Published on The National Law Review https://natlawreview.com

McDermott+ Check-Up: May 9, 2025

Article By:	
Debra Curtis	
Julia Grabo	
Maddie News	
Kristen O'Brien	
Erica Stocker	

THIS WEEK'S DOSE

- Republicans Advance Reconciliation Debate. Work continued behind the scenes among Republicans to reach consensus on Medicaid policies, with a House Energy and Commerce Committee markup announced for May 13, 2025.
- Senate Committees Hold HHS Nomination Hearings, President Trump Withdraws Surgeon General Nomination. Committees considered the nominations of James O'Neill for US Department of Health and Human Services (HHS) deputy secretary and Gary Andres for HHS assistant secretary for legislation. President Trump withdrew Janette Nesheiwat's nomination for surgeon general and nominated Casey Means in her place.
- President Trump Signs Additional Healthcare EOs. The executive orders (EOs) seek to
 increase domestic drug manufacturing, as President Trump continues to hint at forthcoming
 pharmaceutical tariffs, and halt federal funding of certain infectious agents research. The
 president also previewed a forthcoming EO to tie Medicare drug pricing to lower prices
 abroad, often called the "most favored nation" policy.
- Administration Defends FDA in Mifepristone Case. The decision may reflect efforts to protect the executive branch from state intervention.

CONGRESS

Republicans Advance Reconciliation Debate. After key House reconciliation markups expected to occur this week were postponed, Republicans held internal meetings to hash out Medicaid, nutrition, and tax policies to be included in reconciliation. Moderate Republicans continued to urge the House Energy and Commerce Committee not to enact Medicaid policies that could cut coverage or reduce funding for the expansion population. Policies rumored for potential inclusion include work

requirements for able-bodied adults, repeal of Biden-era regulations, restrictions on state coverage of undocumented immigrants, and increased eligibility checks. Conservative Republicans led by House Budget Committee Vice Chair Smucker (R-PA) sent a <u>letter</u> to Speaker Johnson stating that if net savings targets aren't met, tax cuts must be reduced. Senate Majority Leader Thune (R-SD) and Senate Finance Committee Chair Crapo (R-ID) also joined the debate, stating that the House is not pursuing enough spending cuts, including in Medicaid.

The Energy and Commerce Committee announced its markup for May 13, 2025, at 2:00 pm EDT. It is important to remember that just because a markup is announced, it doesn't mean it has to happen. If it goes forward as planned, the markup will likely last all evening and into May 14, 2025. Language will need to be released by 2:00 am EDT on Monday. While nothing is officially off the table, Republicans do not appear to have support for policies that target states, such as provider taxes, state directed payments, or a cap on the expansion population. Once bill text and a Congressional Budget Office (CBO) analysis are released, we will see if the Energy and Commerce Committee has been able to meet its \$880 billion savings target. Democrats will focus on offering amendments to try to undermine the legislation.

As Democrats work to prevent significant Medicaid cuts from moving forward, the CBO, in response to a request from Senate Finance Committee and House Energy and Commerce Committee Ranking Members Wyden (D-OR) and Pallone (D-NJ), <u>released</u> savings estimates for five Medicaid policies that have been under consideration in reconciliation, along with estimates of Medicaid coverage losses attached to those policies. The policies scored include reducing the expansion population federal match, limiting state provider taxes, capping federal spending for all enrollees, capping federal spending for the expansion population, and repealing the Biden-era eligibility and enrollment final rule. CBO <u>previously scored</u> most of these policies, but the figures are now updated. Estimates of Medicaid coverage losses for each proposed policy range from 2.3 million to 8.6 million people.

Senate Committees Hold HHS Nomination Hearings, President Trump Withdraws Surgeon General Nomination. Both the Senate Finance Committee and the Health, Education, Labor, and Pensions (HELP) Committee held hearings for key HHS personnel. The Finance Committee considered the nominations of James O'Neill to be HHS deputy secretary and Gary Andres to be HHS assistant secretary for legislation. Republicans on the committee focused mostly on nominees' views on rural health and pharmacy benefit managers (PBMs) and their previous experiences at HHS and on Capitol Hill. Democrats questioned nominees on the measles outbreak, HHS staffing cuts, and recent statements made by Secretary Kennedy regarding autism. Sen. Cassidy (R-LA) similarly expressed concerns about HHS's restructuring and the agency's stance on vaccines.

The evening before the HELP Committee hearing to consider O'Neill for deputy secretary and Janette Nesheiwat, MD, for surgeon general, President Trump abruptly withdrew Nesheiwat's nomination and instead named Casey Means, MD, for surgeon general. Means is the sister of Calley Means, special government employee for HHS. Both Casey and Calley Means have worked closely with HHS Secretary Kennedy for years and were actively involved in his presidential campaign. The committee will consider Means' nomination at a later date. During the HELP Committee nomination hearing, Republicans focused on the importance of regulatory oversight and safety of drug approvals and expressed interest in preventing the misuse of artificial intelligence (AI). Chair Cassidy continued his focus on the measles outbreak from earlier in the week and asked questions about vaccine mandates for immigrants. Democrats focused on the impact HHS staffing and funding reductions will have on programs, including Medicaid and Head Start.

ADMINISTRATION

President Trump Signs Additional Healthcare EOs. The EO "Regulatory Relief to Promote Domestic Production of Critical Medicines" aims to make the United States more competitive in producing safe and effective medicines. It directs the US Food and Drug Administration (FDA) and the US Environmental Protection Agency, within 180 days, to accelerate domestic pharmaceutical manufacturing inspections and approvals of new and expanded manufacturing capacities. It also directs the FDA to advance improvements within 90 days to the inspection regime of foreign manufacturing facilities involved in the supply of US medicines, funded by increased fees on foreign manufacturing facilities. Read the fact sheet here. The day after the EO was issued, the FDA announced it would increase unannounced inspections at foreign food and drug manufacturing facilities.

The gain-of-function research EO "Improving the Safety and Security of Biological Research" directs federal agencies to halt funding of dangerous gain-of-function research, as defined in the EO, conducted in foreign countries. It directs HHS to include new enforcement terms in research contracts or grants, including a requirement that recipients do not operate or fund dangerous gain-of-function research in foreign countries, with revocation of funding and a ban on HHS funding for up to five years for violations. The Office of Science and Technology Policy will track domestic gain-of-function research under the EO. Read the fact sheet here.

The administration announced that another healthcare-related EO is expected as soon as next week that will pursue "most favored nation" pricing for prescription drugs in the Medicare program. This is a policy the president pursued in his first term and recently promoted to Congress for inclusion in reconciliation for Medicaid.

COURTS

Administration Defends FDA in Mifepristone Case. Idaho, Kansas, and Missouri brought the lawsuit in Texas and challenged the FDA's review and approval of mifepristone, an abortion medication. In 2024, the US Supreme Court ruled that the original plaintiffs in the case – doctors and medical associations – lacked standing to bring the case. The Biden administration previously defended the FDA in this new iteration of the case, a posture the Trump administration is continuing. In a filing to the Texas court, the Trump administration alleged that the plaintiff states lack standing and requested that the case be dismissed. In other words, the administration is avoiding the merits of the case and pursuing dismissal on procedural grounds. Some commenters suggest that this action is intended to more broadly protect federal authority, although during his presidential campaign, President Trump said that he wouldn't restrict access to abortion medications.

QUICK HITS

- HHS OCR Sends Letter on Race-Based Discrimination to Medical Schools. The HHS
 Office for Civil Rights (OCR) issued a <u>letter</u> stating that medical schools cannot use race based criteria or racial stereotypes in admissions, campus life, or hospital operations. OCR
 notes such actions violate Section 1557 of the Affordable Care Act, Title VI of the Civil Rights
 Act, and the Equal Protection Clause of the US Constitution. Read the press release <u>here</u>.
- ACL Announces \$1 Billion in OAA Funding. The Administration for Community Living (ACL) released \$1.1 billion in state funding through Older Americans Act (OAA) programs to complete fiscal year (FY) 2025 funding.

- NIH, CMS Announce Autism Research Partnership. The National Institutes of Health (NIH) and Centers for Medicare & Medicaid Services (CMS) <u>partnership</u> continues HHS's focus on researching the root causes of autism. CMS will provide data on Medicare and Medicaid enrollees with autism, in compliance with privacy laws, to the NIH to examine trends, health outcomes, access to care, and the economic burden of autism.
- FTC, DOJ Continue Anticompetitive Regulation Emphasis. The Federal Trade Commission (FTC) and US Department of Justice (DOJ) sent a <u>letter</u> to federal agencies instructing them to develop a list of regulations that reduce competition. The action follows an FTC <u>request for information</u> on anticompetitive regulations, with comments due May 27, 2025.
- FDA Will Adopt Al in Review Process by June 2025. FDA completed its first <u>Al-assisted</u>
 <u>scientific review pilot</u> and aims to accelerate review processes by having all centers integrate
 Al by the end of June 2025.
- Trump Administration Fires Acting FEMA Administrator After Congressional Hearing. Acting Federal Emergency Management Agency (FEMA) administrator Cameron Hamilton testified before the House Appropriations Committee that FEMA should not be eliminated, after which he was fired. The Trump Administration aims to eliminate or reduce FEMA and shift disaster response to states.

BIPARTISAN LEGISLATION SPOTLIGHT

Sens. Hawley (R-MO) and Welch (D-VT) reintroduced the <u>Fair Prescription Drug Prices for Americans Act</u>, which was also introduced in the 118th Congress. The legislation would prohibit pharmaceutical companies from setting drug prices above the international average, and violating companies would be subject to civil monetary penalties. Read the press release <u>here</u>. This topic is receiving increased attention from the Trump administration, as noted above.

NEXT WEEK'S DIAGNOSIS

HHS Secretary Kennedy will be on Capitol Hill on May 14, 2025, testifying in front of the House Appropriations Committee and the Senate HELP Committee on the FY 2026 skinny budget proposal released last week. It will be his first appearance in Congress as HHS secretary. Democrats will likely question Kennedy on his response to the measles outbreak and HHS restructuring and reductions in force. HELP Committee Chair Cassidy may echo some of those concerns, as he did in the HHS nomination hearings this week, and may continue his focus on vaccines. On May 13, 2025, the Senate Judiciary Committee will examine pharmacy benefit managers, and the House Energy and Commerce Committee plans to hold its reconciliation markup.

© 2025 McDermott Will & Emery

National Law Review, Volume XV, Number 129

Source URL:https://natlawreview.com/article/mcdermott-check-may-9-2025