The FDA Device Accountability Act

Senators Richard Burr and Al Franken

The FDA Device Accountability Act "The Device Act" will help ensure that Americans are able to benefit from new medical devices in as timely a manner as possible by ensuring that the Food and Drug Administration (FDA) eliminates unnecessary burdens when evaluating devices (aka the "least burdensome" requirements); permitting the use of centralized Institutional Review Boards (IRBs) for medical device trials; and requiring the FDA to update guidance on certain diagnostic tests performed in doctors' offices.

Section 2: Ensuring the Least Burdensome Means of Evaluating Devices

A central purpose of the FDA Modernization Act of 1997 (FDAMA) was to ensure the timely availability of safe and effective new products that will benefit the public. FDAMA required the FDA to take steps to eliminate unnecessary burdens imposed on device manufacturers, so as to allow proven technologies to come to market more quickly. FDAMA did not alter the statutory requirements for FDA's medical device review and approval standards; it merely specified that these processes should be conducted in the "least burdensome" manner. The goal of the "least burdensome" requirements was to streamline the regulatory process and reduce the amount of time and resources required to get new devices approved by the FDA. Unfortunately, these principles have not been consistently applied.

The consistent and meaningful application of the "least burdensome" principles is a critical part of improving and accelerating patient access to potentially life-saving medical devices. The Device Act requires the Secretary of Health and Human Services to ensure that FDA reviewers receive training regarding the intent and application of the least burdensome requirements. The Device Act also requires an audit by the FDA ombudsman as well as an assessment of the measurement used to track the implementation of the least burdensome requirements. It also makes clear that FDA reviewers shall consider the least burdensome appropriate means necessary for demonstrating a reasonable assurance of safety and effectiveness when requesting additional information from manufacturers during the pre-market approval process. Finally, this legislation requires the FDA to disclose how they considered and applied the least burdensome requirements in their rationale for significant decisions.

Section 3: Permitting Non-Local Institutional Review Boards

Today, FDA may permit the use of non-local or centralized IRBs for drug clinical trials; however, current law does not extend this same flexibility for medical device trials.

The Device Act eliminates this illogical inequity by permitting the sponsor of a device trial to seek approval using either a local or centralized IRB. The use of a centralized IRB can streamline device trials occurring in multiple geographic locations, which may ultimately reduce the total time and resources required for manufacturers to study devices and get them approved by the FDA.

Section 4: Clarifying CLIA Waiver Study Design Guidance for *In Vitro* Diagnostics

Point-of-care diagnostics enable doctors and patients to make informed treatment decisions by providing quick and convenient test results. The FDA reviews these diagnostics to assess their complexity, and for such diagnostics found to have low complexity, Clinical Laboratory Improvements Act (CLIA) requirements are waived. FDAMA clarified that the standards for such waivers should focus on the effect that the user has on results, such that if a test performs the same in the hands of untrained users as it does in the hands of laboratory professionals, then it may be administered in CLIA-waived labs (e.g. a doctor's office).

The Device Act requires that the FDA update its existing regulatory guidance to clarify the criteria for waiving CLIA requirements, specifically certain considerations for *in vitro* diagnostics. By applying this kind of user-focused regulatory approach, more diagnostics can be performed at the point-of-care; thereby expanding patient access to these important tests and encouraging further innovation in such technologies.