ML STRATEGIES

Next Steps for 21st Century Cures 2.0

May 07, 2020 | |

On Monday, April 27, Representatives Diana DeGette (D-CO) and Fred Upton (R-MI) announced the next steps for 21st Century Cures 2.0 ("Cures 2.0"), legislation that will build on the original **21st Century Cures Act**, which was enacted in December 2016 ("Cures 1.0"). While Cures 1.0 aimed to speed up the process of bringing new treatments to market, Cures 2.0 is generally envisioned to emphasize public health and streamlined care delivery, particularly in light of the COVID-19 pandemic. Elements envisioned to be in Cures 2.0 were outlined in a recently published **concept paper**, some of which are discussed below.

COVID-19

Unsurprisingly, the proposed legislation includes provisions to improve the national pandemic response capability for current and future pandemics as well as to mitigate some of the issues facing patients in the COVID-19 crisis. The pandemic response strategy envisioned includes a national testing and surveillance program and encourages the strategy to include discussion of vaccine development and administration. It also highlights continuous manufacturing as a potential solution to expanding domestic drug manufacturing.

The details are scant, requiring the Secretary of Health and Human Services to develop these and other strategies and plans with only general direction from Congress. However, the concept paper is far from enacted law, so there is still opportunity to develop more detailed recommendations and mandates.

Antimicrobial Resistance

An area that benefits from a more detailed roadmap is how to respond to antimicrobial resistance, thanks in large part to a March 2020 Government Accountability Office (GAO) **report**. Cures 1.0 required FDA to create a streamlined development program for certain antibacterial and antifungal drugs; FDA has since published a draft guidance for such program. Cures 2.0 seeks to build on that mandate by looking beyond the regulatory realm to financial considerations for antimicrobial drug developers. As noted in the GAO report, "experts and antibiotic developers told [GAO] that the economic challenges have remained despite the available federal…incentives for antibiotic R&D." Further, "The current significant federal investment…will ultimately be ineffective if companies receiving this investment are unable to sustain their business once their treatment reaches the market…Until additional postmarket incentives are developed, more drug companies may exit the antibiotic development sector, and the pipeline of new treatments for antibiotic-resistant infections may continue to decrease." Essentially, it's not profitable to develop antimicrobial drugs, which means fewer companies are pursuing development of those important drugs.

The Cures 2.0 concept paper suggests that at least some in Congress do not want to wait for the Department of Health and Human Services to act on the GAO's recommendation to "develop a strategy that includes the use of postmarket financial incentives to encourage the development of new treatments for antibiotic-resistant infections". Rather, the concept paper envisions legislation that gives the Secretary of Health and Human Services "the resources and regulatory authorities necessary to fix the commercial market for new antibiotics." This is just one example of how Congress is looking to expand on a Cures 1.0 initiative in Cures 2.0, though what those resources and authorities are remain to be determined.

Health Literacy

The COVID-19 crisis has illuminated the importance of strengthening health literacy and taking steps to improve the role of patients in health care, according to the Cures 2.0 concept paper, which outlines a plan to provide grants for programs that provide caregivers with education and skills that would allow them to complement professional health care providers and services. If enacted, the law would also require CMS to seek from the public additional ideas for improving health literacy.

Clinical Trials

To make clinical trials more diverse, the concept paper proposes improving reimbursement for clinical trial subjects as well as requiring FDA to report on its work to improve demographic subgroup representation in trials. These provisions would build on FDA's existing patient engagement programs—some of which were bolstered by Cures 1.0 requirements to better incorporate patient experience data into the regulatory decision-making process—to improve the role of patients in health care delivery.

Regulatory & Reimbursement Modernization

Modernizing government is typically a political win for all sides and the bipartisan Cures 2.0 effort may be no exception: the concept paper outlines plans to modernize both FDA and CMS to get medical products to patients more quickly.

A common refrain since before Cures 1.0 was enacted was the FDA's disjointed approach to digital health regulation and oversight. Indeed, the Cures 2.0 concept paper states: "Currently, there are multiple efforts at FDA to advance the vision of Cures on digital technologies." The Cures 2.0 concept paper is not lacking for detail in this area. The paper envisions better coordination between FDA's drug, biologic, and device centers on digital health regulation and outlines specific topics that Congress could direct FDA to address in guidance, including the use of digital endpoints for regulatory review, the acceptance of decentralized trials, the use of digital health technologies in patient-focused development of medical products, and coordination with foreign regulators.

FDA is not designed to encourage the collaboration envisioned in the Cures 2.0 concept paper. Medical product centers each have cultures that in some ways are barriers to collaboration, including different perspectives on benefit and risk. From the standpoint of infrastructure, FDA's information systems do not support easy sharing of information between centers and the physical location of employees does not encourage collaboration. Congress has tried to address some of these shortcomings in various ways in the past, including by creating the Office of Combination Products in 2002 and refinements to combination products policies in more recent legislation, including Cures 1.0. Congress, also in Cures 1.0, mandated the creation of "one or more Intercenter Institutes" to "develop and implement processes for coordination of activities" relating to a major disease area or areas among the drug, biologic, and device centers. There is currently a single intercenter institute: the Oncology Center of Excellence. FDA has indicated a desire to set up others, including a Digital Health Center of Excellence; however, in the agency's FY2021 budget request, FDA describes their vision for that Center as focusing "specifically on advancing and promoting the development of consumer-friendly AI/digital health medical devices through improved device-user interfaces"—nothing about drugs or biologics.

Another modernization proposal pertains to policies and processes to improve communication between FDA and CMS with respect to breakthrough therapies. As noted in the Cures 2.0 concept paper, "we need to foster better communication and collaboration between the agency in charge of reviewing new product applications (FDA) and the agency in charge of making coverage determinations (CMS)" because doing so "would afford CMS the opportunity to access additional expertise and insight when considering the functional aspects of a new product".

This longstanding criticism of CMS is that it is slow to make coverage decisions for products that have met FDA's approval standard. Generally, CMS' challenges are not owing to lack of capability to understand the technical considerations required to make coverage decisions; rather, CMS lacks capacity. This program needs sufficient resources—i.e., staff—to succeed.

The Cures 2.0 concept paper does not include solutions for every coverage-related problem. The paper asks questions of stakeholders to help inform what other legislative improvements may be included in the bill, including:

- Are the current coverage and reimbursement approaches to new medical products or other modern technologies adequate to keep up with the pace of innovation? If not, why?
- What are the biggest impediments to new cures development for small patient populations?
- What, if any, barriers exist that impede coverage for cell and gene therapies and other novel products?

We encourage stakeholders to consider these and other challenges for which a solution may be appropriate for inclusion in the Cures 2.0 legislation. Like Cures 1.0, Cures 2.0 could become a catchall for many health-related policies, including those moved to the back burner during the COVID-19 pandemic (e.g., surprise billing) or otherwise secondary to addressing the public health emergency (e.g., medical device servicing). We will continue to monitor and analyze Congressional action related to Cures 2.0 and other health legislation in 2020.

Hannah Merrill and Margaret Jewett assisted in research for this post.

Authors