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UNITED STATES DISTRICT COURT

NORTHERN DISTRICT OF CALIFORNIA

SAN FRANCISCO DIVISION

UNITED STATES OF AMERICA, Plaintiff, v. LINDSAY MARIE CLARK AND LINDSAY CLARK, M.D., MEDICAL CORPORATION, Defendants.	)	NO. 3:21-CR-00132-SI **SENTENCING MEMORANDUM**

I. INTRODUCTION

For years, Dr. Lindsay Clark, an internal medicine physician specializing in cosmetic procedures, injected at least several hundred unsuspecting patients with hundreds of thousands of dollars' worth of products that she bought from foreign online sellers, outside of the regulated, lawful supply chain. Clark carefully concealed the source of the products from patients, who specifically sought out a licensed physician to provide their aesthetic medical procedures and were led by Clark to believe that they were receiving safe, FDA-approved, prescription drugs and devices. She did so to boost her own profits.

Dr. Clark performed services at her home and at her practice, Lindsay Clark, M.D., Medical Corporation ("LCMC"), which today does business as Entrada Medical Group and once did business as Physicians Youthful Resolutions and later Enhance Medical Group. *See* Clark Plea at 2; LCMC Plea at 2. Clark is and has always been the Chief Executive Officer and sole shareholder of LCMC. LCMC Presentence Investigation Report ("PSR") ¶ 45. Among other services, Clark offered injections of Botox, a drug that uses botulinum toxin to prevent muscles from moving, and Juvederm, a dermal hyaluronic acid filler, which treats wrinkles by being inserted under the skin. Clark PSR ¶¶ 10, 14; LCMC PSR ¶¶ 9, 13. Both products are manufactured by Allergan. Clark PSR ¶ 10; LCMC PSR ¶ 9.

Under the federal Food, Drug & Cosmetic Act ("FDCA"), Botox is a prescription "drug" and Juvederm is a prescription "device." Clark PSR ¶ 10; LCMC PSR ¶ 9. Both are subject to various requirements under the FDCA and its implementing regulations, including that they be obtained from lawful sources like the prescription's manufacturer or a licensed pharmaceutical wholesaler. Clark PSR ¶ 9-10; LCMC PSR ¶ 8-9. In the United States, the only lawful suppliers are Allergan and a few authorized distributors.

Contrary to these requirements, from at least April 1, 2016, until June 3, 2020, Clark's administrative staff, at Clark's explicit direction, obtained products purporting to be "Botox" and "Juvederm" from online "pharmacies" that were not authorized to sell these products in the United States.[1] Clark Plea at 3; LCMC Plea at 3. Clark purchased these products at suspiciously large

[1] The PSRs suggest that these sellers were not authorized to sell Allergan products in the United States because the products were intended for distribution in foreign countries, Clark PSR ¶ 16, but the fact is that these foreign online "pharmacies" were violating U.S. law in selling the products here. Furthermore, some of the products that Clark purchased and injected patients with have lot numbers—

discounts—often around 40% of Allergan's price—yet charged patients the same price that she did when selling legitimate, FDA-approved Allergan products. Clark Plea at 2-3; LCMC Plea at 4. Even after four of Clark's orders from online suppliers were detained at the U.S. border, and Clark was formally notified by letter that these shipments appeared to be contraband drugs and devices, Clark *continued* in her unlawful sourcing and *continued* to conceal the source of these products from patients and Allergan. Clark Plea at 2-3; LCMC Plea at 4-5; Clark PSR ¶¶ 10, 36; LCMC PSR ¶¶ 9, 35. Clark's revenue from the use of these illegal products exceeded $1 million (and likely amounted to much more, given her deficient patient record-keeping, more on which below). Clark Plea at 3; LCMC Plea at 3.

As a doctor, Clark was—and is, as Clark is still a licensed physician—entrusted with ensuring the safety of her patients and required to comply with the FDCA. The FDCA protects the public from unscrupulous actors and ensures that the prescription drugs and devices given to patients are safe, effective, and what they purport to be. Clark betrayed her patients' trust by flouting these mainstay laws of the American medical system and instead injecting her patients with products of unknown quality and authenticity, all for her own personal financial gain. At least several hundred patients fell victim to Clark's risky and fraudulent conduct. To this day, many experience significant anxiety about what Clark injected into their faces and have expressed that their trust in the American medical system has been shaken.

The government submits that a sentence of imprisonment is necessary for Clark to reflect the severity of this conduct. The government respectfully requests that the Court impose a sentence within the range associated with the Sentencing Guidelines—that is, one year.[2] The government submits that Dr. Clark's practice, LCMC, which has pleaded guilty to a felony, should likewise be subject to a sentence that reflects the severity of the conduct. In light of the practice's apparent inability to pay a Guidelines fine, the government requests a fine of $70,000, significantly below the Guidelines range. The government also requests a term of probation at the top of the Guidelines range—*i.e.*, five years.

identifying numbers assigned by Allergan to a particular batch of product—that Allergan does not recognize and thus do not appear to have been legitimate Allergan products. *Id.*

[2] "Where the statutorily authorized maximum sentence is less than the minimum of the applicable guideline range, the statutorily authorized maximum sentence shall be the guideline sentence." U.S.S.G. § 5G1.1.

II. PROCEDURAL HISTORY

On April 1, 2021, the grand jury returned an indictment against Clark charging her with receipt and delivery of misbranded and adulterated drugs and devices in violation of 21 U.S.C. §§ 331(c) and 333(a)(2), provisions of the FDCA. Dkt. No. 1. On November 18, 2022, the government filed an information against Clark's practice, Lindsay Clark, M.D., Medical Corporation, charging it with receipt and delivery of misbranded and adulterated drugs and devices in violation of 21 U.S.C. §§ 331(c) and 333(a)(2), a felony, and a superseding information charging Dr. Clark with receipt and delivery of misbranded and adulterated drugs and devices in violation of 21 U.S.C. §§ 331(c) and 333(a)(1), a misdemeanor. Dkt. Nos. 83, 84. On November 22, 2022, Clark and her practice pleaded guilty to their respective charges. Dkt. No. 89.

III. OFFENSE CONDUCT

A. Regulatory Background

In the United States, prescription drugs must be obtained from lawful sources like the drug's maker or a licensed pharmaceutical wholesaler. This so-called "closed" supply chain protects Americans by establishing comprehensive control over prescription drugs and devices—from how they are made to how they are prescribed and every important element in between: traceability, safe transportation, counterfeit deterrence, and more. Put simply, Congress determined over a century ago that to protect the public from powerful but potentially dangerous drugs and devices—as well as quack nostrums, unethical practitioners, and careless manufacturing, transportation, or storage, among other things—the nation's drug supply would be highly regulated.

The Supreme Court, too, long ago recognized that the "lives and health" of patients in modern American life are "largely beyond self-protection." *United States v. Dotterweich*, 320 U.S. 277, 280 (1943). The FDCA replaced the old "buyer beware" regime, in which injury was relatively common and victims had a liability suit against the doctor as their principal remedy for harm. Today we have a prophylactic system to prevent injury in the first place. *See, e.g., Wyeth v. Levine*, 555 U.S. 555, 566-67 (2009). Patients are entitled to trust that their physicians don't cut corners to make a buck.

The statutes in 21 U.S.C. §§ 331(c) and 333(a) promote this objective by making it a crime to receive and deliver what the FDCA labels "misbranded" or "adulterated" drugs or devices. The

elements of a misdemeanor offense under 21 U.S.C. §§ 331(c) and 333(a)(1) are that: (1) the defendant received in interstate commerce; (2) a drug or device; (3) that is adulterated or misbranded; (4) and delivered or proffered delivery of it for pay or otherwise. The felony offense under Section 333(a)(2) requires an additional element, namely, that the conduct be committed with the intent to defraud or mislead. *United States v. Watkins*, 278 F.3d 961, 963 (9th Cir. 2002).

Botox is an Allergan-made drug that uses botulinum toxin to prevent muscles from moving and may be used to reduce the appearance of wrinkles. Clark PSR ¶ 10; LCMC PSR ¶ 9. A dermal filler has a similar effect but instead of a toxin, it uses other substances, in this case hyaluronic acid, a natural component of the skin's connective tissue. Clark PSR ¶ 10; LCMC PSR ¶ 9. One such type of dermal filler is manufactured by Allergan under the name Juvederm. Clark PSR ¶ 10; LCMC PSR ¶ 9. FDA-approved Juvederm products that are lawfully marketed in the U.S. under the name Juvederm include Juvederm Ultra, Juvederm Ultra Plus, and Juvederm Voluma XC. Clark PSR ¶ 10; LCMC PSR ¶ 9. But Allergan also sells products abroad under the Juvederm name, such as Juvederm Ultra 2, 3, and 4, that do not have FDA approval for *any* use in the U.S. Clark PSR ¶ 10; LCMC PSR ¶ 9.

Botox is regulated under the FDCA as a "drug," while a dermal filler like Juvederm is considered a "device." 21 U.S.C. § 321(g)(1)(B), (C), and (D); 21 U.S.C. § 321(h); Clark PSR ¶ 10; LCMC PSR ¶ 9. A "prescription" drug or device is one deemed unsafe for use except under the supervision of a licensed practitioner. 21 U.S.C. § 353(b)(1); 21 C.F.R. § 801.109. Prescription drugs and devices may be "misbranded" in several ways, including where they have false or misleading labeling or lack adequate directions for use. 21 U.S.C § 352. Devices that lack requisite FDA approval or clearance are both "misbranded" and "adulterated." 21 U.S.C. §§ 352(o), 351(f)(1).

Injectable treatments like Botox and Juvederm are tremendously popular—but this creates a large illicit market. Clark PSR ¶ 12; LCMC PSR ¶ 11. Many sellers abroad acquire Allergan-made product destined for other countries and then illegally redirect it to U.S. customers at steep discounts. Other sellers, also profiting from the high demand, counterfeit these products. Clark PSR ¶ 12; LCMC PSR ¶ 11. But what is critical is that, regardless of how the product was originally made, *none* of these products are lawful under the FDCA. And under that law, so-called "Botox" or "Juvederm" products that do not comply with these requirements simply cannot be called Botox and Juvederm—they are, instead,

unapproved injectable botulinum toxins and hyaluronic acid fillers. That is because the bottom-line reality is that no one really knows what these vials and syringes actually contain. Not Allergan. Not the government. Not Clark. Not the patients. And because Clark's products were injected long ago, no one will ever know.

Dr. Clark's conduct illustrates why laws like the FDCA are crucial. Clark, a trained and licensed medical doctor, defied the trust of her patients by obtaining prescription products whose provenance, and hence safety and efficacy, she took on faith from dubious, law-breaking foreign-based suppliers. In doing so, Clark put profit over safety and gambled with her patients' health.

B. Clark and Lindsay Clark, M.D., Medical Corporations' Practices

Dr. Clark is the Chief Executive Officer of Lindsay Clark, M.D., Medical Corporation and directed its purchasing of drugs and devices. Clark PSR ¶ 13; LCMC PSR ¶ 12. The only other officer of Lindsay Clark, M.D., Medical Corporation is Clark's mother, Terice B. Clark, who at times performed office management tasks for the practice.

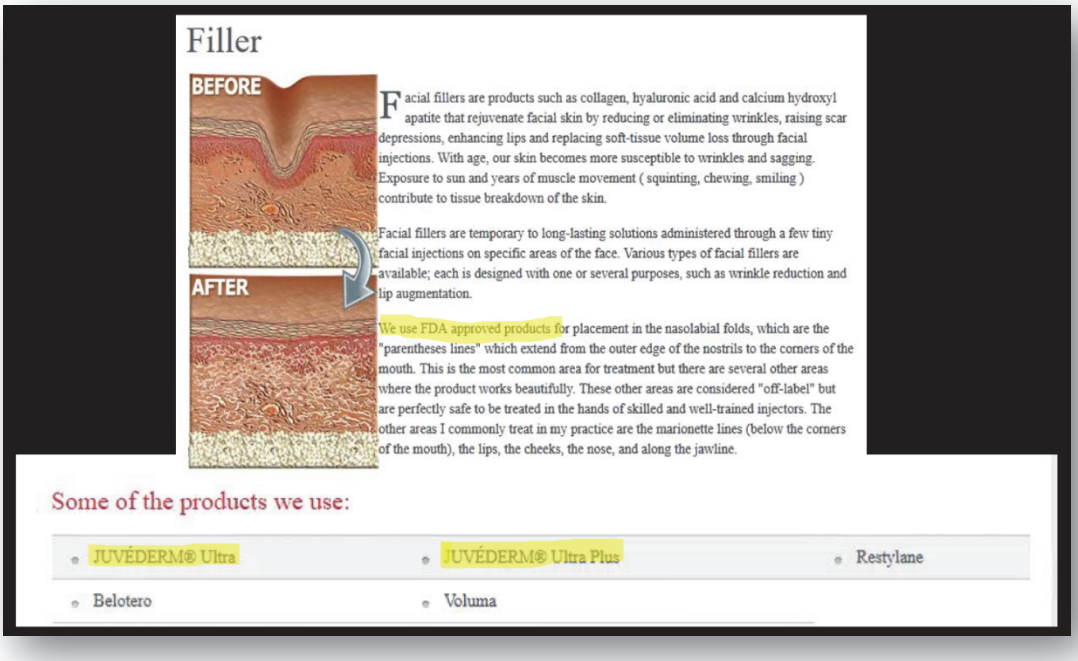
Dr. Clark purchased for her medical practice products purporting to be Botox and Juvederm from a series of foreign online "pharmacies" that bore names such as "Inject Medical," "Rose Pharmacy," "Filler Depot," "Medica Depot," "Knightsbridge Cosmetics," "Team Medical," and "Ritz Pharmacy." Clark Plea at 2-3; LCMC Plea at 3; Clark PSR ¶ 14; LCMC PSR ¶ 13. Not a single one of these suppliers had valid FDA registration or FDA or state licensure to allow them to sell prescription drugs or devices. Clark PSR ¶ 14; LCMC PSR ¶ 13. These suppliers were not authorized to sell these products in the United States. Clark Plea at 2-3; LCMC Plea at 3; Clark PSR ¶ 14; LCMC PSR ¶ 13.

Clark purchased these products at immense discounts—often around 40% of the price that Allergan charged Clark. Clark Plea at 3; LCMC Plea at 4; Clark PSR ¶ 17; LCMC PSR ¶ 16. But Clark sold them for the same amount as legitimate Allergan products. Clark Plea at 3; LCMC Plea at 4; Clark PSR ¶ 17; LCMC PSR ¶ 16. And this wasn't occasional conduct but the cornerstone of her business model: Clark's records reveal that between 2016 and 2020 she purchased at least $270,951 in products from these foreign suppliers and earned at least $1,069,880 in injecting them into patients. Clark Plea at 3; LCMC Plea at 3; Clark PSR ¶ 17; LCMC PSR ¶ 16. These included products labeled as "Juvederm Ultra 2" and "Juvederm Ultra 3," which have no FDA approval for use in the United States. Clark PSR

¶ 10; LCMC PSR ¶ 9. Most of these unapproved and unlicensed injectable botulinum toxin drugs and hyaluronic acid Class III devices appear, assuming the packaging wasn't tampered with, to have been manufactured for distribution in foreign countries that included Argentina, Bangladesh, Ecuador, the United Kingdom, Czech Republic, and India. Clark Plea at 3; LCMC Plea at 3. The government was able to ascertain this by taking the lot numbers recorded by Clark in patient records and requesting the intended-destination information for these lot numbers from Allergan. But in doing so, the government found that yet other products that Clark purchased and used had *no* recognized Allergan lot numbers and therefore, so far as anyone is aware, are of unknown manufacturing origin—meaning that they may have been counterfeit. Clark Plea at 3; LCMC Plea at 3; Clark PSR ¶ 16; LCMC PSR ¶ 15.

Clark's staff all confirmed that the practice purchased products from these sources at Dr. Clark's sole direction. Clark PSR ¶ 18; LCMC PSR ¶ 17. They also confirmed that patients who received these products were charged the same amount as patients who received products obtained in compliance with the law (and that cost Clark significantly more). Clark PSR ¶ 18; LCMC PSR ¶ 17.

Dr. Clark admitted that she took steps to conceal, from patients, Allergan, and the FDA alike, that she was buying products from unauthorized foreign sources. Clark Plea at 3; LCMC Plea at 4-5.



First, the practice's website featured the claim that Clark used "Botox Cosmetic®," which she described as "approved by the Food and Drug Administration (FDA)." Clark PSR ¶ 19; LCMC PSR ¶ 18. When describing the Juvederm products Dr. Clark offered, the website likewise listed only the versions that have been approved for use in the U.S. and described the products as "FDA approved." Clark PSR ¶ 19; LCMC PSR ¶ 18. (See screenshots from her website above.)

Dr. Clark's practice also used a "Botox consent form" that stated that Dr. Clark would administer "Botox®" (using the trademark symbol) and referenced its FDA safety approvals. Clark PSR ¶ 19; LCMC PSR ¶ 18. She had patients sign this regardless of whether she was using actual Botox. She also had patients sign a consent form for the use of Juvederm®. But Clark's records show that she injected non-FDA-approved dermal fillers into these same patients. Clark PSR ¶ 19; LCMC PSR ¶ 18.

Dr. Clark carefully tracked which products came from Allergan and which from foreign "pharmacies." Clark PSR ¶ 20; LCMC PSR ¶ 19. This is how she knew how much money she was making. Because she charged the same price for her injectable services regardless of how much she paid for the product, more illicit product meant more profit. (Clark's employees were told to mark boxes with tiny lettering to denote the product's source, such as "A" for Allergan, "FD" for Filler Depot, and "IJM" for Inject Medical.) Clark PSR ¶ 22; LCMC PSR ¶ 21.

But Dr. Clark and her practice took equally careful measures to conceal this improper sourcing from patients. Clark PSR ¶ 20; LCMC PSR ¶ 19. Internal emails reflect Clark's instructions to staff never to discuss the origin of the product. For instance, in a July 18, 2017, exchange, a Clark employee named Courtney Allyn wrote Clark's accountant, Karen Davis, who was working to keep track of product sources so that she, Davis, could keep the books on the practice's profit:

> Just yesterday Lindsay used a vial from FD [Filler Depot, an online "pharmacy"] and one from Allergan for one patient's treatment, so I had to guesstimate how many were taken from each. I'm not sure if maybe we can try to ask Lindsay how many she thinks she got from each vial, ***bc we don't really want to verbalize that we get our Botox from anywhere other than Allergan in front of the patient.***

Clark PSR ¶ 20; LCMC PSR ¶ 19 (emphasis added).

Davis wrote back, acknowledging the practice of secrecy toward patients, but expressing curiosity about why the practice used different Botox "vendors" in the first place:

> I'm guessing there are many factors, but don't know what all might factor into the decision to use one botox vial over another, if a patient isn't particular. I agree, no need for a patient

> to know the vendor of the botox, and my unknowing assumption is that sometimes if a patient is often allergic to certain things, the Allergan botox would be used over another?

Clark PSR ¶ 21; LCMC PSR ¶ 20.

In fact, the only "factor" for Clark in choosing what "vendor" to use was that the "vial from FD" was cheap and illegal and the "Allergan botox" was not. The problem wasn't that patients were "particular" or not—it was that they were never told of the "decision to use one botox vial over another."

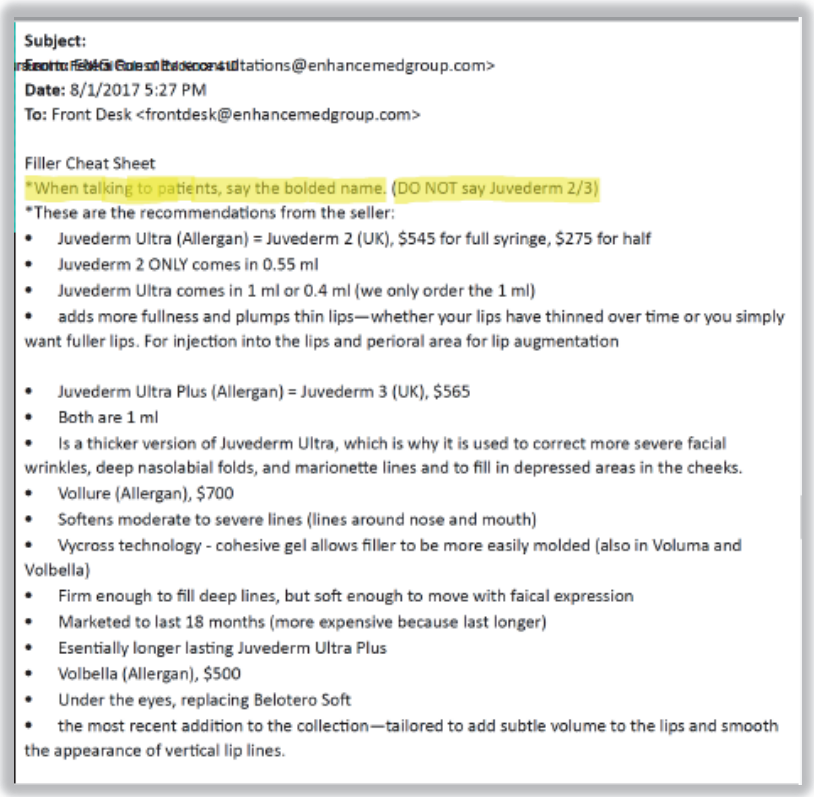
A few weeks later, on August 6, 2017, Davis again reminded employees to track product sources. Clark PSR ¶ 22; LCMC PSR ¶ 21. She wrote:

> ***Allergan's botox is way more expensive than FD and IJM's***, and there is a price difference between FD and IJM, too. ***The patients are charged $12 per unit regardless of where the botox comes from***, but EMG's cost vs $12 per unit sales price can make a big difference in the bottom line…. The patient should not be aware of the different vendors, but it's important EMG be. Courtney was trying to help figure out a way to make sure the patient invoices are noting the correct vendor when botox (and other fillers) are used in appts, as well, though a difficulty is that the Drs are busy and may not be able or want to note how many units were used from whichever vendor's vials, etc. Do you have ideas of how to make that happen, ***unbeknownst to the patients***, but for EMG's accuracy in recording sales, leading to accurate inventory counts in QB?

Clark PSR ¶ 22; LCMC PSR ¶ 21 (emphasis added).

Employees confirmed that the policy of concealing the non-Allergan sourcing was imposed by Clark herself. For example, Courtney Allyn, in a May 13, 2020, interview, told the agent that (in the agent's words) she was "instructed to tell patients that the products came from Allergan, regardless of the true source." Clark PSR ¶ 23; LCMC PSR ¶ 22. Another employee, Jasmine Catig, said that Clark instructed her not to mention the different kinds of Juvederm in front of patients. Clark PSR ¶ 23; LCMC PSR ¶ 22. Catig assumed Clark did not want patients to hear the actual product names because some of the Juvederm products were not available in the U.S. and the patients, who thought they were getting Allergan products from the U.S., would be "pissed" if they found out otherwise. Clark PSR ¶ 23; LCMC PSR ¶ 22. Catig also told investigators that Clark did not care about patients' well-being and that it was "always about the money. She's there for the money." 9/13/2022 Catig Interview at 4.

As another example, on August 1, 2017, employee Desiree Mathiesen (formerly Rozzi) emailed staff a "cheat sheet" that directed: "When talking to patients, say the bolded name. (DO NOT say Juvederm 2/3)." Clark PSR ¶ 24; LCMC PSR ¶ 23. Juvederm 2 and 3, not coincidentally, are products that Clark favored but that were not approved by the FDA for use in the U.S. In interviews with the government, Rozzi explained that these instructions were dictated directly by Clark. Clark PSR ¶ 24; LCMC PSR ¶ 23. Note, too, on this "cheat sheet," how the practice noted that "Juvederm Ultra" came from "Allergan" but that "Juvederm 2" came from the "UK."



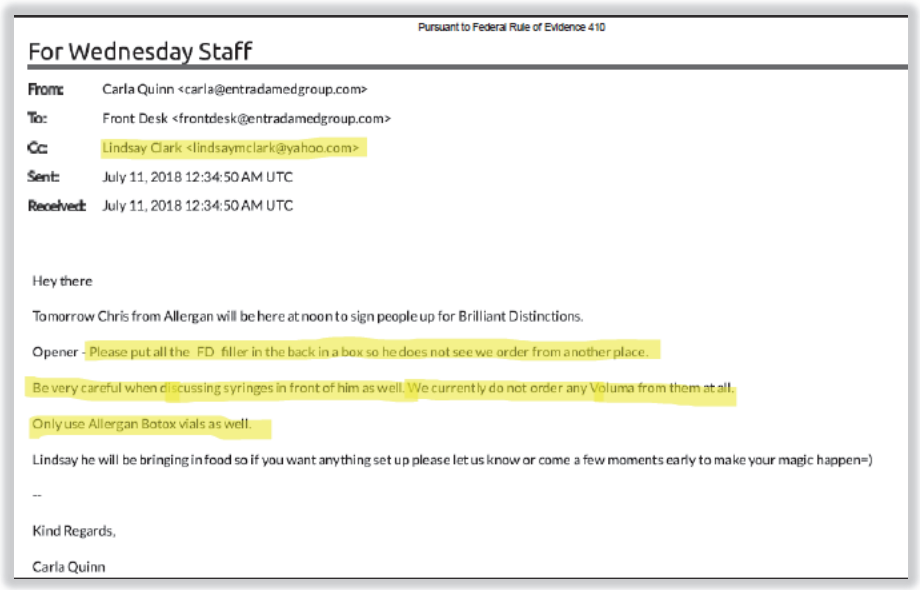
Subject:
[redacted]tations@enhancemedgroup.com>
Date: 8/1/2017 5:27 PM
To: Front Desk <frontdesk@enhancemedgroup.com>

Filler Cheat Sheet
*When talking to patients, say the bolded name. (DO NOT say Juvederm 2/3)
*These are the recommendations from the seller:

- Juvederm Ultra (Allergan) = Juvederm 2 (UK), $545 for full syringe, $275 for half
- Juvederm 2 ONLY comes in 0.55 ml
- Juvederm Ultra comes in 1 ml or 0.4 ml (we only order the 1 ml)
- adds more fullness and plumps thin lips—whether your lips have thinned over time or you simply want fuller lips. For injection into the lips and perioral area for lip augmentation

- Juvederm Ultra Plus (Allergan) = Juvederm 3 (UK), $565
- Both are 1 ml
- Is a thicker version of Juvederm Ultra, which is why it is used to correct more severe facial wrinkles, deep nasolabial folds, and marionette lines and to fill in depressed areas in the cheeks.
- Vollure (Allergan), $700
- Softens moderate to severe lines (lines around nose and mouth)
- Vycross technology - cohesive gel allows filler to be more easily molded (also in Voluma and Volbella)
- Firm enough to fill deep lines, but soft enough to move with faical expression
- Marketed to last 18 months (more expensive because last longer)
- Esentially longer lasting Juvederm Ultra Plus
- Volbella (Allergan), $500
- Under the eyes, replacing Belotero Soft
- the most recent addition to the collection—tailored to add subtle volume to the lips and smooth the appearance of vertical lip lines.

Dr. Clark and her practice also took measures to conceal from *Allergan* that she was obtaining botulinum toxin injectables and hyaluronic dermal fillers from abroad. Clark PSR ¶ 25; LCMC PSR ¶ 24. First, Dr. Clark made sure that when Allergan's sales representative, Chris Corvi, visited the practice, as he did every few weeks, he would not learn of the illicit purchases. Clark PSR ¶ 25; LCMC PSR ¶ 24. For instance, in a November 13, 2017, email, Clark's longest-serving employee Carla Quinn, an office manager of sorts, reminded colleagues: "Ladies please please please remember that we are ONLY to use Allergan Botox Thursday. We CAN NOT use FD. Chris will be there and it makes me nervous that he will catch on to the whole FD thing😳." Clark PSR ¶ 25; LCMC PSR ¶ 24. Another email, dated July 11, 2018, shows Carla Quinn writing to Clark and others: "Tomorrow Chris from Allergan will be here at noon to sign people up for Brilliant Distinctions [an Allergan customer-loyalty program]…. Please put all the FD filler in the back in a box so he does not see we order from another



Pursuant to Federal Rule of Evidence 410

For Wednesday Staff

From: Carla Quinn <carla@entradamedgroup.com>
To: Front Desk <frontdesk@entradamedgroup.com>
Cc: Lindsay Clark <lindsaymclark@yahoo.com>
Sent: July 11, 2018 12:34:50 AM UTC
Received: July 11, 2018 12:34:50 AM UTC

Hey there

Tomorrow Chris from Allergan will be here at noon to sign people up for Brilliant Distinctions.

Opener - Please put all the FD filler in the back in a box so he does not see we order from another place.

Be very careful when discussing syringes in front of him as well. We currently do not order any Voluma from them at all.

Only use Allergan Botox vials as well.

Lindsay he will be bringing in food so if you want anything set up please let us know or come a few moments early to make your magic happen=)

--

Kind Regards,

Carla Quinn

place. Be very careful when discussing syringes in front of him as well. We currently do not order any Voluma from them at all. Only use Allergan Botox vials as well." Clark PSR ¶ 25; LCMC PSR ¶ 24. Clark's concealment was successful: Chris Corvi, despite routine visits, never found out about Clark's ordering practices.

* * *

Dr. Clark concealed her sourcing because she *knew* her patients would be outraged if they learned the truth about how she was acquiring her products. And to be sure patients are outraged. The victim impact statements make this clear. Patients trusted Clark to act lawfully.

But at least one, K.F., took the time to specifically email Dr. Clark before her first procedure to ask Clark where Clark got her "Botox." Clark replied that she only used "Botox from Allergan." US-008909. (As shown repeatedly above, the practice itself, internally, carefully distinguished between "Allergan Botox" and, say, "FD Botox.") The patient, nervous about the procedure, then queried Dr. Clark further at the appointment about the FDA status of the products. Clark reassured the woman—then injected her with a non-FDA-authorized botulinum toxin product. K.F. Interview, 4/25/2022.

It defies reason to think that Clark would believe patients indifferent to the fact that she was injecting them with potentially disfiguring prescription products that she bought from strangers on the internet. Clark may claim that she didn't grasp that her sourcing violated the FDCA. But she knew, then and now, what would have happened if she had said to patients: "In the interest of disclosure, let me explain that I often buy Botox from the sales rep for the manufacturer. In your case, however, I bought this vial off a website at a 40% discount. I'm charging you the same price. Any concerns?"

What's more, following Clark's indictment, Clark's civil attorney, Fletcher Alford—who entered the guilty plea on behalf of the Lindsay Clark, M.D., Medical Corporation—began sending emails to the upset patients who had written Clark directly. In those emails, Alford made representations about the substances that patients were injected with. "It is my understanding," he wrote K.F., for instance, "that the Botox that was administered to you was manufactured by Allergan, and although not authorized for sale in the U.S., is identical to the Botox that Allergan does sell in the U.S. except that it came through a different distribution chain." US-254640. But the fundamental problem is that Mr. Alford *could not possibly know* that the product (which cannot be called "Botox") injected into K.F. was "manufactured" by Allergan or that it was "identical" to the lawful product. That's the whole problem with buying from what he euphemistically calls the "different distribution chain." And emails like this only echo and indeed amplify Clark's original conduct: Alford assured Clark's patients that the product they received was safe and what it purported to be—even as he acknowledged, at the same time, that these products were acquired in defiance of the very laws that serve to ensure safety and genuineness.

As further evidence of Clark doubling down, a patient reported on a Reddit thread shortly after Clark's indictment that Clark told her "that she never bought or used fake Botox in her clients and that she feels Allergan has targeted her for not buying their product through the channels they want everyone to use. She said she bought Botox through her US and Canadian Allergan reps." US-254565. The foreign internet sellers Clark utilized cannot, of course, be truthfully described as "Canadian Allergan reps."

Again, this happened *after* Clark had been charged. Despite her unlawful conduct coming to light, Clark—directly and through her representative—continued to try to conceal her conduct and mislead her patients. This is not indicative of a person or corporation taking responsibility.

* * *

Dr. Clark's failure to honor her patients' rights is seen elsewhere as well. Clark and her practice were made aware of the illegality of purchasing unapproved botulinum toxin and hyaluronic acid products from foreign online sellers in multiple ways—yet she continued to buy and administer the illicit products.

United States Food and Drug Administration
New York District Office
Notice of FDA Action

Entry Number: ----0328857-0
Port of Entry: 4701, JFK Airport, Jamaica, NY
Notice Number: 1
April 18, 2017

Enhance Medical group
215 N San Mateo Dr Suite 1
San Mateo, CA 94401

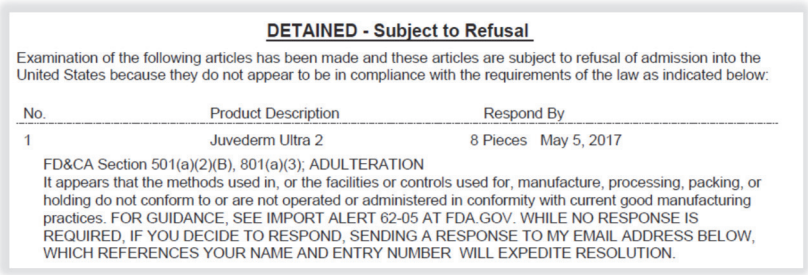
> <

Shipper: Unknown

A mail shipment addressed to you from a foreign country is being held by the post office at the request of the U.S. Food and Drug Administration (FDA).

Summary of Current Status of Individual Lines

No.	Product Description	Quantity	Current Status
1	Juvederm Ultra 2	8 Pieces	Detained 04-17-2017
2	Juvederm Voluma with Lidocaine	8 Pieces	Detained 04-17-2017
3	Juvederm Ultra 3	5 Pieces	Detained 04-17-2017



DETAINED - Subject to Refusal

Examination of the following articles has been made and these articles are subject to refusal of admission into the United States because they do not appear to be in compliance with the requirements of the law as indicated below:

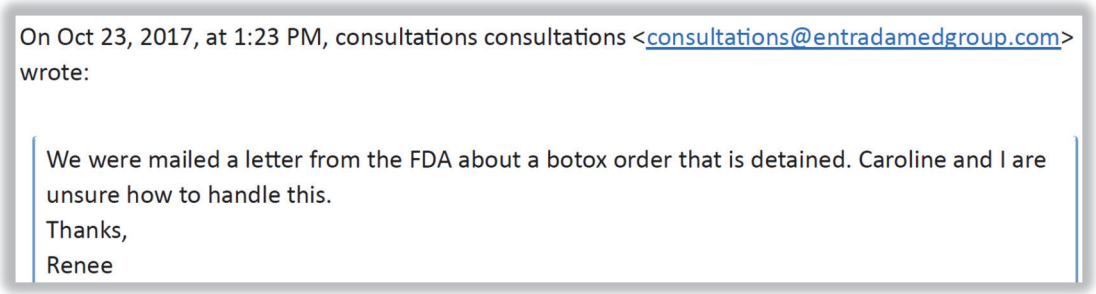
No.	Product Description	Respond By
1	Juvederm Ultra 2	8 Pieces May 5, 2017

FD&CA Section 501(a)(2)(B), 801(a)(3); ADULTERATION
It appears that the methods used in, or the facilities or controls used for, manufacture, processing, packing, or holding do not conform to or are not operated or administered in conformity with current good manufacturing practices. FOR GUIDANCE, SEE IMPORT ALERT 62-05 AT FDA.GOV. WHILE NO RESPONSE IS REQUIRED, IF YOU DECIDE TO RESPOND, SENDING A RESPONSE TO MY EMAIL ADDRESS BELOW, WHICH REFERENCES YOUR NAME AND ENTRY NUMBER WILL EXPEDITE RESOLUTION.

The FDA sent Notices of FDA Action to the practice on *eight* occasions between April 2017 and March 2018. (Excerpts from one notice above.) This occurred when products ordered from overseas were detained at customs and inspected by the FDA; the detection of contraband triggered a seizure and a due-process letter to the addressee on the package. Clark PSR ¶ 36; LCMC PSR ¶ 35. Those notices stated that "[e]xamination of the…articles has been made and these articles are subject to refusal of admission into the United States because they do not appear to be in compliance with the requirements of the law," citing FDCA provisions prohibiting adulterated or unapproved new drugs. Clark PSR ¶ 36; LCMC PSR ¶ 35.

Dr. Clark denies having seen any of the notices at the time, Clark PSR ¶ 36, but the evidence suggests that Clark was at a minimum aware of them when they were received by her practice but chose to ignore them. First, an employee recalled seeing at least one of these FDA notices and her recollection was that she gave it to Clark. 2/3/2021 Mathiesen Interview at 2. Second, employees, where interviewed, consistently stated that Clark directed all of the practice's ordering and tracked when products were expected and received. *See, e.g.*, 9/9/2022 Reyes Interview at 2; 2/3/2021 Mathiesen Interview at 2. Third, the evidence shows that multiple employees were aware of the letters and discussed them among themselves. *See, e.g.*, US-006919 (Oct. 24, 2017, email between Renee Temple

and Carla Quinn regarding letter from FDA about detained botulinum toxin injectable order, noting that it was the second notice); 3/26/2021 Allyn Interview at 2 (recalling that products were detained at the border multiple times and remembering office jokes about how Trump Administration tariffs were the cause). It defies credibility to suggest that Clark's employees, who communicated closely with Clark about ordering, did not tell her about *any* of these eight letters or the fact that the orders had been seized—both of which were evidently a topic of concern among employees.



On Oct 23, 2017, at 1:23 PM, consultations consultations <consultations@entradamedgroup.com> wrote:

> We were mailed a letter from the FDA about a botox order that is detained. Caroline and I are unsure how to handle this.
> Thanks,
> Renee

Subject: Re: Botox hold notice
From: consultations consultations <consultations@entradamedgroup.com>
Date: 10/24/2017 9:17 AM
To: Carla Quinn <carla@entradamedgroup.com>

It really does look like that missing FD box you ordered a while ago, given the dates on there. I think its the second notice we've gotten, but the other one came right before the warm box of FD came in, so we assumed it was in relation to that particular box.

-Caroline

Additionally, in June 2018, employees came across an email that linked to an article about a "federal indictment" of an outfit selling misbranded "Botox" to American doctors. One staffer forwarded this email to Dr. Clark directly, writing that "this is very concerning." Clark herself replied: "I did not see this until now." US-008823. The linked article, entitled "A Conspiracy of Warm Boxes," described an online selling operation much like the one that Clark was availing herself of.[3]

Clark's employees also commented on several occasions that the online suppliers were "fishy" or "sketchy" and that one potential supplier that Clark suggested buying from was selling "like black market Botox or something." Clark PSR ¶ 27; LCMC PSR ¶ 26. For example, on June 22, 2018,

[3] A link to the report is here: https://www.safemedicines.org/2017/06/canadian-drug-importer-responsible-for-2016-fake-botox-warning-pleads-guilty-in-misbranded-drugs-case.html.

Desiree Rozzi wrote a colleague with a concern about Filler Depot, a vendor that Clark used extensively, that it was "scamming for money and sending fake product." Clark PSR ¶ 27; LCMC PSR ¶ 26.

Or on July 13, 2018, an employee complained of Filler Depot:

> [Two salespeople] have been let go from this location due to fraudulent conduct. To my understanding Brian is now our liaison for Fillers Depot - however I am not sure if he is trust-worthy either since Fillers Depot has always gone thru with the [credit card] statement as World Class Imports [another online "pharmacy"] - he is now saying that they changed their name to Ace Med Supplies - however his story of why they changed it is fishy…. [T]hey are being elusive as to where to send the product back - they just want payment and they tried to charge [another doctor's credit card] multiple times for different amounts with an increase of $200 each time - and that the packing list did not look correct.

Clark PSR ¶ 27; LCMC PSR ¶ 26.

Another revealing discussion occurred on March 2 and 3, 2017, when employee Courtney Allyn expressed concerns about Inject Medical: "At least we weren't charged for the Botox, so we can kind of just assume we won't be ordering Botox from them in the future, right? Are we still going to order filler from Inject? I feel like we should really cut ties with them bc of all this run around. Super sketchy." Clark PSR ¶ 28; LCMC PSR ¶ 27.

Rozzi replied:

> I think so. Carla [Quinn—the office manager] found an article about "illegal importations" of botox. So I'm thinking they could risk getting shut down. Understandable, but frustrating. I like ordering from Allergan. They give a ton of perks. They gave us a 1k credit memo for ordering 20k of product last year. That's 5%? Something! Chris [Corvi, the Allergan representative] also agreed to give us 100 units of botox for every 5 boxes we buy. And we get it the next day! The packages don't get lost haha I think it is super sketchy too, but I think Dr. Clark will still order because of prices. We will see. She wanted to order this Turkish botox that never even called me back.

Clark PSR ¶ 29; LCMC PSR ¶ 28.

Allyn responded:

> That's so crazy!! Makes sense though, like black market Botox or something I'm glad Allergan is giving us perks, I'm sure that helps Lindsay feel better about ordering from them. OMG Turkish Botox!? WTH?!

Clark PSR ¶ 30; LCMC PSR ¶ 29.

Rozzi told the government that she relayed her concerns about the practice's sourcing to Dr. Clark who, Rozzi said, simply shrugged them off. Clark PSR ¶ 31; LCMC PSR ¶ 30. Employee

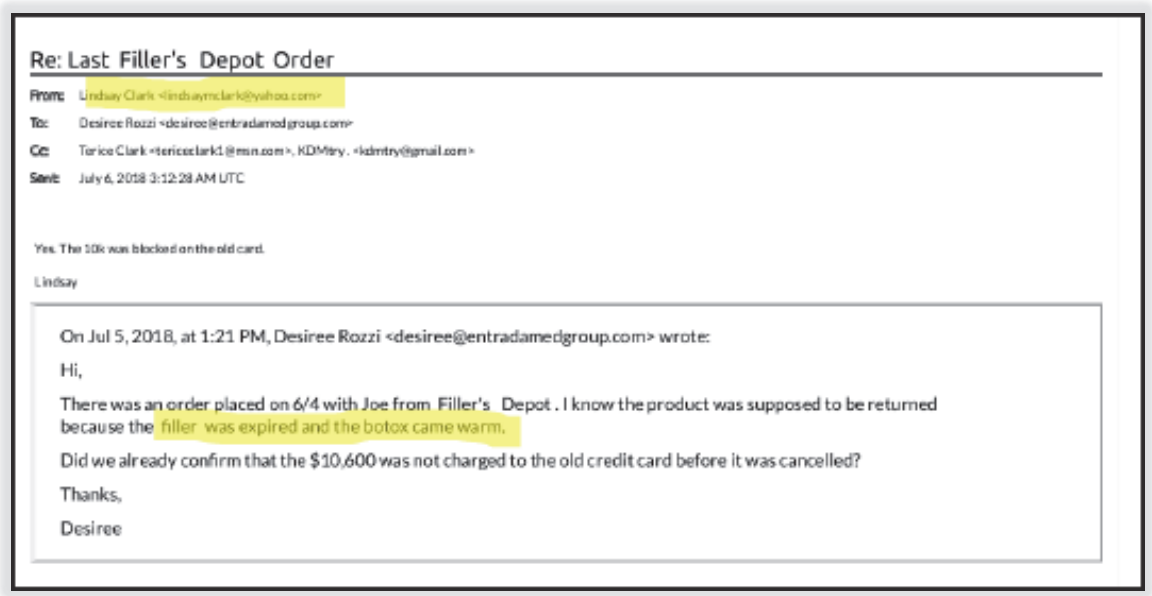
Jasmine Catig, with years of experience in dermatology offices, told investigators that she "found Clark to be 'shady' and that she was not comfortable working at EMG" and eventually left. Clark PSR ¶ 31; LCMC PSR ¶ 30.

On numerous occasions, shipments from the online suppliers arrived warm or expired, meaning that they had likely been in storage or transit for a long time without being maintained appropriately, which, in the case of true Botox, would make them ineffective. (Botox, like certain COVID-19 vaccines, must be cold-stored at very low temperatures to work.) For example, on October 3, 2017, Clark was told that a shipment of "Botox" arrived warm, along with a recommendation from the illicit supplier that Clark "put them in the fridge for 24-48 hours and they should be okay." Clark PSR ¶ 31; LCMC PSR ¶ 30. Clark herself wrote back: "we should of course not pay for the warm first delivery." Clark PSR ¶ 31; LCMC PSR ¶ 30. On July 5, 2018, Rozzi asked Dr. Clark to confirm that she, Clark,

Subject: FD
From: Front Desk <frontdesk@enhancemedgroup.com>
Date: 10/3/2017 11:02 AM
To: Lindsay Clark <lindsaymclark@yahoo.com>, Carla Quinn <carla@enhancemedgroup.com>

Good morning,

Just got a call from Fillers Depot about the delivery of botox from yesterday. Renee sent an email out yesterday after the delivery, and we'd put them straight into the fridge (they are in bubble wrap to keep them separate). There were only seven boxes.
Amy from FD called to say she'd noticed the delivery made yesterday and she recommended that we put them in the fridge for 24-48 hours and they should be okay. They had sent out a replacement but it looks like that one is also being held up. She wanted to know what you wanted to do in terms of charging for payments.


Re: Last Filler's Depot Order

From: Lindsay Clark <lindsaymclark@yahoo.com>
To: Desiree Rozzi <desiree@entradamedgroup.com>
Cc: Terice Clark <tericeclark1@msn.com>, KDMtry . <kdmtry@gmail.com>
Sent: July 6, 2018 3:12:28 AM UTC

Yes. The 10k was blocked on the old card.

Lindsay

On Jul 5, 2018, at 1:21 PM, Desiree Rozzi <desiree@entradamedgroup.com> wrote:

Hi,

There was an order placed on 6/4 with Joe from Filler's Depot . I know the product was supposed to be returned because the filler was expired and the botox came warm.

Did we already confirm that the $10,600 was not charged to the old credit card before it was cancelled?

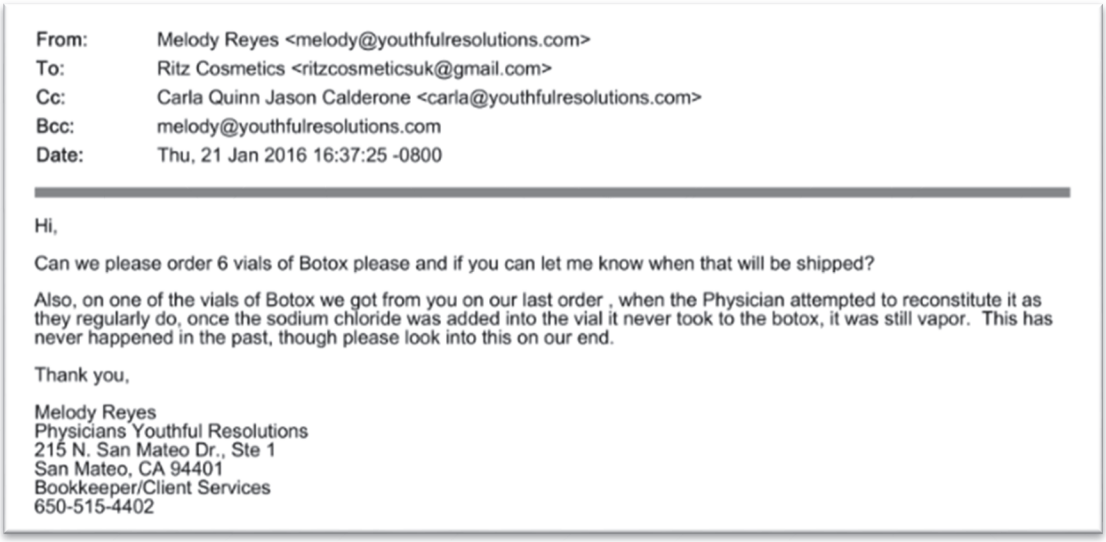
Thanks,

Desiree

wasn't charged on her credit card for a filler order that arrived "expired" and an order of "Botox" that "came warm." Clark PSR ¶ 31; LCMC PSR ¶ 30.

Emails from Clark's staff document numerous other instances when the practice received defective products from these shady sellers, but Clark nevertheless continued to direct staff to order from them. For instance, employee Melody Reyes wrote a vendor called "Ritz Cosmetics" to say that Dr. Clark had received a vial of "Botox" that "did not reconstitute and now also we have one of the syringes of Restylane that when the doctor went to use it today, it just oozed on out and the doctor was not able to use it on the patient. We can send you both of these products back and/or give you the lot #s, but the doctor would like them replaced." Clark PSR ¶ 32; LCMC PSR ¶ 31.

In another email, an employee placed an order with "Ritz Cosmetics" while at the same time noting that "on one of the vials of Botox we got from you on our last order, when the Physician attempted to reconstitute it as they regularly do, once the sodium chloride was added into the vial it never took to the botox, it was still vapor." US-164090.



From: Melody Reyes <melody@youthfulresolutions.com>
To: Ritz Cosmetics <ritzcosmeticsuk@gmail.com>
Cc: Carla Quinn Jason Calderone <carla@youthfulresolutions.com>
Bcc: melody@youthfulresolutions.com
Date: Thu, 21 Jan 2016 16:37:25 -0800

Hi,

Can we please order 6 vials of Botox please and if you can let me know when that will be shipped?

Also, on one of the vials of Botox we got from you on our last order , when the Physician attempted to reconstitute it as they regularly do, once the sodium chloride was added into the vial it never took to the botox, it was still vapor. This has never happened in the past, though please look into this on our end.

Thank you,

Melody Reyes
Physicians Youthful Resolutions
215 N. San Mateo Dr., Ste 1
San Mateo, CA 94401
Bookkeeper/Client Services
650-515-4402

* * *

While Clark was the CEO and sole shareholder of her practice, she at times allowed other doctors to see patients (whom she mainly brought into the practice) on a limited schedule.[4] Statements

[4] Specifically, Eric Schraga, an emergency room physician, saw patients at Clark's practice approximately once per month. Clark PSR ¶ 34; LCMC PSR ¶ 33. Elliot Snyder saw patients in Clark's office once every few months and did not provide injectables to patients. Clark PSR ¶ 33;

from two of these doctors in interviews highlight that doctors generally know that it is illegal to buy powerful prescription drugs and devices off the internet; they must instead be obtained from safe, authorized sources.

Dr. Elliot Snyder, who saw patients at Clark's practice once every few months, told interviewers that the "only appropriate way to order Botox is from Allergan and nobody else," and stated that, "[a]s a doctor, you can't go to a random website and order things randomly." Clark PSR ¶ 33; LCMC PSR ¶ 32.

Dr. Erik Schraga, who saw patients at Clark's practice approximately once per month, told investigators that it seemed like Clark was "hiding some things" from Chris Corvi, the Allergan representative (and, again, the only person from whom the practice could lawfully purchase the Botox and Juvederm). Clark PSR ¶ 34; LCMC PSR ¶ 33. Schraga recalled that just prior to a training hosted by Allergan, Clark took products purchased from online sources from the storeroom and put them in her office, in the back of the clinic, so they wouldn't be seen by Corvi during the training. Clark PSR ¶ 34; LCMC PSR ¶ 33. He recognized that Clark did this to prevent Corvi from learning of her other sources—which, according to Corvi, would have required him to report her or possibly cut her off from the complementary trainings or other benefits that he gave the practice. Clark PSR ¶ 34; LCMC PSR ¶ 33; 3/2/2021 Corvi Interview. Schraga had spent most of his career in a hospital setting and so had no experience in ordering drugs and devices himself; he admitted to the government that he joined in Clark's internet ordering for a time, but he ultimately found Clark's behavior concerning enough to contribute to his decision to leave Clark's practice. Clark PSR ¶ 34; LCMC PSR ¶ 33.

As further evidence of Clark's scheme, investigators learned that Clark developed a way to secure benefits for herself, such as reimbursements, trainings, and free products—and, in the process, defraud Allergan—by recycling Allergan's lot numbers. Clark PSR ¶ 35; LCMC PSR ¶ 34. Specifically, every genuine Botox (and Juvederm) package has a lot number that can be used to identify its manufacture date and intended market. Allergan's frequent-user program required Clark to submit a lot number for the Botox units used on the patient. Clark evidently feared that using lot numbers for non-U.S.-products would tip off Allergan to her scheme. So she directed employees to only use lot

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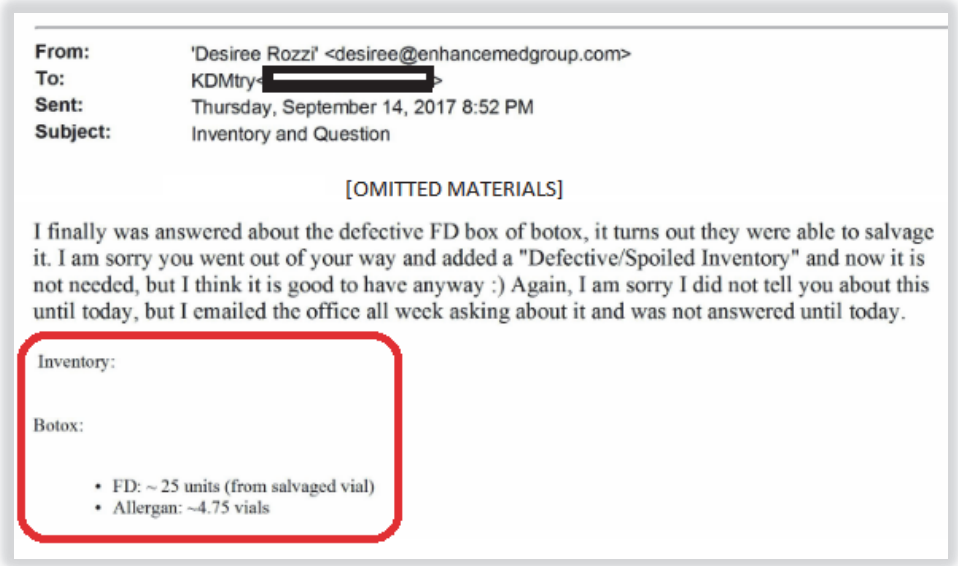
LCMC PSR ¶ 32; Snyder Interview. Barbie Barrett, Clark's mother-in-law, saw patients at the practice a couple of times a month. Snyder Interview.

numbers from lawful U.S. orders when submitting rewards requests, even when using products bought on the internet. Clark PSR ¶ 35; LCMC PSR ¶ 34. Employees recalled a Post-It note at the front desk with this U.S. lot number. Clark PSR ¶ 26; LCMC PSR ¶ 25. Employees confirmed in interviews that Clark's practice deceived Allergan in connection with the rewards program by seeking rewards on behalf of patients whether or not the patient actually received FDA-approved Allergan Botox. Clark PSR ¶ 26; LCMC PSR ¶ 25; Clark PSR ¶ 35; LCMC PSR ¶ 34.

This recycling of lot numbers was discovered by a skilled FDA Special Agent who found that the amount of "Botox" attributed by Clark to certain lot numbers far exceeded the actual amount of product in those lot numbers' vials. For example, the FDA-approved Botox lot number "C4719C3" was recorded in Clark's patient records for a total of 4,340 Botox units (a way to measure injections), yet Clark only received 1,500 units from Allergan with this lot number. Or lot number "C4818C3" was recorded in patient records as having provided 3,708 Botox units' worth of injections, yet Clark only received 1,000 units bearing with this lot number from Allergan.

This means that many of Clark's treatment records are themselves deceptive: the "Botox" that shows up in these records—as lawful, FDA-approved product—was not what was used on the patient; Clark actually used unsafe, untraceable, unauthorized product. Her records, accordingly, undercount the amount of illegal product she used. Clark PSR ¶ 35; LCMC PSR ¶ 34. Even so, Clark's records show that at least several hundred patients unknowingly received non-FDA-approved product.

There are also indications that Clark actually used, on patients, what she *knew* were defective products. Staff discussed how, after the practice had received warm Botox, the sellers said that "if we refrigerated it in the next 24 - 48 hours it should be ok, but that *didnt work for us the last time*." US-006833 (emphasis added). In another email, Desiree Rozzi reported to the accountant that Clark had received a "defective FD box of botox" but that the practice, evidently, was "able to salvage it." The practice kept these vials in inventory, according to the email (below). US-006082.



From: 'Desiree Rozzi' <desiree@enhancemedgroup.com>
To: KDMtry<[redacted]>
Sent: Thursday, September 14, 2017 8:52 PM
Subject: Inventory and Question

[OMITTED MATERIALS]

I finally was answered about the defective FD box of botox, it turns out they were able to salvage it. I am sorry you went out of your way and added a "Defective/Spoiled Inventory" and now it is not needed, but I think it is good to have anyway :) Again, I am sorry I did not tell you about this until today, but I emailed the office all week asking about it and was not answered until today.

Inventory:

Botox:

- FD: ~ 25 units (from salvaged vial)
- Allergan: ~4.75 vials

* * *

This prosecution charged Clark's practices with respect to products that she mispresented as "Botox" and "Juvederm," but Clark also offered other unauthorized products to patients. For example, Clark appears to have ordered, from foreign online sellers, products purporting to be Restylane, another type of injectable manufactured by Galderma. *See* Clark PSR ¶ 32; LCMC PSR ¶ 31. And as part of her "anti-aging" practice, Clark helped her patients to obtain Human Growth Hormone from Mexican pharmacies. *See, e.g.*, US-005893, US-005900. It is illegal to knowingly distribute "human growth hormone for any use in humans other than the treatment of a disease or other recognized medical condition." 21 U.S.C. § 333(e)(1).

IV. SENTENCING GUIDELINES CALCULATIONS

A. Dr. Lindsay M. Clark

The parties agreed in Clark's plea agreement that the Guidelines calculation is as follows:

a. Base Offense Level, U.S.S.G. § 2B1.1(a)(2) 6

b. Special Offense Characteristic: 10 or more victims § 2B1.1(b)(2)(A)(i) +2

c. Special Offense Characteristic: Loss amount of more than $550,000 § 2B1.1(b)(1)(H) +14

d. Special Offense Characteristic: Conscious or reckless risk of death or serious bodily injury – § 2B1.1(b)(16) +2

e. Abuse of Position of Trust or Use of Special Skill – § 3B1.3 +2

f. Acceptance of Responsibility: -3

g. Adjusted Offense Level: 23

Assuming a criminal history category of I, this yields a range of 46-57 months. By statute, the sentence is capped at 12 months, *see* 21 U.S.C. §§ 331(c) and 333(a)(1), so the Guidelines range is 12 months. *See* U.S.S.G. §5G1.1.

B. Lindsay Clark, M.D., Medical Corporation

The parties agreed in Lindsay Clark, M.D., Medical Corporation's plea agreement that the Guideline calculation is as follows:

a. Base Offense Level, U.S.S.G. § 2B1.1(a)(2) 6

b. Special Offense Characteristic: 10 or more victims § 2B1.1(b)(2)(A)(i) +2

c. Special Offense Characteristic: Loss amount of more than $550,000 § 2B1.1(b)(1)(H) +14

d. Special Offense Characteristic: Conscious or reckless risk of death or serious bodily injury – § 2B1.1(b)(16) +2

e. Acceptance of Responsibility -3

f. Adjusted Offense Level 21

g. Base Fine: U.S.S.G. § 8C2.1(a) (applying to count under § 2B1.1)
Greater of $1,500,000 (§8C2.4(a)(1), §8C2.4(d) at OL 21)
and $1,069,880 (§8C2.4(a)(3)) $1,500,000

h. Culpability Score Base score: 5 [§8C2.5]
Acceptance of responsibility: -1 [§8C2.5(g)(3)] 4

i. Guideline Fine Range $1,200,000-$2,400,000

V. SENTENCING RECOMMENDATION

A. Dr. Lindsay Clark

In light of the nature and circumstances of the instant offense and Clark's conduct, the government submits that a Guidelines sentence of one year imprisonment is appropriate. Such a sentence is necessary to reflect the seriousness of the offense, provide just punishment, afford adequate deterrence both to Dr.

Clark and other medical professionals considering similar conduct, and protect the public from further crimes by the defendant. *See* 18 U.S.C. § 3553(a)(2)(A)-(C).

Clark's patients trusted that, as a doctor, she was obeying the law and acting in a manner consistent with protecting their health and wellbeing. Yet her entire practice was predicated on violating her patients' trust and expectations. The more she risked the disfiguration of patient faces, among other serious risks associated with injecting unknown substances into their bodies, the more money she made. That is why so many of her hundreds of patients remain irate with Dr. Clark, years after she defrauded and endangered them.

The Court can consider, as relevant conduct, "all acts and omissions committed, aided, abetted, counseled, commanded, induced, procured, or willfully caused by the defendant . . . that occurred during the commission of the offense of conviction, in preparation for that offense, or in the attempt to avoid detection or responsibility for that offense." U.S.S.G. § 1B1.3(a)(1). Clark pleaded guilty to a misdemeanor, which does not require that the defendant act with intent to defraud. But Clark admitted in her plea agreement that she did, in fact, take steps to conceal her ordering practices from her patients, Allergan, and the FDA. Clark Plea at 3. In determining the appropriate sentence, the Court should also consider the overwhelming evidence detailed above that Clark, who personally directed all ordering for her practice; misrepresented to patients that all the products she administered were FDA-approved Botox and Juvederm and instructed her staff not to reveal otherwise; had her patients sign consent forms containing her misrepresentations; and continue in misrepresentation after being charged.

Clark has claimed that she was unaware that the online suppliers she purchased from were not authorized to sell prescription injectables in the U.S., *see* Clark PSR ¶ 14, LCMC PSR ¶ 15, but this is belied by the many steps Clark took to conceal her ordering practices from her patients and Allergan.

It is implausible that a licensed physician would believe it permissible to order prescription drugs and devices from foreign internet sellers that even her staff—who, unlike Clark, were not medical professionals—recognized as "sketchy" or "black market." Clark PSR ¶ 27; LCMC PSR ¶ 26.

It is implausible that Clark could believe—even supposing her ignorance about the legal regime that bound her—that patients would have been anything other than outraged at her conduct. Why else would she have taken such efforts to hide what she was doing from them?

And it is implausible that Clark failed to appreciate that she risked injecting substances that were not what they purported to be. This is common sense and common knowledge. A person can also purchase, illegally, prescription drugs like oxycodone or alprazolam (Xanax) on the internet. Sometimes that oxycodone or alprazolam is manufactured by a pharmaceutical company. Sometimes it is not—and thousands of Americans die as a result. A doctor, of all people, should grasp that it is dangerous to purchase powerful drugs and devices from fly-by-night foreign internet sellers, and that products purchased in this way may be counterfeited, mishandled, or tampered with and can damage or kill. Clark had no right to take this risk with her patients' wellbeing.[5] Indeed, many of Clark's patients explained that they specifically sought out a doctor to administer Botox and Juvederm so they would receive the highest standard of care and would not be subject to receiving counterfeit products. US-257429 (Interview of N.K.) (specified that she sought out a doctor because she had heard "scary stories" about some medical spas and believed Clark's injections to be of FDA-approved product); US-257901 (Interview of F.D.) (explained that she believed she was receiving FDA-approved product and had "blind faith" that Clark, as a doctor, would do the right thing); US-257907 (Interview of K.L.) (stated that it was important to her that the person she saw for injections was a doctor and believed Clark's injections were of FDA-approved products). And she had no right to trick patients into believing that they were receiving products that the FDA had determined were safe and effective, while evading those safeguards that Congress put in place to ensure their safety and effectiveness.

Clark's conduct is, fortunately, rare among doctors. The undersigned, despite inquiries, are aware of no other case in this district in which a doctor violated these laws for so long, despite so many internal and external warnings and red flags, and pumped so many dollars into this black-market economy. Or as another measure, from the evidence in this case: investigators found a customer list from the inbox of one of Clark's suppliers—"Ritz Cosmetics UK" and "Knightsbridge Cosmetics"—that listed only about 25 customers nationwide (including many "medical spas"). US-251998-252004.

[5] Botox is made from Botulinum Neurotoxin Type A, one of the most potent toxins known. The toxin used in Botox is measured in nanograms, or billionths of a gram. This is one reason that obtaining products purporting to be Botox from unauthorized sellers is so dangerous. In one case, a doctor in Florida administered products purporting to be Botox to patients and caused himself and three others to become paralyzed with botulism. *See* https://www.tampabay.com/archive/2006/01/26/doctor-in-fake-botox-case-sentenced-to-three-years/.

The California Medical Board and FDA, moreover, have repeatedly warned doctors about the danger and illegality of buying prescription drugs off of the internet.[6] The Court should consider what the state of our medical system would be if 5%, 15%, or 30% of doctors behaved as Clark did. The result would be to undermine the integrity of our medical system and leave patients prey to the most unscrupulous counterfeiters.

[6] See more here: https://www.fda.gov/drugs/information-health-care-professionals-drugs/know-your-source-protecting-patients-unsafe-drugs.

FDA
Notice to Physicians

Buying drugs from unlicensed sources is *risky* business.
Know your source. Protect your patients.

If you purchase drugs from illegal, unlicensed sources (foreign or domestic) you are putting your patients at risk
of consuming drugs that may be unapproved, counterfeit, contaminated, ineffective, or dangerous.

You are also breaking the law.

If you purchase drugs from illegal sources you may be subject to criminal investigation
by FDA's Office of Criminal Investigations and prosecution by the U.S. Department of Justice (DOJ).

Since 2012, FDA has notified nearly 3,500 physicians that their drug purchasing practices may be illegal. DOJ has successfully prosecuted more than 95 corporations and individuals, including physicians, for criminal charges related to selling unapproved drug products, or receiving and administering unapproved drug products to patients. These criminal convictions have resulted in jail time and fines of millions of dollars.

Help prevent unsafe or ineffective drugs from reaching patients.
You should verify your wholesale drug distributor or other source is properly licensed at www.fda.gov/licenseddistributors. You should also perform due diligence to ensure that the drugs you purchase are FDA-approved.

Report suspicious activity to FDA's Office of Criminal Investigations at www.fda.gov/oci.

Protect your patients.
Know the law. It's not worth the risk.

* * *

Clark claims to accept responsibility for her conduct, but in her statements to the PSR author she continues to minimize it. In addition to claiming that she did not know the foreign internet sellers were not licensed, she claims, among other things, that she believed all of the product she obtained was Allergan product; that she never saw any of the eight notices the FDA sent to her practice; and that she is now "much more vigilant in overseeing [her] practice's purchase of dermatological products." Clark PSR ¶¶ 14, 41; LCMC PSR ¶¶ 13, 35, 48. The last statement, in particular, falsely implies that Clark merely *oversaw* her practice's purchasing, when she has in fact admitted, and her employees consistently confirmed, that she directed all ordering and told employees precisely which products to order and where to order them from. Clark Plea at 2; Clark PSR ¶¶ 13, 18; LCMC PSR ¶¶ 12, 17. Clark's downplaying of her conduct emphasizes the need for a sentence sufficient to provide just punishment to Clark and afford adequate deterrence to others. It is essential that doctors do not, as Clark did, put their own monetary gain over the basic safety of their patients. Given Clark's minimization of her conduct, and the fact that she hopes to continue practicing medicine, it is also important that she receive a sentence sufficient to deter her and others from engaging in similar conduct in the future.

The government anticipates that Clark will request a non-custodial sentence. But the factors Clark is likely to cite do not justify that. This case involves a multi-year fraud involving at least several hundred victims, over a million dollars in illicit gains—and misconduct that continued despite multiple warnings and cautions from both the government and her own staff. While the government is sympathetic to Clark's desire to be with her children, these charges—and their consequences—are the unfortunate but

foreseeable result of Clark's unlawful conduct that endangered other—innocent—parents.

Further, Clark has agreed to pay restitution, but that is not, in itself, a sufficient punishment given that Clark has simply agreed to return payments that she obtained under false pretenses and was not entitled to in the first place. Other doctors who have purchased and injected their patients with products they falsely represented to be FDA-approved Botox have received custodial sentences. *See, e.g.*, *United States v. McComb*, Case No. 05-cr-60021-JIC-3, Dkt. No. 475 (doctor sentenced to three years imprisonment for administering knock-off Botox product); *United States v. Seldon*, Case No. 2:07-CR-00135-KJD-LRL, Dkt. Nos. 196-197 (doctor sentenced to 46 months in prison and wife sentenced to 30 months in prison for administering knock-off Botox product). A custodial sentence is likewise appropriate here.

Clark's sentence should of course include the restitution she has already agreed to pay. But the government, in speaking to her victims, has learned that Dr. Clark apparently performed medical procedures—injecting botulinum toxin and hyaluronic acid injections—without having made any medical record of it. The result is that the restitution will be less than the amount actually owed to patients. Under the Sentencing Guidelines, when items are sold but "falsely represented as approved by a governmental regulatory agency," the fraud loss amount "shall include the amount paid for the property, services or goods transferred, rendered, or misrepresented, *with no credit provided for the value of those items or services*." U.S.S.G. § 2B.1.(b)(1), App. Note 3(F)(v)(II) (emphasis added). This treats the goods as valueless and makes the loss to patients equal to the amount that Dr. Clark's patients paid for unauthorized products and, in the government's view, the service fee charged in providing it.[7]

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Clark's practice pled guilty to a felony, and a meaningful sentence is necessary to reflect the seriousness of the conduct. As discussed above, this conduct significantly implicated public health and safety concerns, and Clark and her practice betrayed her patients' trust.

In LCMC's plea agreement, the parties agreed to a Guidelines fine range of $1,200,000-$2,400,000. The PSR asserts that the correct range is actually $2,800,000-$5,600,000. The government

[7] *See, e.g., United States v. Bane*, 720 F.3d 818, 825 (11th Cir. 2013); *United States v. Goldberg*, 538 F.3d 280, 290 (3d Cir. 2008), as amended (Nov. 6, 2008); *United States v. Milstein*, 401 F.3d 53, 74 (2d Cir. 2005); *United States v. Townsley*, No. 10-cv-00428-CRB, 2012 WL 3137989, at *15 (N.D. Cal. Aug. 1, 2012).

agrees that, as a matter of law, the PSR's Guidelines calculation appears to be correct. However, the government stands by its plea agreement.

In any event, based on information provided by defense counsel, the PSR reports that LCMC has only one commercial checking account with a current balance of $70,000 and equipment worth approximately $70,000, and concludes that it does not have the ability to pay a fine. LCMC PSR ¶¶ 49, 51. While LCMC does not appear to have the ability to pay a fine within the Guidelines range (which, appropriately, reflects the severity of the conduct), the government submits that a fine of some amount is necessary to reflect the seriousness of the offense, provide just punishment, and afford adequate deterrence. Further, LCMC has limited funds as a result of the conduct at issue and the fact that Clark previously distributed the practice's profits to herself. The government requests a fine of $70,000. For the same reasons, the government requests probation at the high end of the Guidelines range, of five years. *See* U.S.S.G. § 8D1.2(a).

VI. CONCLUSION

For the reasons discussed above, the government submits that, for Clark, a sentence of one year imprisonment would be sufficient, but not greater than necessary, to achieve the purposes of sentencing and would be fair and appropriate in this case. The government submits that a sentence including a $70,000 fine and five years of probation would be fair and appropriate for LCMC.

DATED: April 13, 2023

Respectfully submitted,

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