March 19, 2015

Health care is always a major issue in Washington, DC but recently how to promote innovation in medtech has become a priority within that conversation. Thus far, 2015 has produced a major legislative initiative in the form of 21st Century Cures, a significant report from the Federal Trade Commission (FTC) on the Internet of Things (IoT) and several pieces of guidance from the Food and Drug Administration (FDA) aimed at reducing regulatory burden for digital health. This increased visibility for medtech in Washington bears close attention from company executives and counsel because it will shape the future for regulating medtech at the federal level. Presently, policymakers seem focused on protecting medtech companies' ability to innovate in general, but that climate can change quickly with pressure from consumer groups and other interests. This is an overview of some of the more significant issues being discussed in Washington that could impact medtech growth and innovation.

Internet of Things (IoT) / privacy

The FTC released a report in January, titled "The Internet of Things: Privacy and Security in a Connected World." The report, which is the product of a 2013 workshop of the same name, focused on four areas: security, data minimization, notice and choice. While stopping short of making binding recommendations, the report tries to strike a balance between the potential benefits of medtech and the privacy risks associated with the type and amount of health data collected. The report referenced benefits and risks for connected healthcare devices such as heart monitors and insulin pumps to articulate the difficult balance.

In addition to the IoT report, the Obama Administration released its Consumer Privacy Bill of Rights last week aimed at creating "baseline protections for individual privacy." The bill includes broad definitions of "personal data" and "covered entity" that would include medtech information and companies. While the legislation faces a very uncertain future, and given the recent medical device and software guidance released by the FDA, is seen by some to be unnecessary, its certain the concepts of increased protections for consumer information are likely to emerge in other pieces of legislation or agency action. For example, FTC Commissioner Julie Brill signaled view of some in the agency when she called for comprehensive privacy legislation to address "the proliferation of mobile health apps and connected devices." Until then, Commissioner Brill suggested they will be "keenly attuned to law enforcement violations."

The release of the IoT report and Consumer Privacy Bill of Rights shows the increasing role of the FTC is emerging as a key regulator for medtech beyond its traditional role in antitrust. The FTC has continued to bring enforcement actions under existing legal authorities for privacy violations, as was pointed out in the report. In addition, the Consumer Privacy Bill of Rights would allow the FTC to bring civil monetary penalties for violations of that statue's obligations. Again, notwithstanding how the bill proceeds, we are beginning to understand how the FTC will impact medtech.

21st Century Cures

The 21st Century Cures Initiative (or "Cures") is the signature legislative initiate from the House of Representatives Energy and Commerce Committee to redesign and reform the discovery and delivery of healthcare and increase American competitiveness in health IT. Draft legislative language was introduced earlier this year which included several medtech-related proposals such as regulatory clarity for mobile medical devices, increasing access to Medicare for telemedicine, interoperability and expedited FDA review for certain medical devices. The Energy and Commerce Committee chose to release the legislation as a "discussion draft" with many placeholders to both generate comments from the public and support from interested parties. The leaders of the

Committee are aiming to craft a comprehensive bill and work with their Senate counterparts to produce bipartisan legislation that can be sent to the President by the end of the year. This may be a daunting task for at least these reasons: 1) the packed legislative agenda facing Congress in 2015; 2) the myriad proposals in the draft; 3) fractured support from different parts of the health care and life science industry; 4) limited bipartisan support from members on the Energy and Commerce Committee and 5) the absence of a comparable measure in the Senate. However, if the effort to pass Cures or similar legislation stalls, it is possible that Congress will take up more targeted medtech legislation and that the executive branch agencies could take regulatory action.

Telemedicine

Notwithstanding the fate of Cures, policymakers are keen on increasing access to high quality care outside of the traditional hospital or office-based setting. The beneficial effects of telemedicine's role in providing "connected care" is appreciated by many in Washington, as are the challenges for increasing the services provided. Presently, there is an 8-member bipartisan "task force" charged with crafting legislation (be it for Cures or not) to increase the reach of telemedicine by reducing barriers to the services paid by Medicare. However, until that work is complete, Medicare – and in some cases private insurance – reimbursement are limited which could continue to impede innovation in this space. Understanding the challenge and needs, CMS has taken steps recently to relax some of the restrictions on reimbursements, but specific technologies such as remote patient monitoring are still not considered "telehealth services" under Medicare. It is likely that Congress will continue to investigate how to increase reimbursements from Medicare and private insurers for a more robust range of telemedicine services even if they have to do it outside of the context of Cures.

Interoperability

As is the case with telemedicine, increasing interoperability is proceeding through Congress concurrently with Cures. Draft legislation to ensure interoperability of qualified electronic health records (EHRs) was introduced last week. The bill, which would use a congressionally appointed advisory committee to create a standard for interoperability that EHR systems would be required to meet by 2018 to obtain certification, met with mixed reviews from industry and others. The challenge for Congress is how to develop standards for measuring interoperation without creating federal technical mandates which could have a chilling effect on innovation in the EHR. The key issues to be worked out are the scope of data sharing, how the standards will be established and penalties for noncompliance with the standard. Without question, interoperability is one of the priority issues for Congress but there is much work to be done to ensure an effective framework.

Conclusion

Policymakers are beginning to understand the benefits of medtech for the future of health care. However, public policy issues, politics and competing payor and provider interests, are playing a role in how the medtech space will be regulated. This intense discussion will likely continue throughout 2015 and possibly into 2016. medtech companies in any stage of the corporate lifecycle should monitor the events in Washington to understand the possible business implications.

For more information or questions, please contact one of the attorneys listed above.

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Key Contacts

Vince Sampson Washington, DC	vsampson@cooley.com +1 202 728 7140