



Legislative Updates as of 08/10/2026

Updates from Washington:

- **Congress:** The Senate was in session for its final week ahead of the monthlong August recess.
 - **FY2027 Appropriations:** The Senate **voted 90-6 to pass the continuing resolution (CR)** released last Sunday to fund the government until December and avert a shutdown. The CR includes a provision **limiting the Administration's federal grants overhaul**, and will be considered by the House when it returns from recess.
 - **Committee Hearings, Legislation and Other Activity:**
 - **Nomination Votes:** The Senate **confirmed Dr. Erica Schwartz** to be CDC Director by a vote of **51 to 44**. In line with the committee vote, she garnered the support of all Republicans and Sen. Tim Kaine (D-VA).
 - **340B Reform:** Leaders of the bipartisan Senate 340B working group unveiled legislation to overhaul the drug discount program. The bill, the [SUSTAIN 340B Act](#) includes measures to:
 - **Reaffirm program structure of upfront discounts and end rebate programs**
 - Establish the **definition of eligible patients** and covered services
 - **Codify provider use of contract pharmacies**, with some limitations
 - Establish **auditing and reporting requirements** for 340B compliance, and facilitate removal of covered entities for noncompliance and lack of remedial activity
 - Standardize financial assistance policy for patients **at or below 200% of the federal poverty line**
 - Establish a **340B data clearinghouse to prevent discount duplication** or diversion of funds, paid for by a **user fee program**
 - Authorize **\$15 M for oversight and enforcement** over five years and **\$36 M for bill implementation** over four years
 - **Pharmaceutical Supply:**
 - Sen. Adam Schiff (D-CA) and Sen. Rick Scott (R-FL) have introduced [a bill](#) that would require CMS to provide Congress with **recommendations on how the agency can reduce reliance on**



foreign manufacturers for active pharmaceutical supplies and key starting materials, via its coverage and reimbursement authorities.

- Sen. Scott and Sen. Kirsten Gillibrand (D-NY) have [written](#) to acting FDA Commissioner Kyle Diamantas regarding shortages of generic cancer medications, and their **concerns** with agency proposals to temporarily **permit importation of these drugs from overseas manufacturers that do not typically supply American markets.**
- **Biotechnology:** The Senate Finance's Committee's Health Care Subcommittee convened a hearing titled '[Building a Resilient Health Care Future with Biotechnology](#)', which featured testimony from Dr. Alan Palkowitz of the Indiana Biosciences Research Institute, Dr. Michelle Roza of the National Security Commission on Emerging Biotechnology (NSCEB), Dr. Vera Luther of Dartmouth Hitchcock Medical Center and Kevin Outterson of the Combating Antibiotic-Resistant Bacteria Biopharmaceutical Accelerator (CARB-X). The two overarching themes of the hearing were:
 - Antimicrobial resistance (**AMR**) is a **significant threat to the US**, and development of new antimicrobials hinges on **effective economic incentives and scientific workforce development**. This discussion referenced the bipartisan [PASTEUR Act](#) which would create a **subscription payment model to incentivize antibiotic R&D** that is otherwise uneconomical and fund programs on antibiotic stewardship and surveillance.
 - **Coordinated biotechnology infrastructure, expertise, and investment**, to effectively translate scientific discoveries, prevent early-stage companies from getting trapped in the Valley of Death, and to reduce the growing gap between the US and China in this sector. [The American Innovation and Jobs Act](#), which **expands R&D tax credits and codifies continued R&D expense deduction**, was discussed as a step in the right direction.
- **Other Health-Focused Bills:** The Senate unanimously passed bills to establish a [National Plan for Epilepsy](#) and to authorize or reauthorize research programs focused on [ALS](#), [Down Syndrome](#) and [tick-borne illness](#).



- **COVID-19:** The Senate Homeland Security Committee on Thursday voted 8-7 to hold Dr. Anthony Fauci in contempt of Congress, following his refusal to answer questions at the previous week's hearing. All Committee Republicans voted in favor, and all Democrats voted against. The measure will now be considered by the entire chamber.
- **AI Regulation:** Rep. Jay Obernolte (R-CA) and Rep. Lori Trahan (D-MA) have introduced the [FRONTIER Act](#) to strengthen oversight of advanced AI. This comes a few months after they released a discussion draft soliciting stakeholder feedback.
- **Administration & Agencies:**
 - **CMS:** Several months after the initial announcement, the agency has **published the [Regulatory Alignment for Predictable and Immediate Device \(RAPID\)](#)** coverage pathway in the Federal Register. Comments are due by **October 7**. The proposal would **accelerate Medicare coverage of medical devices** in development and/or under consideration by FDA as outlined below:
 - **Eligible:** Presumptive Class II breakthrough devices participating in TAP planning, Class III breakthrough devices that will be part of a PMA submission regardless of TAP status, and pre-submission devices that will be subject to IDE studies enrolling Medicare beneficiaries.
 - **Not Eligible:** Devices that fall under existing Medicare benefit categories, national coverage determinations, and/or can be separately billed to Medicare.
 - **FDA:** Moderna's mRNA-based flu vaccine has now been approved for adults 50 and over. The approval comes six months after the agency attempted to decline consideration of the application altogether.
 - **White House, Other HHS Agencies & Departments:**
 - **Affordable Care Act:** Democratic state attorneys general have filed a suit to stop implementation of the Administration's recent changes to ACA markets that were announced as part of anti-fraud efforts.
 - **Foreign Companies of Concern:** A federal judge has issued an injunction that temporarily **prevents enforcement of WuXi AppTec's designation as**



a Chinese military company, under Section 1260H of the National Defense Authorization Act (NDAA)

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