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FDA Proposal Gives Patients Easier Way To Give Input on New Medical Products

BY BRONWYN MIXTER

Patients would have an easier way to communicate their views on new medical products to the FDA under a recent proposal.

The Food and Drug Administration is considering establishing an Office of Patient Affairs to support and coordinate patient engagement activities across the agency's medical product centers for drugs, medical devices and biologics, according to a March 14 Federal Register notice (82 Fed. Reg. 13,632).

The Food and Drug Administration Safety and Innovation Act (FDASIA) of 2012 (Pub. L. No. 112-144) directed the FDA to develop and implement strategies to solicit the views of patients on medical product development.

The responsibilities of the office would include handling inbound inquiries from patient stakeholders and developing a platform for communicating with patient stakeholders, the notice said.

The agency is seeking public comments on the proposal, which are due June 12 (Docket No. FDA-2017-N-0455).

Support for Office. ''This is a proposal that we've been in support of for several years,'' and the ''benefits are many,'' Paul Melmeyer, associate director of public policy at the National Organization for Rare Disorders, told Bloomberg BNA March 15.

''The number of patient involvement opportunities at the FDA, specifically within the three medical centers, are growing each year,'' but there hasn't been a lot of coordination, and patient organizations don't always know which one is best for their organization.

''So having a more central body that has a hand in all of these different initiatives, or at least kind of oversees all of these initiatives, that will allow for better coordination,'' Melmeyer said. It also ''will allow for patient organizations to have one central place to go to in order to better understand how best to engage with the FDA.''

Jim Kremidas, executive director of the Association of Clinical Research Professionals, told Bloomberg BNA March 14 ''it's an excellent idea and long overdue.''

The benefits of the proposed office are that patients would be able to weigh in on clinical trial endpoints and what kind of relief they are looking for and what risks they're willing to take with a particular treatment, Kremidas said.

FDA Should Change Policies. Darcy Olsen, chief executive officer of the Goldwater Institute, told Bloomberg BNA in a March 14 email instead of creating a new office, ''the FDA should simply change its internal policy to allow patients, doctors and drug companies to work together directly to ensure patients have access to promising treatments—without requiring complicated advanced paperwork that must also be approved by an outside board even after the FDA has already signed off.''

The FDA has a system that allows patients to get access to experimental treatments on a case-by-case basis, with the manufacturer's approval. The system requires submitting a request that usually has to be approved by an institutional review board (IRB). The IRBs review and approval clinical trials.

''The Trump administration has pledged to streamline the drug approval process and has called for the right to try to become a national law,'' Olsen said. ''As of today, 33 states have adopted right-to-try laws that protect the right of people with terminal illnesses to save their lives with innovative treatments that haven't completed the full gamut of FDA testing.'' Olsen's group is a think tank that advocates for limited government.

State right-to-try laws give patients access to experimental drugs as long as the drugs have completed early safety tests.

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The Federal Register notice is at https://www.gpo.gov/fdsys/pkg/FR-2017-03-14/pdf/2017-04982.pdf.

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