Episode Title: Modernization of Cosmetic Regulations Act of 2022 -- A Conversation with Karin F. Baron

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Lynn L. Bergeson (LLB): Hello, and welcome to All Things Chemical, a podcast produced by Bergeson & Campbell, P.C. (B&C®) a Washington, D.C., law firm focusing on chemical law, business, and litigation matters. I'm Lynn Bergeson.

This week, I welcome back to the studio Karin F. Baron, Director of Hazard Communication and International Registration Strategy here at Bergeson & Campbell and our consulting affiliate, The Acta Group. Karin and I discuss the newly enacted Modernization of Cosmetics Regulation Act of 2022, better known as MoCRA. The U.S. Food and Drug Administration (FDA) has been the subject of criticism for years over what some regard as inadequate regulation of cosmetics and the facilities where they are produced. MoCRA is intended to modernize the regulation of cosmetics and imposes sweeping changes to the review and regulation of cosmetics about which our listeners need to know. In our conversation, Karin addresses the most consequential new regulatory provisions MoCRA imposes and explains when they are effective and how they will impact the manufacture and marketing of cosmetic products. Now, here is my conversation with Karin Baron.

Karin, I am so pleased that you are back to talk about one of your favorite topics, and that's cosmetics.

Karin F. Baron (KFB): Yes, I'm very excited to be here this morning. This is a really fascinating space that we get the opportunity to explore this morning.

LLB: Let's jump right in. As you know, Karin, last year, Congress passed and President Biden signed the Modernization of Cosmetics Regulation Act of 2022, otherwise known as MoCRA. Interestingly, this is the first major amendment to FDA's cosmetic authority since Franklin Delano Roosevelt signed the [Federal Food, Drug, and Cosmetic Act] (FFDCA) back in 1938. Some would argue that's too long before the law has been upgraded. What are your thoughts? What took so long?

KFB: I think that is a very, very interesting question. I did want to try to dissect it a little bit, because I don't think it's necessarily fair to say that FDA hasn't really been modernizing cosmetic regulations. I think it's more reasonable to look at what is within FDA's purview: What do FDA's budgets look like? How do cosmetics fit into FDA's overall responsibilities? That helps lay down some foundation as to why perhaps cosmetics haven't had as much attention as they should have had. But I think --

LLB: Okay, fair enough.

KFB: Yes. A couple of things I wanted to point out is, one, I think we can all agree cosmetics are in our lives every day. Everyone uses cosmetics. But when you look at FDA's space in general, FDA operates on roughly a $6 billion budget, which seems generous, but when you consider what FDA is responsible for -- you have drugs, you have food, you have animal drugs, animal food, you have tobacco, you have devices, you have biologics. In that $6 billion budget, FDA is responsible for many, many, many things. In FDA's view, it looks at its regulations and its framework based on risk. When we look to FDA, it does acknowledge that the higher risk for folks operating within its jurisdiction is drugs. Drugs receive about 33 percent of FDA's attention when they're allocating their budget, and food, not surprisingly, comes in a close second, with about 20 percent of its budget.

What FDA has done is inadvertently regulate certain cosmetics in that drug space. I think one thing we need to look at is how currently FDA regulates some cosmetics as drugs, because those, in FDA's mind, contain ingredients that diagnose, cure, mitigate, treat, or prevent disease. What FDA has done is things like sunscreen, toothpaste that contains fluoride, antidandruff shampoo, anything that has an ingredient that FDA views as being part of its drug definition, is regulated as a drug. Under FDA's current space, cosmetics are meant to be lower risk. They are only intended to promote beautification and making you smell nice.

LLB: They're not intended to be medicinal.

KFB: That's right. And when they do contain medicinal ingredients, then they fall under FDA's drug space. Now, if you inadvertently -- and we'll talk about that later -- include things you're not supposed to, then FDA has a mechanism for addressing that. In introducing the modernization, we're going to start to align cosmetics more with how FDA regulates drugs, food, and other aspects. We're going to include elements that FDA already expects from food and drug manufacturers.

But I think FDA is also acknowledging that it has been a long time, and we're behind the game. If we look at how cosmetics are regulated with our trading partners, like the European Union, and Latin America, and Asia-Pacific, no cosmetic requires pre-market approval. So already, when you look at how others are starting to develop and design and refine cosmetic regs, we're behind. This in some ways is FDA catching up, but in other ways, when you look at how things like sunscreens are regulated -- sunscreens are considered cosmetics in the European Union, they're considered cosmetics in Brazil. They're not considered part of their drug definitions. There is that -- I think it's important to pull those little bits and pieces apart and take a look at them and then recognize that this will be FDA modernizing everything else: all of the things that fall under that general definition of cosmetics.

LLB: The context, Karin, is very, very important. And the FFDCA covers an awful lot of real estate. I think many in the public health community and [non-governmental organization] (NGO) community welcome the opportunity for FDA to modernize these regulations,

largely for the reasons you note. It's been a long time. There's been a lot of new information pertinent to chemical substances included in a lot of cosmetics. This was Congress's attempt of making good on its commitment to update the cosmetic component of the Federal Food, Drug, and Cosmetic Act.

KFB: Fair enough.

LLB: Let's jump into MoCRA, as it has come to be known, and discuss some of the more relevant provisions in the new law. In general, based on my read, and I defer to your superior knowledge of this area, Karin, the law imposes what seem to be a lot of new requirements on a, quote, unquote, "responsible person." Who is a responsible person for purposes of the law?

KFB: If you go right now to the definitions under [21 C.F.R.] Title 21, Part 700, which contains all of the cosmetic requirements, you will not find that definition. In MoCRA, what you're going to see is now the inclusion of the term "responsible person." And FDA broadly defines this as "the manufacturer, packer, or distributor of a cosmetic product" -- and here's the caveat "whose name appears on the label of such cosmetic product." And then, FDA had already defined cosmetic product, but we're going to refine that definition a little bit under MoCRA to mean that it's "a preparation of cosmetic ingredients with a qualitatively and quantitatively set composition for use in a finished product." Two things to recognize: we have a slight revision to the cosmetic product definition, and now we have the inclusion of a responsible person. But that responsible person is going to be the party that makes that cosmetic product and then places their name on the label of that product. I think that's an important distinction for those in the space currently.

LLB: Does that exclude toll manufacturers, since typically the toller's name does not appear on a product?

KFB: Exactly.

LLB: Okay, got it. Section 605 of the new law interests me as a lawyer, because it includes a provision that requires this responsible person to both maintain records of health-related adverse events associated with the use of a product and to report serious adverse events no later than 15 [business] days after learning about that event. What is behind this serious adverse event, and what are the recordkeeping obligations around this? It seems to my ear to be very similar to the [Toxic Substances Control Act] TSCA adverse effects reporting and [Federal Insecticide, Fungicide, and Rodenticide Act] FIFRA adverse effects reporting. Is this simply a comparable reporting requirement in your view, Karin?

KFB: Yes, I do see it as that. And I want to point out a couple things currently, because I think you are pointing out a very important addition. Right now, as strange as this sounds, the law does not require a cosmetic company to report a problem to FDA. When there is an adverse event or a serious adverse event, often the mechanism in which FDA becomes aware of that is through consumers, parties using the product, who are relating complaints to FDA. With the introduction of adverse event and serious adverse event reporting, we're now switching that up a little bit, and we're putting that obligation on the cosmetic product responsible person. In doing so, FDA actually had to define these terms because they do not exist currently within the definitions in the FDA regulations. What we're going to see is adverse event is very broadly defined as "any health-related event associated with use of a cosmetic [that is adverse]. But then we're going to tease out what FDA means by "serious adverse event." I think we can all agree, when I read through this list, that these seem like something

that you would want a responsible party reporting to FDA in a very quick timeframe, and they're events that result in death. So if you're using a cosmetic product and it results in death, that is a serious adverse event. A life --

LLB: No question about that one.

KFB: Yes, no question on that. A life-threatening experience. Anything that results in hospitalization, any persistent or significant disability, anything that causes congenital anomaly or birth defects, infections, and significant disfiguration. Here they call out some things like hair loss, burns, persistent rashes, and anything that requires surgical intervention. The list of serious adverse events then does trigger a 15-day reporting requirement and a recordkeeping requirement. That recordkeeping requirement is to hold onto those records for six years. And there is a provision -- and we'll talk later about small businesses -- but the general requirement is a six-year recordkeeping. I see these provisions as -- as you noted -- aligning to other agencies, but also aligning with how FDA views these types of events in other aspects of its own regulatory framework, so drugs, food, things like that. There are events that occur that require mandatory reporting to FDA within specified timeframes. While this is introduced into the cosmetic space, it's not altogether new to FDA.

LLB: I'm guessing to some extent, Karin, this codifies a course of conduct that responsible cosmetic manufacturers now follow in any event. When a serious adverse event has been made known to a producer before MoCRA was implemented, it's not like it was ignored, right? It is in the company's best interest to act upon and respond to any type of information that suggests a product the company has introduced into the market might be causing an adverse effect, independent of what they are required to do under the law. There's tort liability, product liability, reputational injury. To some extent, this probably -- and again correct me if I'm wrong -- codifies what might be happening in the marketplace in any event.

KFB: Yes, absolutely. Again, as I said, it aligns with -- if you were already operating in another jurisdictional space within FDA, so if you were already making a sunscreen or toothpaste with fluoride, or you were already making food or food additives, you already had this built into your standard operating procedure. This is not a deviation. This is the inclusion of practices that you may have already been carrying out as part of this space.

LLB: Exactly. Let's move on to another section, Section 607, that imposes what I'm guessing might be unwelcome news -- but you can correct me if I'm wrong -- and that is a new requirement that a cosmetic facility register with the FDA and the requirement mandates that cosmetic products and ingredient listings also be registered with the FDA. Can you expand upon these requirements? I'm having a hard time calibrating whether these are expected or kind of *de rigueur* requirements. To my ear, it sounds like it could be more consequential than that.

KFB: No, and it's interesting, again, to look at current state. And current state does not require that you register your cosmetic establishment. It also doesn't require that you provide any kind of product formulations to FDA. There is no registration number required if you import cosmetic products. FDA had a voluntary cosmetic registration program, but it was very voluntary. What you're seeing here is, again, FDA introducing facility registration into cosmetic space, but it's not altogether unheard of. You do need to register a facility when you manufacture food. You do need to register your facility when you manufacture drugs. Bringing this in, yes, it will be new to the cosmetics space. It's already been talked about for

many years under their voluntary program, but now we're going to have to define what this means.

And so, again, in definitions, we have to define facility. We had a very broad definition of establishment, it was just a place of business where cosmetic products were manufactured or packaged. But now we're going to talk specifically about including in that establishment, the establishment of an importer and anyone that manufactures. Of course, there are exceptions to every rule. I would always encourage folks to take a look at the exceptions, but they're going to be very specific to things like hospitals, cosmetic product retailers -- which I thought was interesting. Beauty shops and salons are all exempt. But in that new facility registration requirement, you do have to include the product listing. And the product listing seems innocuous on the surface, but it's actually more detailed than I think folks would recognize because now you're going to have to put in the specific details about the facility, put in the specific details about the foreign facility, and then the contact for the United States for that foreign facility, and then detail out the products associated with that facility, and that includes the list of ingredients in the cosmetic products.

LLB: I'm struggling with understanding what the relevance is from a regulatory perspective of ingredient listing. Does that mean both proprietary and nonproprietary ingredients?

KFB: Yes.

LLB: Wow.

KFB: I'll say this. When you register a facility for food manufacturing, or when you register your facility for drugs, that's all held within FDA. I can't go search to see where food is being manufactured in the United States. I can't -- there's no public database for me to access, to look to see what food is being made where. That makes sense to me that that's proprietary; that puts controls on ensuring our food supply remains safe. But what FDA is asking for is they want to have a better oversight over where these facilities are located, and which products, and what's in those products. I think what you're seeing is the laying down of the details it needs if it ever decides to inspect your facility, because that's the beginning of this.

In this initial registration, you're going to have to put in all these details, but in all fairness, your cosmetic products should already contain a list of ingredients on the label. That's already required. Pulling together the product, and then the associated ingredients, and then completing a facility registration, and tying all that together, it does seem like a burden, but to me it's administrative in its nature. I think where it gets messy is when you get into certain ingredients that are a little bit more problematic, like flavors and fragrances, because those typically have had very flexible ways of being listed. So now having to pull some additional details -- and we'll talk a little bit more about fragrances -- but I see that as one of the challenges of this. But there's also, once you complete that initial registration, you will have a biennial renewal, which is an alignment with how they deal with food. So while, yes, this is introducing something new, it's not altogether new to FDA space. It's kind of yes, again, considering that we need to align everything under FFDCA and bring cosmetics into the fold, and facility registration is one of those big, big pieces that they were missing.

LLB: Got it. As you suggest, Karin, for people in this space, these requirements are not exactly revolutionary. It's more of an alignment with some of the requirements that apply to food facilities, for example. So I get it. I get it.

KFB: Yes. And they already had --

LLB: It just seems like a lot.

KFB: It *is* a lot. They already had a voluntary program, so folks that were participating in that voluntary program, they have a heads up.

LLB: Got it. Well, there's another provision, and all the lawyers listening to this podcast will be interested to know that Section 608 requires responsible persons to ensure and maintain records supporting, quote, "adequate substantiation," close quote, showing that a cosmetic product is safe. Now, as I understand it, MoCRA also establishes a safety standard that products must meet in order to be lawfully marketed in the United States. My questions are twofold: What is the safety standard? And what is the consequence for failing to meet it?

KFB: Inadvertently, I guess, or kind of secretly, FDA --

LLB: Overtly, Karin?

KFB: Covertly, FDA already expected this of you. This is one of those issues where if you are already in the cosmetics space, FDA did require that companies and individuals who manufacture and market cosmetics, they had a legal responsibility to ensure safety of their products. Now, what FDA is going to lay down is, again, what they mean by that. What do they mean by responsibility to ensure that your product is safe? They're going to define safe. I mean, this is basically going to say that "safe" means that your product, including any ingredients, is not injurious to the user under the conditions of use prescribed. Seems like a pretty fair definition. You definitely want your cosmetic product to not induce any kind of adverse event or adulteration.

But they're also going to lay down what they mean by adequate substantiation of safety, and they do include that term. That's the exact term they use. These are "tests or studies, research, analyses, or other evidence or information that is considered" -- and then here's the caveat – "among experts qualified by scientific training and experience to evaluate the safety of cosmetic products …." So what FDA is saying is you were already supposed to do this. Now we want to see that you are doing this. We want to see that you have these records. You've put them together. You have demonstrated that this product and these ingredients are safe for the intended use, that they will not cause injury or harm to the parties using them when used as directed. But they also include this kind of hidden, snuck in the back of Section 3507, an animal testing caveat. It does stipulate that animal testing should not be used for the purpose of safety testing on cosmetic products and that this should be phased out with the exception of appropriate allowances.

While, yes, this does appear to be new, cosmetic product and ingredient manufacturers have long, already established protocols for how to evaluate the safety of their products. Now they just need to document with a safety substantiation that they are safe for their use. There's a lot out there already, so I don't feel like the cosmetic industry is starting from scratch. There are a lot of places to begin. There's a lot of substantiation that already occurred because it wasn't tied into the law per se like this. But cosmetic manufacturers knew the burden rested with them. There was no pre-market approval. In our society particularly, there's the threat always of litigation. This is just laying down -- this is what FDA is defining as safe and adequate safety.

LLB: Again, similar to some of the other requirements we've talked about, this seems to be codifying a course of conduct that is both well understood and to some extent already in place in the cosmetic industry, but does seem to put some particularity around what might

constitute adequate substantiation and what is that safety standard. But it sounds, Karin -- and correct me if I'm wrong -- that those in the cosmetic community now should not be blindsided by this, that this is more an extension of the course of conduct that prevails now in industry.

KFB: Yes, exactly. That's exactly right.

LLB: Let's move on to Section 609, which goes to certain labeling requirements. Again, to my untrained eye, because this is your space and not mine, Karin, there seem to be three major requirements. MoCRA requires cosmetic product labels to include certain contact information relating to that responsible person that we've already defined, so it can receive adverse events reports. And this, I think, takes effect a couple of years from now. It's not immediately effective.

The second labeling requirement requires that labels for professional cosmetic products include the same information that is required for consumer products, and that I think, kicks in about a year from now. And then finally, the law requires cosmetic labels to identify -- I think you alluded to this already -- special requirements for each fragrance allergen in the product, once FDA issues what is required under the law to be a fragrance allergen rule that should be issued 18 months from right around now, and a final rule no later than 100 days after that, the close of the public comment period. I know that's a lot of requirements, but maybe you can break it down for our listeners and identify a little bit more about this fragrance allergen role and what's behind that.

KFB: Sure. Cosmetic labeling is probably one of the provisions that already had a lot of requirements that exist already for cosmetic labeling within [21 C.F.R.] Part 701. What FDA is doing here is they are expanding upon the existing cosmetic labeling requirements. They're differentiating between when we talk about professional use. And I think some of this goes back to facility registration as well, because there are some exceptions for beauty salons and things like that. But ensuring that the information is still available, regardless of whether the product's being used in consumer professional space.

But this inclusion of fragrance allergens is not surprising. If you look, FDA has already started to address common allergens found in cosmetic products, I suspect, because of the reporting that has already been initiated by folks that have managed or dealt with products that had allergens and fragrances. They are particularly a sensitive subject when it comes to this, because there are a lot of fragrance constituents that are known to cause allergic reactions. Even if you go out to FDA's page right now, you're going to see they already look at fragrances that may cause issues with allergens. They already have a list of those particular fragrances. Ironically, the list is from the European Commission (EC), but --

LLB: All right.

KFB: All right. The EC has done quite a bit of work on this. And that's not to say that this wasn't known by U.S. markets or anything like that, or it wasn't already something that the fragrance and flavors industry wasn't aware of. But if it were me and I was looking at FDA establishing a rule on how they're going to call out the specific fragrance as allergens on the label, I would be looking at the ones that FDA is already noting from the EC and starting to consider if those exist.

I view this again as alignment. FDA is particularly sensitive to allergens, not just in cosmetics, but also food. A major aspect of labeling of food is around whether or not food

contains certain allergens or is manufactured in facilities that contain those allergens. This is acknowledging that in the cosmetics space, there are definitely ingredients that are known to elicit allergic reaction and just calling attention to that on the label, so that parties are aware that their product contains it, because right now the label may just say "Fragrance," or the label may have something in it where you are unaware that it contains something that could result in an allergic reaction by the party using it. So yes, it's new, but there's a long way to get to that because FDA does have to issue, as you know, the rule. But it seems to me FDA has already done a lot of the legwork on this space. If I were a fragrance manufacturer, or if I was incorporating fragrance into a product, I would already be looking at what FDA has already noted as a fragrance allergen.

LLB: As you note, it sounds like the European Union might be a step ahead, so the community, an international, multinational community, presumably is well aware of what the U.S. role might outline as requirements --

KFB: -- Yes --

LLB: **-- g**iven that this space is not new to the community.

KFB: Exactly. Exactly.

LLB: I think our listeners would be very interested in FDA's new enforcement authorities, which were awarded it under MoCRA. Specifically, Section 607 enables FDA now to suspend the registration of a facility if it determines that a cosmetic product manufactured by that facility has a, quote, "reasonable probability," close quote, of causing serious adverse health consequences. We lawyers, we're always interested in what might be a *reasonable* probability. And is the standard similar to the authority that FDA already has to suspend a *food* facility's registration? My sense, Karin, given some of the recurrent themes of this conversation, is that some of the *food* authority that FDA has under the FFDCA is now being shared with the cosmetic industry, and perhaps this is among those requirements.

KFB: Yes, I see that, too. We'll talk a little bit more about recall in a minute, but, yes, suspension of a facility registration. Again, first we have to lay down the facility registration requirements. We have to find out where the products are, so that if there is an adverse event or a reasonable probability of a serious adverse event, FDA now has the authority to suspend that facility registration. Now, I will say when you look at this comparatively to food, it's not very often that FDA exercises this type of authority. I would say it has to be pretty extreme for them to exercise this authority. They usually work very cooperatively with parties that might be involved where they see reasonable probability, but it is laying down consistency across the agency in being able to suspend a registration for folks that are either not addressing it in a manner that FDA feels is sufficient and timely. Right now, it says within five business days -- a very short time period.

LLB: Yes, that is *awfully* abbreviated.

KFB: It's very abbreviated, but it's FDA saying if they view that the continued facility registration could result in serious adverse health consequences -- we talked about death and those types of things -- this is something that they're being granted the ability to do. But it is; it's within five business days.

LLB: You alluded a moment ago to recall authority. FDA now *has* mandatory recall authority if it determines there is a reasonable probability that a cosmetic is adulterated or misbranded. What are your thoughts on that new authority?

KFB: I think, too, when you look at -- FDA right now, doesn't have that authority. They do now because of this law, but prior to the law --

LLB: It didn't have it, right?

KFB: Didn't have it. No. Recalls of cosmetics were *entirely* voluntary. Some companies were more responsive than others. The mechanisms afforded to FDA to draw attention to something that it viewed as adulterated -- here we go back to old terminology, but essentially adulterated can mean a lot of things, but if FDA viewed something was adulterated, not manufactured according to FDA standards, or contained something that was a contaminant, or contained something that was filthy or decomposing, it didn't have the authority to order a mandatory recall. It had to nicely ask you to do that.

Now, under [Section] 611, they are giving FDA the authority to mandatorily recall a cosmetic that will cause -- again, it's that serious adverse health consequence. It's not everything, but if FDA does look at your cosmetic and they do view that the adulteration or the misbranding -- and misbranding has a lot to do with the things you say about it or don't say about it -- they can issue a mandatory recall. Now FDA, even in the *food* space, wasn't granted that authority until FSMA [the Food Safety Modernization Act] in 2011, I believe. This is relatively new with respect to cosmetics, obviously. But it is something that FDA -- we start to see the evolution of that growing within FDA, that consistency of giving FDA the authority that when it looks at something, it now has the ability to ask you first to please withdraw your product from the market, to recall your product. But if you do not do so within the timeframe that FDA views as reasonable, it will mandatorily ask you to do that.

LLB: My guess is, Karin, again, similar to some of the other provisions we've discussed, that this certainly codifies FDA's authority to compel a recall. But truth be told, any manufacturer that is told that their product might be not quite up to snuff, they're going to want to recall it in any event, right?

KFB: Exactly.

LLB: This is a truing up of the authorities the FDA has with regard to food and drugs, and now that same authority is commensurate with its authority under FFDCA for cosmetics.

KFB: Absolutely. FDA's mechanisms in the past for dealing with adulteration and misbranding were to issue warning letters and citations. I see that as just now it being able to evaluate some of those warning letters and then to now say, "You need to recall that because the continued use of that will result in a serious adverse outcome." And most companies that have been engaged, and the ones that we've worked with that had unfortunate incidents in food and had to recall food, did so voluntarily and in cooperation with FDA. I don't see, again, FDA exercising this mandatory aspect very often, but it's nice that it's been afforded the power to do so in the event that somebody is not cooperating.

LLB: Exactly. These are a lot of consequential changes to the law, some of them logical extensions of current courses of conduct, and also a very definitive response to critics of the Federal Food, Drug, and Cosmetic Act, who claim that the agency lacked authority that is much needed in areas that are of increasing concern to consumers. Was Congress sensitive

to some of the burdens these provisions might impose on smaller businesses? If so, what are those accommodations?

KFB: Yes, they definitely included some small business provisions within MoCRA. It's meeting that definition of a small business that will be tight. But what FDA -- what's specified here is that if your gross annual sales for the previous three-year period is less than a million, adjusted for inflation, then you are exempted from certain requirements, or your requirements are less burdensome. There were a couple that they spoke to, and we'll talk about one of them shortly -- the GMP, the Good Manufacturing Practices, also facility registration. In addition, when we were talking about serious adverse event reporting and recordkeeping, small businesses will be given a three-year recordkeeping requirement instead of a six-year.

But in the terminology, they actually indicate, even if your gross annual profits meet what they define here as that million-dollar threshold, if your cosmetic products come in contact with mucous membranes of the eye under the conditions of use, then you do not qualify as a small business. What you see here is FDA indicating, even if you're in that small dollar amount, if you have a higher risk cosmetic, if it's injected, or it's intended for internal use, or it does alter appearance for more than 24 hours, then you're automatically out of the small business exceptions.

LLB: Interesting. I did not know that.

Yes, it is very interesting to see that because typically when we look at small businesses under other pieces of legislation like FSMA, the Food Safety Modernization Act, each layer of FSMA --because again, it's not one law, it's several laws -- had a lot of exceptions for small businesses. Here, they're differentiating risk. Again, they're saying, even if your dollar amount meets this, if you're in a higher risk space, then we want all of it; we want you to be part of all of it. And I can understand why; it makes sense to me.

LLB: We've already alluded to one forthcoming rulemaking FDA is required to undertake with regard to fragrance allergen disclosure, but as I understand it, there are some other mandatory obligations imposed under the new law that FDA must take by a date certain. Can you share with our listeners what those might include?

KFB: Yes. In this very tiny paragraph, there's Section 606, where they're introducing the concept of Good Manufacturing Practices to cosmetic products. These are a small paragraph, but I see this as being pretty substantial. What FDA here is being told to do within a certain specified timeframe -- and I think it's two years, and everything done by three -- is to develop GMPs. In doing so, they need to account for the size and scope of the business and to provide sufficient flexibility to be practicable for all sizes and types of facilities. Then, as we talked about small businesses, they're to include a simplified GMP requirement for smaller businesses. That's all it says. We've had a lot of people asking us questions about this GMP piece because this is a pretty big impact right now. There is no GMP requirement. You *cannot* manufacture your cosmetic in a place that would result in adulteration, and that means under insanitary conditions, where it can be contaminated, but actually laying down GMPs, that's a pretty significant burden, but it already exists.

GMP exists under FSMA for food; GMP exists for drugs; so incorporating GMP, however it will look, for cosmetics is again bringing in alignment. But it also introduces some requirements for -- I think it's rules for standardized testing. The one element that they specifically speak to in a separate section is standardized testing for asbestos in talc-

containing products. Anyone who has seen the news knows there's been some litigation around talc-containing products, but I found this element interesting because FDA has already established methods for analyzing asbestos and talc. FDA, in fact, published a report last year about its pulling products off shelves and looking at them for asbestos. This was already something FDA was doing and acknowledged. FDA has an entire web page devoted to talc and asbestos contamination in talc. This to me was something that you're now again putting -- your codifying by saying FDA must now publicly codify how it's going to ask folks to analyze their talc-containing products for asbestos. But it doesn't necessarily stipulate what that means, because again, you're supposed to be doing the safety substantiation. You're supposed to be ensuring your products are safe.

Is FDA laying down the foundation to say any asbestos in talc is not safe? I think most of us would agree that that's probably a good thing to acknowledge, but it's deeper and broader. I don't think folks recognize that talc itself is a naturally occurring mineral. Asbestos is a naturally occurring mineral, and depending on where these minerals are being mined, they can naturally contain certain concentrations of asbestos. This is starting to lay down specific requirements for folks that are using talc as an ingredient and to ensure that they're -- I'm going with asbestos-free. That's where my head's at.

LLB: A lot of people would agree with that choice, Karin. I'm going to note that the law also addresses another very, very ubiquitous substance these days, called [per- and polyfluoroalkyl substances] (PFAS). As I understand it, FDA is required to report on the presence of PFAS-free cosmetics by a date certain under MoCRA. Can you expand upon that provision?

KFB: Yes. This, too, I found -- I find it interesting that they're calling out PFAS and this talc and asbestos issue specifically, but in the PFAS, what they are saying and they -- they don't -- anyone who's been following PFAS in the legislation knows that there is a lot going on with PFAS. There are a lot of restrictions occurring in the European Union. There's a lot with EPA. FDA has received a little bit of heat for having not really addressed some potential areas where PFAS is currently used in food and cosmetics. What they're saying here is that they have to assess the *use* of perfluoroalkyl and polyfluoroalkyl substances -- they didn't define it any further than that -- in cosmetic products, and then any scientific evidence regarding the safety of such use in cosmetic products. They are supposed to be looking at the risks associated with the use to conduct a report and issue the report no later than three years from the enactment of the Act.

It doesn't say what they're going to do with it; it just says they need to start to look at it. They need to put together the scientific evidence regarding the safety of it and issue a report about it. We've seen FDA slowly engaging in PFAS. We've seen some noise around food contact. That's a big element, coatings on cookware. We've seen some issues with fluorinated particles on plastics. I think this is just the next natural progression, but it doesn't say what they're doing with that report. They have three years to put together the report, but it's not necessarily putting in place any kind of restriction because at this point, they're still trying to investigate whether or not it's safe. I think that's an important distinction here.

LLB: And between now and three years from now, we will know much, much more about this very, very broad constellation of chemicals called PFAS chemicals. Right now we don't have specific information on most of them to make any type of informed judgment regarding safety or what might pose a risk. This will be a much anticipated report, and I'm sure one that the cosmetic community will be watching carefully.

KFB: Yes, and I agree. I think, too, as we've talked in the past, we're seeing this in EPA, but we both know that EPA's jurisdiction ends when the PFAS use is in food or cosmetics.

LLB: Right.

KFB: This is FDA engaging in the discussion of PFAS, which is a global concern at this point. It will definitely be interesting to see what comes out of this report, whether or not it is viewed -- how they put together the safety and the effective use of PFAS in cosmetics.

LLB: Agree. We've covered a lot of territory under MoCRA and identified, I think, most of the really, really, really important provisions. I don't know, you might have already answered this, Karin, but what do you think is the *most* consequential aspect of MoCRA?

KFB: Two things that come to mind. The GMP, even though it's like two paragraphs long.

LLB: Right. The mouse that roared here.

KFB: Exactly. I do see that. But what that actually looks like, nobody knows. It has to be issued as a notice of rulemaking. At this point, I do see it as having a pretty significant impact, both on cosmetic products, but inadvertently on cosmetic ingredients, and I'll explain why.

What we see in industry is right now there's a lot of burden placed on the ingredient manufacturer to demonstrate safety for what it's saying, that that ingredient imparts whatever property it imparts, when it provides it to the cosmetic product manufacturer to incorporate into your lotion and your whatever. When you say now products have to be manufactured under GMP, does it inadvertently kind of roll a burden up into the cosmetic ingredients space, where now those ingredient manufacturers would have to provide some assurances that those ingredients are manufactured under GMP? I don't know what the answer to that is, but I do see that as one significant outcome of MoCRA.

I also think the facility registration is an interesting, very interesting introduction. It aligns with how FDA manages other spaces within its jurisdiction, but that doesn't mean that it's not significant. It does mean that cosmetic products -- that your label, your name, your product, you will need to now consider whether you want to be part of the space, continue to be part of this space -- and it's a billion dollar industry! I do appreciate that while it seems simple to register your facility, I do see that as a fairly significant introduction, in addition to the serious adverse event reporting. We talked a little bit about that. You may already have a mechanism for doing that, but does that mechanism align with now what FDA is laying down that requirement, that 15-day requirement? Building in those practices, too, seems to me to be pretty significant.

LLB: Last question, Karin, and it's in two parts. First, what should members of the cosmetic industry be doing right now in response to MoCRA to prepare for it? And where might our listeners find additional information on everything that we've been discussing here?

KFB: There are definitely things that FDA has already laid out for you that are already part of MoCRA that you can be doing now. You don't need to wait for the proposed rule to come out in the *Federal Register*. I would start with your safety substantiation. Put together, look at how FDA is defining safe. Look at how FDA is defining adequate substantiation, and ensure that your ingredient and your products all have the records that demonstrate that you have done your due diligence to ensure that your product is safe for its intended use. I would definitely be looking at whether or not your products contain ingredients that FDA already

notes as an allergen in a fragrance. If you incorporate fragrance or you see that list of allergens, I would be pulling apart some of your formulations and ensuring that you have a mechanism to address that, if and when that does become part of mandatory labeling, because label changes are complicated. I don't care which industry you're in. Any time you have to impart a change to your label, that does result in time -- you need time to take care of that. Take a look to see where that might be potentially impacting you in the future.

Those are definitely two things you can do now. Then I would be pulling your product details. While there still may be time to develop the facility registration, you will have to incorporate in that registration your product listing. Have all of that information in hand, so when FDA does initiate facility registration, you're ready to do it, and you can accomplish that within the timeframe that FDA specifies. Those things can be done right now. No need to wait.

LLB: Excellent recommendations, Karin.

KFB: Where to find out information about MoCRA? You and I talked a little bit about this. One of the surprising things, I guess, to me was that this was part of the appropriations bill that was issued and signed in December. Actually finding it was a little tricky -- did have to navigate through a lot of stuff to find Subtitle E, which talks about this MoCRA, this modernization aspect. I would be taking a look at all of the language that's specified there.

I did searches. I can tell you at this point in time, I'm not seeing anything on FDA's website about it at all. I will continue to track through that, so pay attention to B&C and Acta as we continue to look for that. I've not seen anything in the *Federal Register* yet about potential rulemaking related to MoCRA. Again, B&C and Acta will be tracking that. I would also be looking to some of the trade organizations because while cosmetics space, up until this point, has been very self-regulated, there are a lot of really very, very powerful and informative trade associations that have a lot of information available on their sites. I'm sure they are also tracking this as well, so be on the lookout for those things.

LLB: Excellent, Karin. Thank you for your counsel, your recommendations, and for a very informative conversation. I think our listeners will find it most helpful. I want to thank you for gracing our studios again. We always enjoy having you.

KFB: Thank you. Have a good day.

LLB: Thanks again to Karin for speaking with me today about the Modernization of Cosmetics Regulations Act of 2022 and the many consequential changes in cosmetics regulation the new law invites.

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