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Doctoring the Law: Congress May Let FDA Regulate the Practice of Medicine

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Back in June, when Congress was negotiating the User Fee Acts, FDA asked Congress to add in some provisions reversing several lawsuits that it had just lost. Ultimately, FDA lost that fight, and a slimmed down version of the FDA Safety and Landmark Advancements ("FDASLA") passed without those sections. That fight has now been moved to the Appropriations Bill, where Congress is trying to integrate certain provisions that would reverse—at least in part—some of those litigation losses with little scrutiny, either by Congress or other stakeholders.

One of the more concerning provisions in the Appropriations Bill can be found in section 3306, which addresses "Bans of Devices for One or More Intended Uses." This section is directly in response to the 2022 D.C. Circuit decision in *Judge Rotenberg Educ. Ctr., Inc. v. FDA*, which held that that banning a single intended use of a specific device was inconsistent with the Federal Food, Drug, and Cosmetic Act's ("FDC Act") clear pronouncement that FDA cannot regulate the practice of medicine. (Hyman, Phelps & McNamara, P.C., was co-counsel for the Judge Rotenberg Center in this litigation.) In brief, that case involved the appeal of a 2020 Final Rule in which FDA banned the use of an Electrical Stimulation Device ("ESD") *only* in the treatment of self-injurious behavior or aggressive behavior.

The site offering the treatment, the Judge Rotenberg Educational Center, and parents of patients that were treated with an ESD for self-injurious or aggressive behavior filed a Petition for Review in the D.C. Circuit of FDA's Final Rule banning the ESD specifically for those purposes. The Petitioners alleged multiple violations of the Administrative Procedure Act, as well as alleged that FDA violated the FDC Act itself by banning a particular use of a device rather than the device itself. The Court agreed with the Petitioners, holding that banning the use of the device would regulate the practice of medicine or prohibit the off-label use of a device. Now, Congress seeks to overturn that decision by amending the FDC Act to permit FDA to ban a specific intended use.

In the Appropriations Bill, the proposed provision amends section 516(a) of the FDC Act (21 U.S.C. § 360f(a)) to allow FDA to ban a device "for one or more intended uses" and states that "A device that is banned for one or more intended uses is not a legally marketed device under section 1006 when intended for such use or uses." Section 1006 refers to the "Practice of Medicine" provision of the FDC Act (21 U.S.C. § 396), which prohibits FDA from limiting or interfering "with the authority of a health care practitioner to prescribe or administer any legally marketed device to a patient for any condition or disease . . . ." In other words, Congress is proposing to let FDA ban devices for

particular uses, including off-label uses.

This provision represents a complete shift in the way FDA is allowed to regulate products. Previously, FDA determined whether a product was safe and effective for its intended use but could not dictate the way a practitioner used that product. That, of course, is reserved for the practice of medicine, and FDA does not govern the practice of medicine. This proposed revision turns that premise on its head: If FDA can say that a given device *can't be used* for a specific treatment, then the practice of medicine is inherently subject to FDA discretion, regardless of the provisions in section 1006. Congress has effectively narrowed Section 1006 by giving FDA the authority to ban off-label uses of devices.

At first blush, this might not seem like such a big deal. After all, FDA has only used its banning authority 3 times since 1976. Yet this provision would have serious implications. Firstly, the proposed provision, should it pass, would allow FDA to ban a device in a way it has never been allowed to, ultimately giving the Agency authority to dictate the practice of medicine. Secondly, the proposed provision would be implemented with no scrutiny, public input, or public hearing. Yet this provision could potentially have far-reaching consequences. Even if FDA has infrequently used its banning authority, nothing would stop FDA from seeking to use this power much more extensively in the future. Giving FDA the power to ban off-label uses could preclude patient access to off-label therapies that FDA objects to even though their physicians deem the treatment essential. Thirdly, this provision erodes a bedrock principle: FDA does not have the power to regulate the practice of medicine. This particular provision may seem like a small exception, but small holes in the fabric of the law can grow into gaping holes over time.