



Health Policy Briefing

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Cassidy Releases FDA Modernization Recommendations

Senate Health, Education, Labor, and Pensions (HELP) Committee Chair Bill Cassidy, MD has released a new [report](#) that makes legislative and regulatory recommendations for modernizing the Food and Drug Administration (FDA). The 20-page report, titled “Patients and Families First: Building the FDA of the Future,” recommends:

- Congress and FDA should apply the “least burdensome” approach beyond medical devices to other product categories.
- To reshore early-stage clinical research, FDA should launch a voluntary program in which FDA pilots a notification pathway for eligible Phase 1 clinical trials.
- As clinical trials continue to evolve from three-phase, site-based studies towards more decentralized and innovative designs, FDA should continue supporting the use of digital health technologies, while ensuring that validation requirements for these tools are tailored to their relative risks.
- To ensure that AI standards and frameworks do not conflict, and that FDA grows its talent pipeline, FDA should further its partnerships across U.S. Department of Health and Human Services agencies while expanding external fellowships.
- FDA should consider how to improve predictability in the drug review process, which should include more judicious use of clinical holds and greater transparency in its dialogue with sponsors.
- Congress should codify recent agency actions to tailor chemistry, manufacturing, and controls (CMC) requirements for therapies intended for small populations.
- To accelerate rare disease drug development, FDA should more consistently use tools like accelerated approval and better coordinate reviews across its divisions and offices.
- Congress should create a new streamlined intermediate pathway for biologics through which more innovative and affordable products can get to patients.
- Congress should simplify the current requirements for new biologics, including simplifying the outdated interchangeability designation and streamlining the studies needed to obtain biosimilar approval.
- Congress should pass bills advanced by the HELP Committee to address abuses in the health care system that permit FDA to reject frivolous citizen petitions aimed at delaying generic entry and

Inside

NIH Director Bhattacharya to Lead CDC in Acting Capacity.....	2
Senate Republicans Urge Recovery of Fraudulent ACA Subsidy Payments.....	2
New GAO Reports on Impact of No Surprises Act, Gain-of-Function Research.....	2
ACIP Delays February Meeting.....	2
Upcoming Congressional Hearings and Markups.....	3
Recently Introduced Health Legislation.....	3

- tackling exclusivity “parking” to incentivize timely market entry of competitive generic products.
- Congress could require FDA to provide clearer guidance on the clinical data and evidence needed to support premarket submissions, especially for novel, complex health technologies.
- Congress should consider ways to change or supplement the existing medical device review pathways to properly evaluate software, so these new products have an efficient and appropriate pathway to market.
- Congress should ensure that FDA implements guidance on clinical decision support (CDS) in the spirit of what it directed in the 21st Century Cures Act.

NIH Director Bhattacharya to Lead CDC in Acting Capacity

Director of the National Institutes of Health (NIH) Jay Bhattacharya, MD has been tapped to serve as Centers for Disease Control and Prevention (CDC) acting director. Bhattacharya replaces previous CDC acting director and U.S. Department of Health and Human Services deputy director Jim O’Neill, who was recently removed from those positions as a part of a broader restructuring across the Department. The administration reportedly plans to nominate O’Neill to lead the National Science Foundation. Bhattacharya will continue in his role leading the NIH while at the helm of the CDC.

Senate Republicans Urge Recovery of Fraudulent ACA Subsidy Payments

A group of Senate Republicans are [requesting](#) that the Department of Justice (DOJ) investigate and pursue civil remedies to recover Affordable Care Act (ACA) marketplace subsidies paid to insurance companies due to fraudulent, unauthorized, or improper enrollment in insurance plans. The letter, signed by 17 lawmakers, highlights that the Government Accountability Office could not identify evidence of reconciliation for over \$21 billion in ACA marketplace subsidies in tax year 2023. The lawmakers praise the recent reconstitution of the False Claims Act Working Group, while underscoring DOJ’s “responsibility to ensure taxpayer funds are not misused and to enforce federal civil fraud remedies, when necessary.”

New GAO Reports on Impact of No Surprises Act, Gain-of Function Research

The Government Accountability Office (GAO) has published a new report examining provider participation and payments for selected services before and after the enactment of the No Surprises Act (NSA). Among the specialties most likely to be affected by the law – emergency medicine, radiology, anesthesiology, and air ambulances – the GAO found that the percentage of in-network claims increased for three of the four specialties since the NSA was implemented. The report also details how payment changes for the selected services largely reflect continuations of trends that existed prior to the NSA taking effect. The full report can be found [here](#).

The GAO also released a [report](#) on high-risk, gain of function research. The agency found that the U.S. Department of Health and Human Services does not consistently disclose important details about its process for weighing the risks and benefits of this research or reveal how many projects involve these potentially dangerous pathogens, and recommends that the Department address this issue to ensure public trust in federally funded research. The report was requested by Republicans on the House Energy and Commerce Committee.

ACIP Delays February Meeting

The Advisory Committee on Immunization Practices (ACIP) will delay its next meeting amidst an ongoing lawsuit brought by public health and medical groups questioning the legality of recent changes to the nation’s vaccine policy and recommendation processes by the U.S. Department of Health and Human Services. ACIP had been scheduled to meet February 25-27. While an agenda for the meeting had not yet been published, the panel typically discusses the effectiveness of upcoming seasonal influenza vaccines during its February meeting. ACIP now plans to meet in March, with an exact date yet to be determined.

Upcoming Congressional Hearings and Markups

House Ways and Means Subcommittee on Health hearing “Advancing the Next Generation of America’s Health Care Workforce;” 10:00 a.m.; February 24

Senate Health, Education, Labor, and Pensions (HELP) Committee hearing on the nomination of Casey Means to be Medical Director in the Regular Corps of the Public Health Service and Surgeon General of the Public Health Service; 10:00 a.m.; February 25

Senate HELP Committee markup of legislation including S. 1782, Charlotte Woodward Organ Transplant Discrimination Prevention Act; S. 1552, Living Donor Protection Act of 2025; and S. 3315, Health Care Cybersecurity and Resiliency Act of 2025; 10:00 a.m.; February 26

Senate Special Committee on Aging hearing “From Regulator to Roadblock: How FDA Bureaucracy Stifles Innovation;” 9:30 a.m.; February 26

Recently Introduced Health Legislation

H.R.7590 – To promote minimum State requirements for the prevention and treatment of concussions caused by participation in school sports, and for other purposes; Sponsor: DeSaulnier, Mark [Rep.-D-CA-10]; Committees: House - Education and Workforce