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IN THE UNITED STATES DISTRICT COURT

DISTRICT OF UTAH, CENTRAL DIVISION

UNITED STATES OF AMERICA, Plaintiff, vs. MARK WRIGHT, Defendant.	MISDEMEANOR INFORMATION Count 1: 21 U.S.C. §§ 331(a), 333(a)(1); (Introduction of Misbranded Devices into Interstate Commerce) Count 2: 21 U.S.C. §§ 331(a), 333(a)(1); (Introduction of Adulterated Devices into Interstate Commerce)

The United States Attorney charges:

1. At all times relevant to this Information, the Defendant, MARK WRIGHT, was a resident of Scottsdale, Arizona.

2. Defendant MARK WRIGHT was the Chief Executive Officer ("CEO") of Dolor Technologies, LLC ("Dolor"), a medical device company, from on or about July 15, 2013, until he ceased employment with Dolor on July 31, 2017.

3. At all times relevant to this Information, Dolor was engaged in the medical device business throughout the United States, including the District of Utah.

4. Dolor developed, manufactured, marketed, sold, and distributed a medical device that was called the SphenoCath and that was Dolor's only product. Dolor shipped the SphenoCath in interstate commerce, and the SphenoCath was ultimately delivered to health care providers throughout the United States.

FDA and the FDCA

5. The United States Food and Drug Administration ("FDA"), an agency within the United States Department of Health and Human Services, was responsible for protecting the health and safety of the American public by enforcing the Federal Food, Drug, and Cosmetic Act ("FDCA"). 21 U.S.C. § 301 *et seq*.

6. Under the FDCA, a "device" was defined, in relevant part, as "an instrument, apparatus, implement, machine, contrivance . . . or other similar or related article, including any component, part, or accessory, which is . . . intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man or other animals, or . . . intended to affect the structure or any function of the body of man or other animals, and which does not achieve its primary intended purposes through chemical action within or on the body of man or other animals and which is not dependent upon being metabolized for the achievement of its primary intended purposes." 21 U.S.C. § 321(h)(1).

7. The FDCA required devices to meet certain requirements before they could be introduced into interstate commerce. The requirements differed depending on which of three classes—class I, class II, or class III—a device fell into, with class III devices subject to the most

stringent regulatory requirements. A device's classification was determined by the degree of regulatory control necessary to provide reasonable assurance of the device's safety and effectiveness when used as intended. 21 C.F.R. part 860.

8. By default, any device proposed for marketing after May 28, 1976 was assigned to class III and was required to obtain premarket approval ("PMA approval") from FDA. 21 U.S.C. §§ 360c(f), 360e. PMA approval generally required that, among other things, the manufacturer submit to FDA clinical trial data regarding the device's safety and efficacy. 21 U.S.C. § 360e(c)(1)(A), (d)(2).

9. A manufacturer could remove its device from class III, and thus avoid the PMA-approval requirement, if the manufacturer obtained from FDA a finding that the device was substantially equivalent to a predicate device that was already legally marketed in the U.S. 21 U.S.C. § 360(k). This process was referred to as "510(k) clearance" or submitting a "premarket notification."

10. Certain types of low-risk class I and class II devices were exempt from the PMA-approval and 510(k)-clearance requirements. 21 U.S.C. § 360(*l*). Before distributing exempt devices, a manufacturer was required to register with FDA and list the product code and proprietary name for each device that the manufacturer claimed either qualified for an exemption to PMA-approval requirements and 510(k)-clearance requirements or was in commercial distribution prior to May 28, 1976. 21 U.S.C. § 360(b)(2); 21 C.F.R. §§ 807.20(a), 807.25(g).

11. By regulation, FDA classified broad categories of devices into regulatory classes (generally class I or class II), and a manufacturer of a device that fell into those generic categories would be exempt from PMA-approval requirements (for class I and class II devices)

or 510(k)-clearance requirements (for class I devices) "to the extent that that the device has existing or reasonably foreseeable characteristics of commercially distributed devices within that generic type." The regulations required a manufacturer to submit a 510(k) notification to FDA if the device was intended for a use different than the intended use of a legally marketed device in that generic type of device (*e.g.,* the device was intended for a different medical purpose). 21 C.F.R. § 874.9.

12. Regardless of how a manufacturer was authorized to introduce a device into interstate commerce, it was required to market the device consistent with the proposed labels and intended uses set forth in the PMA approval, 510(k) clearance, or exemption category.

13. Under the FDCA, a class III device was adulterated if it was required to have an approved PMA but did not have one in effect. 21 U.S.C. § 351(f)(1)(B).

14. Under the FDCA, a device was misbranded if the manufacturer failed to file a 510(k) notification with FDA ninety days prior to introducing the device into interstate commerce for such use. 21 U.S.C. § 352(o).

15. The FDCA prohibited the introduction, delivery for introduction, or causing the introduction or delivery for introduction into interstate commerce of a device that was adulterated or misbranded. 21 U.S.C. § 331(a).

DOLOR'S SPHENOCATH MEDICAL DEVICE

16. The SphenoCath was a medical device within the meaning of the FDCA.

17. In or around February 2013, Dolor began selling and distributing the SphenoCath device within and throughout the United States.

18. In his capacity as Dolor's CEO, WRIGHT directed and participated personally in marketing the SphenoCath. WRIGHT, among other things, provided marketing materials to and communicated directly with purchasers and potential purchasers of the SphenoCath.

19. WRIGHT and Dolor intended that the SphenoCath be used to treat migraine headaches by administering sphenopalatine ganglion ("SPG") nerve blocks, and WRIGHT and Dolor marketed the SphenoCath for this intended use. A nerve block was the interruption of signals traveling along a nerve generally caused by applying an anesthetic drug, such as lidocaine, to the nerve endings. Typically, a nerve block was performed to reduce pain. The SPG was a bundle of nerves located behind the bony structure of the nose. The SphenoCath was a catheter with a specially curved tip.

20. In its required registration with FDA, Dolor listed the SphenoCath as a "class I exempt" device, meaning that the SphenoCath was claimed to be exempt from the PMA-approval and 510(k)-clearance requirements as an "[e]ar, nose, and throat drug administration device" under 21 C.F.R. § 874.5220. That regulation identified exempt devices as those that were "intended specifically to administer medicinal substances to treat ear, nose, and throat disorders" and gave as examples "powder blowers," "droppers, ear wicks, manual nebulizer pumps, and nasal inhalers."

21. In fact, the SphenoCath failed to qualify for the exemption under 21 C.F.R. § 874.5220 because WRIGHT and Dolor intended that the SphenoCath treat a neurological disorder—migraine headaches—and not an ENT disorder, and because WRIGHT and Dolor intended that the SphenoCath target a neurological site—the SPG nerve—and not the ear, nose, or throat.

22. On or about April 17, 2014, Dolor, through its counsel, submitted an "informal request for product classification and jurisdictional assignment" to FDA. Dolor's informal request, as supplemented on April 25, 2014, asked the FDA's Office of Combination Products whether the SphenoCath device could be cleared for the "trans[-]nasal administration of local anesthetic into the region of the sphenopalatine fossa, the ethmoidal crest and the vidian (or petrosal) canal to perform neuro-modulation [nerve block] of the sphenopalatine ganglia, pterygopalatine ganglia and the maxillary branch of the trigeminal ganglia." This was not a notification pursuant to the section 510(k) clearance process, but rather was Dolor's exploration of, among other things, whether the SphenoCath would require further study in order to receive section 510(k) clearance.

23. On or about June 13, 2014, FDA's Office of Combination Products informed Dolor that, "[a]fter review of the information, we are unable to provide a definitive answer to your question regarding classification of your product. . . . [W]e recommend that you contact CDRH [FDA Center for Devices and Radiological Health] to proceed with investigational studies regarding the proposed product."

24. Neither WRIGHT nor Dolor responded to FDA concerning its recommendation of "proceed[ing] with investigational studies." Neither WRIGHT nor Dolor ever submitted a section 510(k) clearance notification to FDA for the SphenoCath, and neither WRIGHT nor Dolor ever sought or obtained PMA approval for the SphenoCath.

25. Instead, WRIGHT and Dolor continued to market the SphenoCath with the intention that it be used to treat migraine headaches by administering SPG nerve blocks. For example, Dolor's website described the SphenoCath as a "revolutionary" device that "delivers

anesthetic through the nasal cavity, effectively delivering an SPG block for migraine pain." WRIGHT and Dolor also distributed marketing materials, intended for health care providers, that included claims such as "The SphenoCath Solution" for "The Pain Management Problem" of "episodic & chronic migraine and cluster headaches." As part of marketing efforts, WRIGHT and Dolor provided unsolicited directions to health care providers on how to fill the SphenoCath with lidocaine and/or other anesthesia drugs, insert the SphenoCath into the nose, angle the curved tip towards the nasal cavity, and flood the nasal cavity with a specific drug which would reach the SPG nerve and trigger the nerve block.

26. WRIGHT ceased employment with Dolor on July 31, 2017.

COUNT 1
21 U.S.C. §§ 331(a) and 333(a)(1)
(Introduction of Misbranded Devices into Interstate Commerce]

27. The United States incorporates by reference paragraphs 1-26.

28. From about on or about July 15, 2013, and continuing until at least July 31, 2017, Defendant

MARK WRIGHT

in the District of Utah did introduce and deliver for introduction into interstate commerce, and cause the introduction and delivery for introduction into interstate commerce of, misbranded devices, specifically SphenoCath catheters, that were misbranded because the required notification was not made to FDA prior to their distribution as is required by section 510(k) of the FDCA, 21 U.S.C. § 360(k).

All in violation of Title 21, United States Code, Sections 331(a), 333(a)(1), and 352(o).

COUNT 2
21 U.S.C. §§ 331(a) and 333(a)(1)
(Introduction of Adulterated Devices into Interstate Commerce)

29. The United States incorporates by reference paragraphs 1-28.

30. From about on or about July 15, 2013, and continuing until at least July 31, 2017, Defendant

MARK WRIGHT

in the District of Utah did introduce and deliver for introduction into interstate commerce, and cause the introduction and delivery for introduction into interstate commerce of, adulterated devices, specifically SphenoCath catheters, that lacked an approved application for premarket approval, or an approved application for an investigational device exemption, prior to their distribution.

All in violation of Title 21, United States Code, Sections 331(a), 333(a)(1), and 351(f)(1)(B).

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