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29 Mar 2022 | **Opinion**

Opinion: MDUFA V Agreement Enables Bold Medtech Vision To Become Reality

by

As the US Congress prepares to take up a proposed medical device user fee deal for 2023-2027, AdvaMed president and CEO Scott Whitaker offers his perspective on a potential "golden age" for medtech innovation.

An exoskeleton that helps a paraplegic Marine walk with his kids. An artificial pancreas preventing dangerous glucose level drops in a diabetic patient. A brain-controlled prosthetic leg allowing an amputee to climb mountains.

These are all near or available medical technology innovations. Emerging from the two-year onslaught of a global pandemic, medtech pioneers are innovating at never-before-seen levels. Their tenacity and enterprising spirit are ushering in new areas of growth, new levels of treatments, and an even broader range of clinical applications. Our society stands at the edge of a golden age of medical technology.

However, none of this would be possible without an effective regulatory and policy environment. Thanks to the US Food and Drug Administration and Congress, the medical device industry in the United States is well-equipped to continue delivering the innovations that save and enhance lives worldwide. The FDA review of medical devices for safety and effectiveness is the global gold standard.

The latest agreement on the Medical Device User Fee Amendments (MDUFA) reauthorization between the FDA and the industry builds on and enhances the solid foundation previous agreements have built.

As *Congress holds hearings this week* to examine the MDUFA V agreement, the medtech industry stands ready to work with lawmakers and the FDA to ensure all the elements of the package make for sound policy and reflect the intent we all share – saving patient lives.

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ADVAMED PRESIDENT AND CEO SCOTT WHITAKER *AdvaMed*

History is on our side. Enhancements in each iteration of past MDUFAs have improved patient care, given medtech companies the consistency and transparency they need, and given the FDA the resources it needed to hire staff and ensure the thorough, timely review of medical technologies.

Now with MDUFA V, the golden age of innovation is even more of a reality with the historic milestones we have set and mutually aim to achieve.

The agreement could not have come at a more pivotal time. As the medtech industry responded to COVID-19, so did the FDA.

The agreement recognizes the unprecedented workload caused by the pandemic and the FDA's tireless response to it. That's why the agreement calls on the agency to improve performance beyond levels achieved in MDUFA IV, with additional resources and new full-time equivalent (FTE) employees for the agency to fulfill its mission to patients.

Reflecting the pandemic experience, and the need for agility and preparedness as demands increase or fluctuate, this is the best agreement yet for achieving our shared goals, with several "firsts" that will lead to even greater performance, predictability, and consistency, including enhanced hiring and performance goals that, if met, will result in first-ever additional funding. Further, we all agree on clear pre-submission goals that will reduce the total time to issue FDA decisions for medical devices, and first-ever policies on carry-over balances and unused funds.

In addition to these new policies, this agreement includes the largest single contribution to the device user fee program, which will dramatically and positively impact the future of medtech innovation. It secures a guaranteed funding amount of $1.784 billion while offering the agency the opportunity to collect up to an additional $115 million for supplemental program enhancements if clearly defined process targets are met. These funding levels keep pace with industry innovations and FDA workloads.

Beyond the dollars, the essence of the MDUFA V reauthorization was and is a tremendous opportunity to bring the industry's innovation and FDA's know-how together to help patients. Our agreement preserves everything that works well in the current system, builds in 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.

There's no way to do this alone. Congress, industry and the FDA must step into this bold new world of patient treatments and cures together.

Together, we face the questions that have inspired and motivated the best minds in medical technology. What new treatments can we offer patients? What new tools can enhance a physician's ability to diagnose a hidden health condition? What's next to accelerate the time from test to treatment? After all, life moves quickly. And now more than ever, medtech innovation must match that speed, step for step. The FDA deserves the support it needs to maintain its unparalleled review standards and help deliver the highest quality medical devices to the American people.

AdvaMed stands ready to do our part to ensure the successful enactment of this historic agreement.

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