

# Health Industry Alert

**Akin Gump**  
STRAUSS HAUER & FELD LLP

## Five Health Care Areas Worth Watching in 2022

February 2, 2022

With the second session of the 117th Congress underway, stakeholders are poised for another busy legislative session set against the dynamic backdrop of an ongoing global pandemic and midterm election year. Numerous high-profile health care measures have carried over from the first session of the Congress, such as consideration of the Build Back Better Act, expiring provider-related provisions and the annual appropriations process. There are also several other legislative issues on policymakers' health care agenda that will be of interest to a broad range of stakeholders, including patients, providers, innovators, medical product manufacturers and many more. Below we highlight five such health care policy areas worth watching as this year's legislative session unfolds.

### 1. FDA User Fee Program Reauthorizations

This year marks the 30th anniversary of the Prescription Drug User Fee Act (PDUFA). The law, which is reauthorized every five years, authorizes the Food and Drug Administration (FDA) to collect user fees from companies that produce certain human drugs. In addition to PDUFA, the "UFA" reauthorizations have also included user fee programs for medical devices (MDUFA), generic drugs (GDUFA) and biosimilars (BsUFA). The current authorizations for the FDA user fee programs for human prescription drugs, medical devices, generic drugs and biosimilars are set to expire at the end of this fiscal year (September 30, 2022). These user fees are integral to supporting the agency's timely and efficient review of medical products for patients as part of its public health mission.

Reauthorization of these user fee programs will drive this year's health care agenda because, as the largest health care-specific "must-pass" legislative vehicle, legislators may try to attach other priorities to it. As with previous reauthorization cycles, there is no shortage of potential FDA-related topics that may come up as the legislative process advances. Lawmakers may consider including provisions from the 21st Century Cures 2.0 package released last year by Reps. Diana DeGette (D-CO) and Fred Upton (R-MI), bicameral, bipartisan diagnostics reform introduced by Sens. Richard Burr (R-NC) and Michael Bennet (D-CO), or other "hot topics" such as clinical trial modernization or real world evidence.

### Contact Information

**If you have any questions concerning this alert, please contact:**

**Ileana Ros-Lehtinen**

Senior Advisor  
[iros-lehtinen@akingump.com](mailto:iros-lehtinen@akingump.com)  
Washington, D.C.  
+1.202.887.4135

**M. Todd Tuten**

Senior Advisor  
[ttuten@akingump.com](mailto:ttuten@akingump.com)  
Washington, D.C.  
+1 202.887.4203

**Matthew Hittle**

Senior Policy Advisor  
[mhittle@akingump.com](mailto:mhittle@akingump.com)  
Washington, D.C.  
+1 202.416.4687

**Michael S. Barnard**

Senior Policy Advisor  
[mbarnard@akingump.com](mailto:mbarnard@akingump.com)  
Washington, D.C.  
+1 202.887.4036

**Julie E. Nolan**

Senior Policy Advisor  
[jnolan@akingump.com](mailto:jnolan@akingump.com)  
Washington, D.C.  
+1 202.887.4213

**Louis T. Agnello**

Counsel  
[lagnello@akingump.com](mailto:lagnello@akingump.com)  
Washington, D.C.  
+1 202.887.4212

This week, the House Energy and Commerce Committee will hold the first hearing focused on PDUFA, GDUFA and BsUFA reauthorization. While Congress is expected to pass reauthorization legislation before the September deadline, the exact timing is unclear given the need to balance Members' priorities and avoid disruptions to user-fee funded activities at FDA that could adversely impact patients.

## 2. Pandemic Preparedness

Pandemic preparedness and response continues to drive much of the health care agenda in Washington. On the legislative front, the Senate Health, Education, Labor and Pensions (HELP) Committee will attempt to advance bipartisan preparedness legislation this Congress. On January 25, 2022, HELP Committee Chair Patty Murray (D-WA) and Ranking Member Richard Burr (R-NC) released a discussion draft of the Prepare for and Respond to Existing Viruses, Emerging New Threats and Pandemics Act (PREVENT Pandemics Act). The much-awaited bipartisan package is focused on strengthening the nation's public health and pandemic preparedness infrastructure and addresses a wide range of issues, including medical countermeasure development; biosurveillance capabilities; public health data systems modernization; access to behavioral health services during public health emergencies; advanced manufacturing technologies; and FDA policies to support the development and review of medical products. The Committee is accepting comments on the discussion draft until February 4, 2022. These provisions could move as part of the HELP Committee's legislative package to reauthorize FDA user fee programs.

There is also a high degree of interest in the renewal of the COVID-19 public health emergency (PHE) declaration. Health and Human Services (HHS) Secretary Xavier Becerra recently renewed the COVID-19 PHE for another 90-day period. The move extends many associated blanket waivers and flexibilities through April 16, 2022. HHS officials have pledged to give providers at least 60 days' notice before a final expiration of the PHE and stakeholders will continue to closely watch developments on this front.

Finally, there are shifting political considerations as both parties continue to debate what constitutes "the end" of the pandemic. While renewal of the PHE is one waypoint, declaring the end of the pandemic will have consequences on acquisitions practices for the Strategic National Stockpile (SNS) as well as realignment of authorities among the HHS Assistant Secretary for Preparedness and Response, Federal Emergency Management Agency and Centers for Disease Control and Prevention.

## 3. Medical Supply Chain

Supply chain resiliency continues to be an area of legislative focus. House Democratic leaders recently unveiled the America Creating Opportunities for Manufacturing, Pre-Eminence in Technology and Economic Strength Act (America COMPETES Act), legislation to strengthen the United States' competitiveness in key areas. The bill, which serves as a counterpart to the Senate-passed U.S. Innovation and Competition Act, includes \$45 billion for grants and loans to improve U.S. supply chains and mitigate shortages of critical goods. There is also overlap with the Senate HELP Committee's pandemic preparedness package; both bills include provisions related to advanced pharmaceutical manufacturing, SNS improvements and grants to fund state stockpiles of medical products. It is clear Congress has bipartisan interest in supply chain issues, but it remains unclear what of these interests will become law.

**Mario Luis Ramirez, MD**  
Consultant  
[mramirez@akingump.com](mailto:mramirez@akingump.com)  
Washington, D.C.  
+1 202.877.4000

**Sean Feely**  
Policy Advisor  
[sfeely@akingump.com](mailto:sfeely@akingump.com)  
Washington, D.C.  
+1 202.416.5537

## 4. Telehealth and Broadband Infrastructure

There has been much attention on telehealth throughout the pandemic with the flexibilities facilitated by the COVID-19 PHE, including significant funding for investments in broadband expansion. The perspectives gained on the role of telehealth in health care during the pandemic could provide an impetus for Congress to consider legislation to continue the Medicare telehealth and other flexibilities that were implemented under the PHE. Late last year, bipartisan leaders of the House Ways & Means Committee introduced legislation that would permanently eliminate various geographic and originating site restrictions on telehealth coverage; extend the COVID-19 emergency telehealth waivers for two years; and grant broad authority for the HHS to authorize telehealth flexibilities during future emergencies. Similar telehealth language was also included in the Cures 2.0 legislation.

Meanwhile, telehealth and broadband expansion also continue to be areas of focus for the Biden-Harris administration, paired with efforts to address health equity concerns. The White House Office of Science and Technology Policy (OSTP) released a Request for Information (RFI) to gather feedback on how stakeholders used digital health tools, including telehealth, during the pandemic suggesting that there is interest in applying the lessons learned with respect to telehealth and digital health technologies in health care more broadly. RFI responses are due by February 28, 2022.

## 5. GOP Healthy Future Task Force Agenda

This year's health care legislative agenda is set against the backdrop of an election year. Traditionally, the President's party loses seats in Congress in the President's first midterm election. Congressional Democrats have seen more than 20 retirements and Republicans are preparing to retake the House. In preparation for setting House Republicans' agenda in the 118th Congress. Republican Leader Kevin McCarthy (R-CA) established the House Republican Healthy Futures Task Force. The goal of the Task Force is to develop the GOP's agenda in various areas, including health care.

The Task Force's Security Subcommittee, Affordability Subcommittee, Treatment Subcommittee and Modernization Subcommittee have released RFIs to solicit input from stakeholders. There is also a Doctor/Patient Relationship Subcommittee, but that subcommittee does not currently have plans to release an RFI. Stakeholder responses to the RFIs and listening sessions in the coming months will be used to develop a report later this year on Republicans' policy agenda for 2023.

Health care policy will continue to drive the legislative agenda. The stage is set for a busy and potentially defining year in health care given the significant issues before Congress and broad stakeholder interest in them.

[akingump.com](http://akingump.com)