

# Device And Drug Accelerated Approval Pathways Important To Cancer Patients, US FDA Oncology Chief Pazdur Says

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## *Executive Summary*

The Food and Drug Administration's increased use of hastened approval pathways for innovative medical products, including new genomic device/drug combinations, has come in for criticism from some US Senators recently. But the patient group Friends of Cancer Research (FOCR) endorsed the approach at a 10 December meeting on Capitol Hill featuring FDA's Oncology Center of Excellence director Richard Pazdur.



Source: Sue Darcey

Prominent Democratic Senators Elizabeth Warren of Massachusetts and Patty Murray of Washington have recently criticized the FDA’s “progressive approval pathway” to bring devices and diagnostics more quickly to market, arguing that it could weaken medtech rules.

But on 10 December, FDA’s Oncology Center for Excellence director Richard Pazdur defended the agency’s practice of offering swifter product approvals via the breakthrough therapy program for cancer drugs, which uses a similar model to the breakthrough devices program at the agency’s device center. The approach, he said, is just what the doctor and patient ordered.

Pazdur told senatorial staff members at a recent Friends of Cancer Research (FOCR) briefing that breakthrough therapy drug designations on drugs and drug/device combination products do not convey lower approval standards by FDA. In recent years, providers have been relying more frequently on genomic diagnostic device and drug combinations to select the most targeted cancer therapies for patients.

“The breakthrough therapy pathway never was meant to really be a [comparative] rating system for drugs – it was meant to marshal the efforts of the agency to get these important drugs out,” Pazdur said. He emphasized that the pathway is designated only for those medical products that show “substantial early benefits” for patients.

“I’m a little surprised we have to defend the breakthrough pathway, as it really is a very well-vetted process at this point.”  
– Richard Pazdur

Similarly, FDA’s popular [Breakthrough Devices Program](#), an accelerated development pathway for medtech products including molecular-based diagnostics that the agency finds can provide a more effective treatment or diagnosis of life-threatening or irreversible debilitating diseases or conditions, addresses many unmet needs of patients, FDA device center chief Jeff Shuren said in December 2018. (Also see "[FDA Marches Forward With 'STeP' Program To Aid Development Of Significantly Safer Medtech Products](#)" - Medtech Insight, 18 Dec, 2018.)

Ellen Sigal, a physician and chair and founder of FOCCR, confirmed that cancer patients, particularly those who have no alternative products to allay the progress of their disease, welcome the small amount of risk that use of a drug or drug/device combination going through FDA’s accelerated breakthrough pathway may entail.

She added that the agency tends to conduct a “thorough review,” under the accelerated pathway, and stated “both the science is better and the regulatory advances” for breakthrough therapies are better.

## Senators Say Accelerated Pathways Weaken Standards

In a 4 November **letter** to FDA officials, Sens. Warren and Murray said they were worried about how the agency intends to maintain device safety and efficacy through use of a progressive regulatory pathway. (**Also see "[Senators Question FDA’s Proposed Progressive Approval Pathway For Devices](#)" - Medtech Insight, 12 Nov, 2019.**)

The lawmakers further criticized FDA for employing the same type of conditional approval regulatory route that allows certain animal drugs to stay on the market, for humans as well. Under the conditional (or “progressive”) approval regulatory route, all the pathway would have to show to FDA is “a reasonable expectation of effectiveness,” the senators claimed.

But despite the senators’ criticism, FDA has emphasized in its FY 2020 budget justification [document](#) that devices eligible for marketing via the progressive approval pathway must provide a “demonstration of safety and performance

plus additional risk mitigations,” and “could remain on the market ... only after a demonstration of reasonable assurance of safety and effectiveness.” The agency further stated that if a company does not demonstrate reasonable assurance of safety and effectiveness within a reasonable amount of time after initial approval, “the initial approval would automatically sunset and the device could no longer be legally marketed.”

Also, Pazdur argued that FDA needs to have the flexibility to use accelerated approval processes to get medical products to market quickly for patients in need.

“I’m a little surprised we have to defend it,” Pazdur said. “It really is a very well-vetted process at this point.”

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