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User Fee Reauthorization Bill Includes Legislation Proposed to Improve Medical Device Regulation

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Last week, the Senate Committee on Health, Education, Labor and Pensions (HELP Committee) advanced the Food and Drug Administration (FDA) Reauthorization Act of 2017 (S. 934), by a vote of 21–2. The proposed legislation seeks to reauthorize user fees for medical products (including medical devices) for another five years through 30 September 2022. While the reauthorization package has not yet been brought before either house of Congress, its passage is considered inevitable, with House and Senate members on both sides of the aisle recognizing the user fee program's importance in providing the FDA the resources required to fulfill its mission to protect the public health, while ensuring that safe and effective medical technologies reach the public in a timely manner. Of particular interest to medical device manufacturers, the current reauthorization package proposes to extend the device user fee framework to include a new fee for *de novo* reclassification requests equal to 30 percent of the fee for a premarket application (PMA). In addition, several individual bills related to the regulation of medical devices are incorporated in this draft legislation, including:[1]

- S. 670 / H.R. 1652, Over-the-Counter Hearing Aid Act, which would enable the sale of certain hearing aids without a prescription.
- S. 404 / H.R. 1736, to amend the Federal Food, Drug, and Cosmetic Act (FDC Act) to improve the process for inspections of device establishments and for granting export certifications.
- H.R. 2009, Fostering Innovation in Medical Imaging Act, which would enable FDA to authorize use of a contrast agent with an imaging device in an indication different from that for which the agent was approved as a drug.

A fourth bill introduced in the House as H.R. 2118[2], the Medical Device Servicing Safety and Accountability Act, did not make it into S. 934, likely because of contention over its proposal to bolster FDA regulation of independent third party medical device servicing organizations. Specifically, the bill would require these entities to register with FDA, maintain a complaint handling system per 21 C.F.R. § 820.198, and submit medical device reports (MDRs) for adverse events. Original equipment manufacturers are already subject to these obligations, but FDA has, to date, used enforcement discretion with respect to their application to third-party servicers.

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[1] *See* full text of legislation.

[2] The Fostering Innovation in Medical Imaging Act and Medical Device Servicing Safety and Accountability Act does not appear to have been separately introduced in the Senate, so S. 934 incorporated language from the bills as introduced in the House of Representatives.

S. 934 as passed through the HELP Committee also incorporated the Risk-Based Classification of Accessories Act of 2017 (S. 1070 / H.R. 2144), which is intended to supplement a provision in the recently enacted 21st Century Cures Act. Specifically, 21st Century Cures and FDA's accessories guidance (as finalized) call for classification of *new* medical device accessories based on the risk they present rather than automatically placing them in the same class as the parent device; however, they do not address the longstanding industry concern that certain previously classified accessories are subject to over-regulation. The proposed language would enable reclassification of marketed accessories, provided FDA agrees with the manufacturer's application explaining why an alternative risk-based classification is appropriate. It would also reduce unnecessary regulatory burdens for new, low-risk accessories by allowing manufacturers to recommend a separate risk-based classification for an accessory within the context of the premarket submission for its parent device.

In addition, the reauthorization package includes a few other device-related provisions designed to:

- Enhance pediatric access to innovative medical devices, and establish within CDRH a structure and designated expert staff to help device manufacturers develop, approve, and label devices for children.
- Support device pilot projects assessing the use of real-world evidence for postmarket surveillance about safety or effectiveness.
- Facilitate re-inspection and/or approval for products for which a prior inspectional observation is the only barrier to approval and the sponsor has notified FDA that necessary changes have been made to the establishment in question to address prior findings or deficiencies.

The HELP Committee's passage of the reauthorization package comes on the heels of related action in the House of Representatives. At a hearing on 2 May 2017, members of the House Energy and Commerce's Subcommittee on Health, Center for Devices and Radiological Health (CDRH) Director Jeffrey Shuren, M.D., J.D., testified followed by a panel representing key stakeholder groups that would be affected by the passage of four proposed bills, three of which were subsequently incorporated into the Senate draft discussed above. The following provides a summary of each of the proposed measures discussed at the hearing, as well as the tone of the conversation on each and the potential impact of each on the medical device industry.

H.R. 1652, Over-the-Counter Hearing Aid Act[3]

This measure would require FDA to promulgate regulations that establish a category of over-the-counter (OTC) hearing aids intended to be used by adults to compensate for perceived mild to moderate hearing impairment. The bill is crafted with the belief that the current requirements for purchasing hearing aids, which in most states include a medical evaluation or signed waiver, are unduly burdensome and result in 80% of people who might benefit from such technology never obtaining it. FDA has shown agreement with this position, issuing guidance in December 2016 indicating that the Agency would no longer enforce these requirements for patients over 18 years old.[4] Proponents at the hearing opined that creating a market where hearing aids can be more easily purchased is likely to enhance competition, affordability, and access, and may even encourage more individuals to seek professional help by increasing awareness in the general public.

[3] For current legislative language, *see* Section 711 of S. 934, *supra* note 1.
[4] *See* *Immediately in Effect Guidance Document: Conditions for Sale for Air-Conduction Hearing Aids* (12 Dec. 2016).

Of the four bills discussed at the hearing, this one had the most vocal support from leaders on both sides of the aisle, and raised little contention. The biggest question seemed to be whether it is appropriate to include those with "moderate" hearing loss in the eligible population, with some arguing that OTC aids should be available only for people with mild hearing loss and should be subject to strict labeling requirements to mitigate risks of improper use (*e.g.*, in children). Passage of the bill—which appears very likely—would present significant new commercial opportunities for hearing aid manufacturers, in addition to potential public health benefits.

H.R. 1736, Amendments to Inspection Processes and Export Criteria in the FDC Act[5]

This measure would amend the FDC Act to revamp the existing processes for inspections of device establishments and for granting export certifications. Specifically, the bill is intended to modernize FDA's risk-based approach to inspections and improve communications between Agency investigators and industry.

The bill comes partly in response to complaints of discrepancies in the inspection process, including domestic inspections taking longer than foreign ones and companies occasionally being held to different standards at different facilities. Dr. Shuren explained that domestic inspections may take longer because investigators may be called upon to inspect a for-cause site as they are conducting a scheduled inspection. For foreign sites, on the other hand, investigators normally enter the country, perform the inspection over one week, and depart to the next inspection. Dr. Shuren noted that the upcoming realignment of FDA's Office of Regulatory Affairs should reduce the amount of time for domestic inspections and said FDA will be shifting from assigning inspections on a geographic basis to having inspectors looking at facilities across the country under the same line of management. Members of the subcommittee and industry representatives concurred that the legislation would increase the predictability and transparency of FDA's routine inspections and ensure that both FDA and industry resources are best targeted to meet public health needs. In response to questions from some Congressmen, Dr. Shuren commented that certain improvements could occur relatively quickly, while others would take more time because they require a shift in the Agency's culture.

While streamlining facility inspections is a commonly discussed goal in the medical device industry, it is unclear whether this bill would have a significant impact. Notably, the "risk-based" approach to inspections touted by proponents is in fact already implemented by FDA, at least to some extent. As confirmed by Dr. Shuren at the hearing, the Agency simply lacks the resources to fulfill its statutory mandate of inspecting over 25,000 device facilities worldwide every two years, and is thus left to spread the available resources to provide the most comprehensive view possible of the field. In practice, this often means prioritizing inspections based on the level of risk associated with a facility and its products. Thus, while the bill may lead to more consistent application of a risk-based approach in this area, it is consistent with FDA's current thinking.

H.R. 2009, Fostering Innovation in Medical Imaging Act[6]

This measure would clarify the FDA review process for medical imaging devices intended to be

[5] For current legislative language, *see* Sections 701-704 of S. 934, *supra* note 1.
[6] For current legislative language, *see* Section 707 of S. 934, *supra* note 1.

used in conjunction with contrast agents, which are drugs that enhance the contrast between a patient's targeted tissue and the surrounding areas to facilitate diagnosis and treatment. Specifically, the bill would authorize FDA to clear/approve an imaging device for use with a contrast agent in a new indication (*e.g.*, a new anatomical location) that is not among the approved indications of the contrast agent. At present, the Agency cannot clear/approve a medical device with a contrast agent for a use that is inconsistent with that agent's approved drug labeling.

A witness representing the Medical Imaging Technology Association testified that since a contrast agent manufacturer often has no need or incentive to revise the drug's labeling, such updates are not keeping pace with the technological advancements of medical imaging devices. As a result, such advancements cannot be approved or cleared by FDA. Proponents of the bill claim that resolving this problem will encourage innovation and enhance access to technologies that help physicians to better diagnose and treat patients consistent with international practice.

Members did not devote much attention to this bill at the hearing, but Chairman Burgess (R-TX) expressed a willingness to evaluate the issue and take appropriate action. Of note, Congressional action is needed to generate change in this area, because FDA has already advanced as far as current law allows.[7] Passage of the bill would enable imaging technologies that utilize contrast agents in innovative ways to reach the market more easily, as long as safety and efficacy with respect to the proposed intended use were shown; however, the exact mechanism by which this would occur is unclear.

Conclusion

Because the current user fee legislation expires on 30 September 2017, the proposed reauthorization package is expected to proceed through both houses of Congress and be enacted into law before the August recess. Of note, the House Energy and Commerce's Subcommittee on Health is scheduled to vote on the FDA Reauthorization Act of 2017—the same language passed through the Senate HELP Committee—tomorrow, 18 May 2017. We expect the legislation's final language to be similar to the current working draft, though the reauthorization package could still be further tweaked, and even additional measures included, if there is sufficient bipartisan support for such changes.

[7] *See Guidance for Industry: New Contrast Imaging Indication Considerations for Devices and Approved Drug and Biological Products* (Dec. 2009).

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