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Combination Products

Senate Bill Aims to Streamline FDA Approval of Combination Products

Approvals of medical products containing both a drug and device or biologic component would be overhauled under legislation introduced in the Senate recently.

The proposed Combination Product Regulatory Fairness Act (S. 1767) would allow the FDA to rely on prior findings of safety and efficacy when deciding whether to approve a combination product. It also would make it easier for the Food and Drug Administration to address whether a product is reviewed as a drug, device, or biologic, based on the primary intended purpose for the product.

The bill was introduced by Sen. Johnny Isakson (R-Ga.), and bipartisan co-sponsors include Sens. Bob Casey (D-Pa.) and Pat Roberts (R-Kan.). It has been referred to the Senate Health, Education, Labor, and Pensions Committee.

Clear Regulatory Pathway. The legislation “will eliminate the high level of uncertainty in approval standards that currently exists for innovative companies, both small and large, when deciding to invest in a new product,” Isakson said in a July 17 statement. “This bill creates a clear regulatory pathway for products to come to market that will directly translate to greater access and more innovative medical products for patients who will benefit most.”

Currently, the FDA doesn’t take into account prior findings of safety and effectiveness of components of a combination product when approving products. The bill proposes to allow the FDA to rely on prior findings of safety and efficacy for a previously approved drug component and rely on previously approved pre-market approvals.

Additionally under the current process, the sponsors of combination products are left with “uncertainty as to what regulatory center will ultimately be charged with review of their application,” the senators said in a joint statement. The legislation would assign a lead center within the FDA to address whether a product is reviewed as a drug, device, or biologic, based on the primary intended purpose for the product. The bill would allow sponsors to submit and work out an agreement with the FDA on a Combination Product Review Plan that details a clear regulatory process for the combination product, addressing necessary clinical studies, timelines, and an evaluation of incremental risks posed by the combination product, the lawmakers said.

Device Industry Support. The bill drew support from the medical devices industry. In a July 20 statement, the Advanced Medical Technology Association (AdvaMed) commended the senators for their bill introduction.

“Combination products—whether device/drug, device/biologic or drug/biologic—represent some of the most innovative treatment options for American patients. Unfortunately, FDA’s process for determining which of its centers has primary responsibility for reviewing these products, as well as the actual review itself, often lacks predictability and efficiency, delaying patient access to these cutting-edge advancements,” Stephen J. Ubl, president and chief executive officer of AdvaMed, said in the statement. Ubl promised to work with Congress and other stakeholders to move the bill forward.

Bill Premature? An attorney who represents makers of combination products said the bill addresses important concepts, but added that legislative changes may be premature.

Bradley Merrill Thompson of Epstein Becker & Green PC told Bloomberg BNA July 21 that the Combination Product Coalition “would like to focus our energies on working with FDA to improve the process administratively.” He is general counsel to the coalition.

Thompson said, “We have been meeting with FDA officials, and we find them to be very genuinely interested in improving the process. Indeed, they are so interested that they have recently completed a very significant internal study of how to make the process better. We hope, and frankly anticipate, that FDA will publish the results of that study and initiate a series of reforms to make the process work more smoothly. We want to collaborate with the agency on that effort.”

Thompson added that the coalition has been working on some suggestions for the agency, “with the hope that FDA would test these improvements to see if they actually work. Our fear would be that at this point to lock-in changes through legislation would be premature simply because we are not yet confident what would actually improve the process.”

Thompson said, “There may indeed be opportunities to legislate in the future after we know more what will truly improve the regulatory process. And we would love to work with Senators Isakson, Casey and Roberts to get their input on our thinking as well as keep them informed of the agency discussions.”

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Bill text is at <https://www.congress.gov/bill/114th-congress/senate-bill/1767/text>.