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Medical Products & FDA: What to Watch for in 2019

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Major legislation impacting FDA often accompanies user fee reauthorizations every 5 years. However, Congress has acted to address public health issues between user fee cycles. FDA regulates 20¢ of every U.S. consumer dollar spent on products ranging from heart valves to insulin to breakfast cereal, so there's always something Congress can do in the realm of FDA's statutory authorities. Many FDA-related bills are often bipartisan, too, which suggests action despite different parties in power in the House and Senate. Here are a few key medical product issues we'll be tracking in 2019.

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Laboratory Developed Tests (LDTs)

An LDT is a type of in vitro diagnostic test that is designed, manufactured, and used within a single laboratory. In recent years, FDA has attempted to more actively regulate LDTs, claiming they are more complex now than when the agency was granted authority to regulate devices in the 1970s (FDA had, until recently, generally ignored LDTs using a policy known as enforcement discretion). A few years ago, the agency published a proposed approach that caused a stir in Congress and the lab industry and after years of debate Congress seems ready to act on LDTs, which some are now calling In Vitro Clinical Tests (IVCTs). However, New Jersey Democrat Frank Pallone, the likely incoming chairman of the House Energy & Commerce Committee has expressed concern with FDA's proposed approach to IVCT regulation, especially its heavy reliance on review by accredited persons (i.e., third party review) and pre-certification. FDA's position was outlined by Commissioner Scott Gottlieb, who in a September 2018 speech stated that FDA envisions reviewing only 10% of IVCTs, 40% would use the pre-certification model, and the remainder would not be subject to FDA premarket review.

Who blinks first? Based on my experience at FDA, the agency is likely to wait for Congress to make the first move largely because FDA went all in by submitting 59 pages of "technical assistance"—essentially a draft bill—to Congress in August 2018. A Democrat-controlled E&C may push for more oversight or a phased-in approach, which is something FDA has resisted. Sure to further complicate discussions is the role of user fees in funding an IVCT regulatory program. Among the questions that need to be answered: how much IVCT oversight will FDA have relative to third parties, how much will that cost, and who's paying the bill? As a former user fee negotiator for FDA, I can tell you those conversations are not going to be easy.

Digital Health

FDA's exploration of a new regulatory paradigm for digital health products hit a bump in the road on October 10 when Senators Warren, Murray, and Smith (all Democrats) sent a letter to FDA asking, among other things, what the legal basis is for the digital health pre-cert program. Because FDA does not have the staff capacity or expertise to review all digital health products (including software), part of its solution is to rely on certifications that a product developer has a culture of quality and organizational excellence. FDA also says the current review paradigm is not well-suited to software and similar products that have fast, iterative development cycles. This idea has merit but the details need to be hammered out—likely in statute. And while 2019 is too early to expect

legislation, the October 10 letter foreshadows intense scrutiny from HELP Committee Democrats. The agency is still collecting comments on its proposed framework.

Medical Device Cybersecurity

FDA recently made a splash with its cybersecurity playbook and a recently updated premarket cybersecurity guidance. However, while I was at FDA we responded to a lot of requests for technical assistance from both sides of the aisle on legislative language that would: mandate convening stakeholders to recommend guidelines for improving cybersecurity of devices, mandate software bills of materials, or provide basic cybersecurity operational standards for Internet-connected devices, among other ideas. The jury is out on how much any of these ideas would meaningfully improve the nation's cybersecurity infrastructure at least as it pertains to medical devices. Considering cybersecurity is a hot topic in other contexts (e.g., election security, personal computing), the 116th Congress will likely continue to look for legislative wins in this space and we'll be watching closely to see what the impacts could be on medical products.

Device Servicing

FDA continues to look for a solution to problematic device servicing and will be holding another public meeting in December 2018. While we're optimistic FDA will come out of that meeting with a draft policy (the agency said it plans to issue a draft guidance document before October 2019), we see challenges with some of the ideas mentioned in a discussion paper the agency released in October 2018. Even as FDA reviews public comments and publishes guidance, there could be a role for Congress, such as to ensure appropriate oversight of servicing through mandated inspections. We're looking forward to seeing how interaction between OEMs, servicers, and FDA at the December workshop could influence the draft guidance.

OTC Monograph Reform

As noted in our Lame Duck Preview for health issues, OTC monograph reform legislation passed the House but awaits action in the Senate, where it's stuck in committee. An OTC monograph is like a recipe for an over-the-counter drug that, once approved by FDA, can be used by any drug manufacturer without FDA pre-approval of the manufacturer's specific drug. The bill would speed up the regulatory process for OTC monographs by allowing use of administrative orders rather than rulemaking. Both bills authorize FDA to grant exclusivity for the monograph developer, which would protect market access, though the amount of exclusivity differs (18 months in the House bill; 24 months in the Senate bill). Likely incoming House E&C Chairman Pallone is—again—who we're looking to regarding action on this. Despite voting for the House version, it is well-known that Rep. Pallone has concerns about the exclusivity provision. The OTC monograph process has not changed since 1972 and reform efforts have been brewing for a while; if this does not move in the lame duck, this could be in play in 2019.

Opioids

Congress passed major opioids legislation in September 2018 so while Congress may shift its focus to other issues, we'll be keeping an eye on how the administration is implementing its mandates. FDA in particular has as full plate with:

- Holding a public meeting to address challenges of developing non-addictive medical products for acute or chronic pain;
- Issuing new or updating existing guidance documents addressing, among other topics, how FDA considers pain, pain control, or pain management in assessing whether a disease or condition is serious or life-threatening and how FDA may require postmarket studies to assess reductions in effectiveness of a drug that change the drug's benefit-risk profile;
- Issuing prescribing guidelines for the indication-specific treatment of acute pain;
- Developing a list of controlled substances to refer to Customs and Border Protection and other import controls; and
- Implementing new authority to require unit dose packaging (aka blister packs).

This list is not exhaustive, yet it's clear FDA will be busy. We'll be keeping a close eye on administration and congressional actions related to these and other important public health issues in 2019.