that they should keep in mind now that they're moving to making these new products candy?

Speaker 3: There are various requirements at the federal state and local level. Um, companies should really consider two things. First. Um, companies should understand the regulations and guidance documents that apply to them. Um, and the intended product that they would [00:03:30] like to create. Second companies should determine whether their facilities are capable of complying with these standards. Of course, a company is going to have to be flexible and creative to meet compliance standards as just one example, you may find a non-medical grade manufacturing plant. They launch to retool its process to make surgical masks. Uh, at this time, the plant may have to consider

producing [00:04:00] a non-medical grade product while it's awaiting for regulatory approvals from the FDA, ultimately burn each industry may have its own considerations. So we would recommend a careful evaluation of products, compliance requirements.

Speaker 1: That makes sense. Well, what are some of the environmental compliance considerations companies should evaluate before making new products? Jillian?

Speaker 2: [00:04:30] I think there are two main ways of looking at it. I mean, first of all, you want to question, are you making the right stuff? And is it compliant with the requirements, whether that's FDA and medical grade, as candy alluded to, or also other standards of, um, you know, what you're allowed to make at your plant under your air, water or waste related permit. Um, and there's some risks posed by potentially running [00:05:00] a foul of these requirements, so that could include penalties or also facing a future suit from a government or a private party. Um, especially if it turns out that the plant wasn't producing materials that met the relevant standards. Um, you'll see a little bit of this as well. When you look at the fact that enforcement discretion has been dialed back a bit at the federal level, but it varies, and it's a bit of a patchwork throughout the municipal and state level.

Speaker 2: And so while, [00:05:30] you know, you can clinical get away with certain things during this time period. That doesn't mean that there won't be ramifications down the road. So making sure that all the I's are dotted and the T's are crossed in terms of compliance with not only the permits that you already have, but any standards that may apply due to either a change in the substance of what you're making and the affluent or the emissions that come along with that. But also in terms whether the size of your manufacturing [00:06:00] operation has changed, and that may also come with its own requirements.

Speaker 1: So have you found candy that, or are you recommending, or do you think it's good practice for companies right now, as they're making these kinds of transitions to reevaluate their environmental health and safety management systems? What, what sort of considerations relate to that?

Speaker 3: Yes, I am seeing [00:06:30] companies take a hard look at their environmental safety management systems, um, and overall considering the implementation of federal state and local requirements on your business and the new intended products that companies are making at this time.

Speaker 1: Well, thanks for that candy and Jillian, I know that you've paid some special attention to environmental health and safety management systems and considerations [00:07:00] for those even outside a pandemic times. Could you say a few words about that?

Speaker 2: Yeah. Bernie I'd love to. So I think environmental management systems can sometimes be overlooked in terms of their purpose and how valuable they can be, particularly in situations like this. So whether you're talking about extreme weather events like hurricane season, or you're talking about a pandemic, having a holistic system [00:07:30] for environmental health and safety management allows for a better

understanding of what the risks are at a particular plant. So that allows you to be better prepared for the unknowable things that can happen, but it also is helpful in instances like this, where it's not entirely clear, um, what your process might be changing. You don't know if you can get permits, it's difficult to get permits because you know, everyone's working remotely, having those systems in place [00:08:00] down the road. If you do face litigation or penalties from the government, it is better to be able to say that you had this robust environmental management system and they, uh, you know, did a thorough analysis and evaluation of risks throughout your plant. So it's, um, a way to be better prepared, um, for all of those things that, you know, seem like you can't prepare for them.

Speaker 1: Right. Well, thank you, Julian Kern, and thank you also to candy wild. You've been listening to [00:08:30] getting through the Greenberg trolley podcast, miniseries for environmental concerns during the pandemic. We hope all of you are staying safe and stay tuned for our next episode. Thank you. [inaudible].