



Biden Administration Requests Additional Funds for COVID-19, Monkeypox, Ukraine, and Natural Disasters

The White House has sent a [50-page compilation of requests](#) for additional spending and legislative changes for Congress to include in a continuing resolution (CR) that must be passed before the end of the fiscal year on September 30. The request includes \$22.4 billion for COVID-19 resources, \$13.7 billion in aid to Ukraine and related energy issues, \$6.5 billion for disaster aid, and \$4.5 billion for the monkeypox response. The \$4.5 billion monkeypox request includes \$3.9 billion in domestic resources (which includes \$1.6 billion for vaccine and therapy procurement) and about \$600 million in international aid. The White House also asks Congress to require laboratories that perform or analyze monkeypox tests to report the results to the U.S. Department of Health and Human Services.

FDA Warns of Pink Slips in Absence of UFA Deal

The Food and Drug Administration (FDA) will begin notifying employees who are paid by user fees of impending layoffs by the first week of September, unless agency leadership is assured that lawmakers in Congress are close to an agreement to reauthorize the FDA’s medical product user fee programs. The current authority to collect user fees expire September 30. Employees whose salaries are covered by the Prescription Drug User Fee Act program – more than 60% of the Center for Drug Evaluation and Research’s budget – would be the first to receive layoff warnings.

FDA Launches Opioid Review

Commissioner of Food and Drugs Robert Califf announced that the Food and Drug Administration has initiated its review of past opioid regulations, including labeling decisions, intending to prevent overdose-related deaths across the nation. Califf first committed to such a review during his Senate confirmation hearing in 2021. The agency’s new [framework](#) for overdose prevention includes four priorities: supporting primary prevention by eliminating unnecessary initial prescription drug exposure and inappropriate prolonged prescribing; encouraging harm reduction through innovation and education; advancing the development of evidence-based treatments for substance use disorders; and protecting the public from unapproved, diverted, or counterfeit drugs presenting overdose risks. Califf has stated that the review will likely take a “matter of months” to complete.

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Inhofe, Burr Push Operation Warp Speed 2.0

Sens. Jim Inhofe (R-Okla.), ranking member of the Senate Armed Services Committee and Richard Burr (R-N.C.), ranking member of the Senate Health, Education, Labor, and Pensions (HELP) Committee have sent a [letter](#) to the White House urging President Joe Biden to launch an Operation Warp Speed 2.0. The lawmakers ask the administration to ramp up coordination with the private sector and military in response to the emergence of new COVID-19 variants. The letter characterizes Operation Warp Speed as “the most successful public health program since smallpox” and highlights the continued need to develop better vaccines, nasal products, and pan-coronavirus approaches. They ask the President to provide Congress with an outline of the successes and lessons learned from Operation Warp Speed, a plan to recreate it, a description of the defense and health department’s proposed support, and a cost-saving program for private-public partnerships by the end of the year.

OMB Clears FDA Human Research Protection Rule

The Food and Drug Administration’s proposed rule to align its human subject protection regulations with those of the U.S. Department of Health and Human Services – known as the Common Rule – has cleared the Office of Management and Budget review. The *21st Century Cures Act* (Public Law No. 114-255) required the two research volunteer protection rules to be harmonized by December 13, 2019. The FDA’s proposed regulation can now be published at any time.

AK Democrat Peltola to Serve Remainder of Late Rep. Young’s Term

Democrat Mary Peltola defeated Republicans Sarah Palin and Nick Begich in the second round of Alaska’s ranked-choice special election to serve the remainder of the late Republican Rep. Don Young’s term. Peltola is the first Alaska Native elected to Congress. Her victory flips the state’s single House seat and increases the Democrats’ narrow majority in the House of Representatives. Peltola, Palin, and Begich have all stated that they will seek a full two-year term in November. In other election-related news, Rep. Charlie Crist (D-Fla.) resigned his seat in Congress last week. Crist is currently campaigning to unseat Florida governor Ron DeSantis (R).

Recently Introduced Health Legislation

H.Res.1327 — Expressing the sense of the House of Representatives that fentanyl-related substances is a weapon of mass destruction and should be classified as such; Sponsor: Dunn, Neal P. [Rep.-R-FL-2]; Committees: House - Energy and Commerce

H.R.8745 — To direct the Secretary of Health and Human Services to maintain a National Concussion and Traumatic Brain Injury Clearinghouse; Sponsor: Connolly, Gerald E. [Rep.-D-VA-11]; Committees: House - Energy and Commerce

H.R.8746 — To amend title XVIII of the Social Security Act to restore physician judgment to prescribe the appropriate mix of skilled modalities that constitute an intensive rehabilitation therapy program in an inpatient rehabilitation hospital or unit; Sponsor: Courtney, Joe [Rep.-D-CT-2]; Committees: House - Ways and Means

H.R.8747 — To amend title XVIII of the Social Security Act to extend Medicare-dependent hospital and Medicare low-volume hospital payments; Sponsor: Miller, Carol D. [Rep.-R-WV-3]; Committees: House - Ways and Means

H.R.8750 — To require the Secretary of Veterans Affairs to carry out a pilot program to provide assisted living services to eligible veterans, and for other purposes; Sponsor: Slotkin, Elissa [Rep.-D-MI-8]; Committees: House - Veterans’ Affairs

H.R.8751 — To direct the Director of the Centers of Disease Control and Prevention to submit a report to Congress on the feasibility of reporting data relating to injuries in high school sports to improve the safety of student athletes; Sponsor: Veasey, Marc A. [Rep.-D-TX-33]; Committees: House - Energy and Commerce; Education and Labor