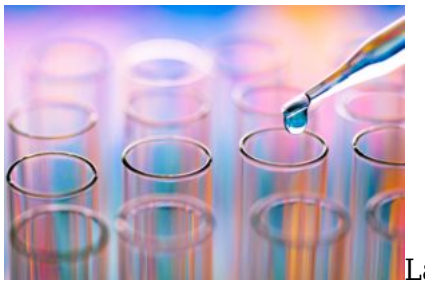
# Things for Pharma and Biotech Companies to Watch in the Cures 2.0 Proposed Legislation

 Last week, Diana DeGette (D-CO) and Fred Upton (R-MI) introduced in the House highly anticipated bill language for "Cures 2.0", a follow-up to the transformational 21st Century Cures Act enacted in 2016. For full text of the bill, click **here**. The 21st Century Cures Act included a variety of measures seeking to accelerate medical product development and bring advancements and innovations to patients more efficiently. Cures 2.0 seeks to improve and expand on those strides, as well as address pressing public health priorities that became apparent through the COVID-19 pandemic.

The Cures 2.0 bill is structured around five main topics:

- Title I—Public Health
- Title II—Patients and Caregivers
- Title III—Food and Drug Administration
- Title IV—Centers for Medicare & Medicaid Services
- Title V—Research

While all of these sections are ripe for further analysis, we selected a few provisions to highlight here that may be of particular interest for the pharmaceutical and biotechnology companies out there. We'll keep tracking these as the bill moves through the legislative process:

**Section 204**: Patient Experience Data

- Would require sponsors developing a drug under an IND to collect standardized patient experience data during clinical trials and include that patient experience data "and such related data" in an NDA or BLA; and
- Would direct FDA to consider this patient experience data and "related information" in its approval decision for the NDA or BLA.
- These proposals to standardize and require patient experience data collection could be significant, and they underscore lawmakers' continued interest in elevating the relevance of clinical outcomes that are meaningful to patients living with a disease or condition.

**Section 302:** Grants for Novel Trial Designs and Other Innovations in Drug Development & **Section 310:** Recommendations to Decentralize Clinical Trials

- Section 302 would appropriate $25 million annually, for 3 years, for the FDA to award grants to clinical trials conducted under an IND with protocols incorporating complex adaptive or other novel trial designs and that collect patient experience data. The section further specifies that grant awards should prioritize the incorporation of digital health technologies and real world evidence.
- Section 310 proposes a multi-stakeholder meeting, including industry representatives and patient advocacy groups, to discuss incentives to adopt decentralized clinical trials. The

section also would adopt a definition of decentralized trials: “a clinical trial method that includes the use of telemedicine or digital technologies to allow for the remote collection of clinical trial data from subjects, including in the home or office setting.”
- These provisions reflect a sustained emphasis on fostering clinical trial innovation, including building on the experience with remote clinical trials during the COVID-19 pandemic.

**Section 304:** Increasing Use of Real World Evidence (RWE) & **Section 309:** Post-Approval Study Requirements for Accelerated Approval

- Section 304 would call for new guidance on the use of RWE in post-market review of drugs that were designated as a breakthrough therapy or fast track product, or considered for accelerated approval. Section 309 would further specify that the post-approval study requirements to verify and describe the clinical benefit for products granted accelerated approval could be satisfied through RWE, including analyses of data in clinical care repositories or patient registries.
- Section 304 also would establish a permanent Real World Evidence Task Force to coordinate programs and activities within the Department of Health and Human Services related to the collection and use of RWE.
- These and other sections of Cures 2.0 share a common theme of enhancing the use of RWE in regulatory decision-making. Although the inherent variability in RWE likely will continue to present challenges to doing so, the signal is clear that legislators would like to see FDA and HHS continue to move forward in this area.

Last week’s introduction of Cures 2.0 and President Biden’s announcement that he will nominate Robert Califf for FDA Commissioner contributed to a newsworthy week for those of us who follow the FDA.  We look forward to seeing how Cures 2.0 develops and how the Agency’s policy priorities unfold in the coming months.