

Clearing the Path for Medical Device Innovation

Did you know that it is [estimated that health-related apps](#) will be downloaded 1.7 billion (yes, with “b”) times by the end of this year? This includes everything from personal fitness apps to clinical decision support software. It is no surprise that digital technologies have and will continue to transform health care in important ways. They help address public health crises, enable faster diagnosis and treatment by clinicians, and empower consumers to take control of their health. But the line between private innovation and public health is ambiguous at best.

Make no mistake. The government must walk a tightrope when it comes to regulating medical devices and apps. On one hand, it has the responsibility to ensure that the technology companies produce are safe and effective. On the other hand, the government doesn’t want to overstep and stifle innovation that could lead to life-saving technology. This balance can be hard to find. However, one agency is making plans to walk that fine line.

In a [recent blog post](#), the Food and Drug Administration (FDA) Commissioner Scott Gottlieb, M.D. announced the administration’s new Digital Health Innovation Plan. The plan proposes to eliminate ambiguities (as they currently exist) in the 21st Century Cures Act and provides increased guidance for digital health products.

While the program is still being developed, the FDA appears to be pursuing a third-party process that would eliminate a full FDA review for lower-risk products, making it easier for higher-risk products to work their way through the pipeline. The plan also includes provisions for post-market research and data collection that is promised to spur even more innovation

down the line.

As one industry stakeholder told [Fierce Healthcare](#), “All in all, I feel like I’ve died and gone to heaven.”

Good work, FDA. We look forward to seeing how this plan enables innovative health IT products. What do you think of the FDA’s announcement? How else can the government aid the development of health IT? Join the conversation by tweeting us [@CNSIcorp](#).