



Health Policy Briefing

October 31, 2022

FDA Considers Rulemaking to Overhaul Diagnostics Regulations

Food and Drug Administration (FDA) officials have suggested in recent weeks that the agency may use its rulemaking authority to overhaul the regulation of diagnostics and laboratory-developed tests (LDTs) if Congress fails to do so before the end of the year. Lawmakers are considering the inclusion of the *Verifying Accurate Leading-edge IVCT Development (VALID) Act* (S. 2209/H.R. 4128) in an end of the year package after it was dropped from the medical product user fee reauthorization included in the Continuing Resolution (CR) passed last month. Commissioner of Food and Drugs Robert Califf and Center for Devices and Radiological Health Director Jeff Shuren have expressed support for the approach taken in the *VALID Act* and stated last week that federal rulemaking “is always an option” if the legislation is not successfully passed by Congress before adjournment.

HELP Committee GOP Release Report on COVID-19 Origin

Republicans on the Senate Health, Education, Labor, and Pensions (HELP) Committee released an interim [report](#) last week considering the theory that the COVID-19 pandemic originated from a laboratory leak. The report summarizes publicly available, open-source information related to the potential origin of SARS-CoV-2. HELP Committee Ranking Member Richard Burr (R-N.C.) has said that he hopes the report will guide international institutions and researchers, congressional Democrats, and the Biden administration in further investigating the origin of the virus, while acknowledging that there is a lack of indisputable evidence to support findings that COVID-19 started in a lab. Committee Chair Patty Murray (D-Wash.) has underscored her commitment to investigating the origins of COVID-19, stating that this effort is included as a part of the bipartisan pandemic preparedness package (S. 3799) advanced by the panel in March.

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Wegrzyn Makes First Official Remarks at ARPA-H Launch Event

The Biden administration held a launch event for the new Advanced Research Projects Agency for Health (ARPA-H) last week. During the event, Director Renee Wegrzyn stressed the importance of making ARPA-H's discoveries widely accessible and affordable starting from their early phases of development. Wegrzyn aims to build equity into the new agency's processes and make ARPA-H's discoveries scalable and applicable to multiple diseases and conditions. She said that her top priority will be hiring program managers who have a clear vision for a specific problem that needs to be addressed.

Boyle Considers Run for Budget Leadership Post

Rep. Brendan Boyle (D-Pa.) is expected to run for the position of lead Democrat atop the House Budget Committee next Congress following the retirement of current Chair John Yarmuth (D-Ky.). Boyle is the first lawmaker to join the race for Democratic seniority on the panel. The position will be key in negotiations to increase or suspend the debt limit in 2023; the deadline to do so is likely to fall in the third quarter of the calendar year. Current Republican Ranking Member Jason Smith (R-Mo.) is seeking the top Republican spot on the House Ways and Means Committee. If he wins that position, Reps. Jodey Arrington (Texas), Buddy Carter (Ga.), and Lloyd Smucker (Pa.) have expressed an interest in replacing him atop the Budget Committee.

WH Continues Push for COVID Boosters Ahead of Possible Winter Surge

The Biden administration is pushing to expand COVID-19 booster uptake ahead of an expected winter wave of COVID-19 cases that could result in increased hospitalizations and deaths. Only 20 million Americans have received the updated bivalent booster vaccine. The White House is engaging the private sector – working with CVS, Rite Aid, and Walgreens – given its tight budget for COVID-19 vaccines and treatments and Republican opposition to passing additional pandemic response funding. During an event last week at which the President received his own booster shot, Biden asked employers to host on-site clinics for flu and COVID-19 vaccines, urged employees to get vaccinated, and offered paid time off for those who experience side effects of the shot. President Biden also touted a program being launched by Walgreens to allow socially vulnerable Americans to have Paxlovid prescriptions delivered for free by Uber and DoorDash drivers.

CDC Considers Use of Polio Vaccine to Address NYC Outbreak

The Centers for Disease Control and Prevention (CDC) is considering the use of the oral polio vaccine for the first time in more than two decades in response to the outbreak in greater New York City. The agency is currently collaborating with the New York State Department of Health to address the outbreak. The state has detected poliovirus in 70 sewage samples dating back to April and as recently as September across Rockland, Sullivan, Orange, Nassau, Kings, and Queens counties.

Recently Introduced Health Legislation

H.R.9205 — To allow certain public health funds appropriated by the American Rescue Plan Act of 2021 to be used to address the monkeypox public health emergency; Sponsor: Casten, Sean [Rep.-D-IL-6]; Committees: House - Energy and Commerce; Oversight and Reform; Ways and Means

H.R.9209 — To improve access to the Program of All-Inclusive Care for the Elderly, and for other purposes; Sponsor: Dingell, Debbie [Rep.-D-MI-12]; Committees: House - Energy and Commerce; Ways and Means

H.R.9220 — To amend the Public Health Service Act to provide for a national public awareness campaign to inform health care professionals and health care professional students on how to help patients navigate the legal landscape in the United States with respect to abortion and other reproductive health care services following the Supreme Court's decision to overturn Roe v. Wade, and for other purposes; Sponsor: Trahan, Lori [Rep.-D-MA-3]; Committees: House - Energy and Commerce

H.R.9222 — To amend title XXVII of the Public Health Service Act to increase health insurance access for individuals placing their newborns up for adoption; Sponsor: Van Duyne, Beth [Rep.-R-TX-24]; Committees: House - Energy and Commerce

H.R.9227 — To direct the Secretary of Health and Human Services to establish and maintain a local gun violence prevention laws database, and for other purposes; Sponsor: DeSaulnier, Mark [Rep.-D-CA-11]; Committees: House - Energy and Commerce

H.R.9228 — To amend the Public Health Service Act with respect to the information security policies and practices of the National Institutes of Health, and for other purposes; Sponsor: Griffith, H. Morgan [Rep.-R-VA-9]; Committees: House - Energy and Commerce

H.R.9229 — To amend the Public Health Service Act to codify certain recommendations made by the Government Accountability Office with respect to the Department of Health and Human Services and cybersecurity, and for other purposes; Sponsor: Guthrie, Brett [Rep.-R-KY-2]; Committees: House - Energy and Commerce