RealClearHealth

Op-ed: New Law Will Help FDA, Medical Technology Industry to Better Serve Patients

SCOTT WHITAKER, PRESIDENT AND CEO, ADVAMED
OCTOBER 26, 2022

Every day, headlines reflect medical technology advancements ushering in medical miracles, from regaining the ability to walk or hear or see to faster and earlier disease detection, from chronic condition relief to literally lifesaving technologies.

Behind those headlines, there is a complex system that can either help or hinder medical technology innovators, depending on how well it works and how well it adapts to the fast pace of the medical technology community racing to better treat or fully cure the countless diseases and ailments we face.

The Medical Device User Fee Agreement—it even has its own Washington-speak acronym: MDUFA—system is absolutely critical to millions of patients across the U.S., every single second of every single day, in every single clinic, doctor's office, and operating room.

Every five years, this program must be updated and renewed (or "reauthorized," in Washington speak). FDA and the medical technology industry first work together to determine the resources FDA needs in order to keep up with the medical technology industry's rapid growth and innovation, and then Congress works with our industry and FDA to give its input on what the FDA and industry agreed to. All of us share a single goal: to prioritize innovation and increase patient access to safe and effective medical technologies.This work has always been bipartisan, reflecting our shared drive to ensure FDA meets the needs of the millions of American patients who depend on lifesaving medical technology.

The legislation Congress just approved and President Biden signed into law, the fifth generation of MDUFA known as "MDUFA V," includes historic provisions for greater predictability, consistency, and communication between medical technology innovators and FDA.

The law preserves everything that works well in the current system, adding support of specific needs to fulfill the critical mission of device review, and reflects lessons learned about shifting workloads and priorities in device development and review during a global pandemic.

Industry user fees will help fund more FDA employees to evaluate new medical devices for patient use, with first-ever additional funding if the agency meets clearly defined process targets. Adding to the FDA's workforce will help the agency manage a constantly increasing device review workload, as innovations soar from the smallest start-ups to the largest companies. Digital health alone is a tremendous growth area. Equipping the FDA to add to its highly skilled workforce will help innovators get their products in the review pipeline, respond to the FDA's critiques and requests for more information, and ultimately reach patients sooner with their products if they earn agency approval.

> **"The result will be more timely consideration, ideally resulting in faster patient access to the latest and greatest advances in safe, effective medical technologies."**

AdvaMed
Advanced Medical Technology Association

The result will be more timely consideration, ideally resulting in faster patient access to the latest and greatest advances in safe, effective medical technologies.

We are in a golden age of medical technology innovation, and the reforms in this new law will help Medtech developers do what they do best: create new diagnostic, digital, and treatment tools earning the FDA's stamp of approval for ever-greater health for as many patients as possible.

It's important to note that as beneficial and welcome as MDUFA V is, Congress could and should do even more to serve patients with new medical technology. Legislative proposals would add value in areas key to promoting better patient outcomes. These proposals include modernizing diagnostic test regulation, streamlining the review of proposed device modifications, and improving the certification of FDA approval to foreign governments. Our industry will continue to urge congressional action on those reforms, as we, like Congress and the FDA, are always looking for ways to better serve patients in need.

The medical technology industry continues to work with Congress to break down barriers that impede access to the best medical technology for all patients. Everyone deserves the benefit of FDA-approved medical technologies—and MDUFA V will make that world-class agency, the FDA, the global gold standard for medical technology review, even better for the patients we all serve.

Scott Whitaker is President and CEO of the Advanced Medical Technology Association (AdvaMed), the world's largest trade organization representing medical technology developers and manufacturers.

Available online at t.ly/Dz-T