CAPITOL STREET

February 22, 2026

Health Policy Peek: Week of Feb. 23-27

FDA Announcement "n of 1," Tariff Fallout, State of the Union, Senate Hearing on Rare Diseases

ICYMI

SCOTUS Strikes Down IEEPA Tariffs: The Supreme Court on Feb. 20 issued a 6-3 ruling blocking the use of IEEPA tariffs (here), leaving Pharma and MedTech in the same position with Sec. 232 tariffs still at the Administration's disposal.

OUR TAKE: We had expected this action, or a more limited strike as also being possible, despite the high court's 6-3 conservative majority (our take here). Trump will utilize Sec. 122 to keep a global 15% tariff in place (here), but they have a 150-day limit. He also indicated that several Sec. 301 and other investigations will be initiated over the next five months to address unfair trading practices. Additionally, the administration may be more aggressive in advancing Sec. 232 tariffs as a result of this decision.

CDC ACIP Feb 24-25 Meeting Postponed Until March: The CDC's next Advisory Committee on Immunization Practices (ACIP) meeting was postponed from Feb. 24-25 until March due to ongoing legal challenges (here). ACIP is conducting an ongoing review of the immunization schedule for children and adolescents, and overall vaccine safety.

OUR TAKE: As we noted last week (here), there's been a noticeable shift in tone from the administration on vaccines ahead of the mid-term elections in November. There appears to be less focus on anti-vaccination efforts (more towards "medical freedom"), exemplified by leadership changes at HHS.

FDA Will Standardize One Pivotal CT: FDA officials on Feb. 19 announced their intention to change the FDA's "default position" to require one pivotal study instead of the current guidance of two pivotal studies (here).

OUR TAKE: FDA leadership will roll out new standards for clinical trials that may not significantly shift the status quo, but instead create increasing uncertainty. We note that this clinical trial change was previewed by Makary in December 2025, and is a formal announcement of the flexibilities that the FDA already allows. The one-trial rollout is being paired with a new post-market initiative, which may in the end be more burdensome to developers. See our analysis here.

MON, FEB 23

FDA Plausible Mechanism Guidance: On Feb. 23, HHS and the FDA are set to formally announce the new approval pathway for individualized therapies (n of 1 or plausible mechanism) that was previously previewed by leadership for months and initially announced via *NEJM* editorial Nov 12 (our take from JPM here).

OUR TAKE: The n of 1 and one clinical trial FDA announcements we are seeing are part of a larger “flood the zone” tactic to attract media & industry attention as it provides a slew of CRLs, prior to the midterms (after which we could see HHS leadership changes). The pathway will offer manufacturing and review flexibility for individualized therapeutics that treat diseases for which the biologic cause is known. The FDA will likely prioritize rare diseases here, particularly those that are fatal or associated with severe disability in childhood.

TUES, FEB 24

State of the Union Address: President Trump’s annual State of the Union (SOTU) speech is set for primetime (9 p.m. ET) on Feb. 24. Over the next few weeks, the administration is also expected to unveil the president’s FY 2027 budget proposal (unofficially March 10 or March 17).

OUR TAKE: We expect the majority of the address will be spent on items outside of healthcare including foreign affairs (Iran, Russia/Ukraine), the economy, and tariffs. In terms of healthcare, which we expect to be more minimal, President Trump will likely discuss affordability, highlighting the administration’s efforts to lower healthcare costs, including MFN deals with drugmakers. Trump may discuss efforts to reduce waste, fraud, and abuse in federal programs, possibly mention supply chain or middleman reform (PBM), and other food/nutrition MAHA priorities vs. vaccine public health policy or *One Big Beautiful Bill Act,* as the latter policies have resulted in reductions in Presidential polling.

House Hearing on Healthcare Workforce (here): The House Ways & Means Health Subcommittee (Chair Buchanan, R-FL) will hold a 10 a.m. hearing on “Advancing the Next Generation of America’s Health Care Workforce.” Witnesses include providers and academia.

WED, FEB 25

Senate Hearing on Surgeon General Nomination (here): The Senate HELP Committee will hold a nomination hearing for Casey Means to be Medical Director in the Regular Corps of the Public Health Service and Surgeon General of the Public Health Service.

OUR TAKE: Casey Means is a functional medicine doctor in the MAHA orbit. We expect her to face pointed questions from Senate Dems on the MAHA movement and its impact on public health. She is an author and public figure who is focused on chronic diseases and nutrition as a form of disease prevention. She co-founded the health technology company Levels, which promotes bio-sensors for metabolic tracking.

THURS, FEB 26

Senate Hearing on FDA’s Role in Rare Diseases (here): The Senate Aging Committee (Chair Scott, R-FL), will hold a 9:30 a.m. hearing on “From Regulator to Roadblock: How FDA Bureaucracy Stifles Innovation.” Witnesses include Massachusetts General, Everylife Foundation's Annie Kennedy & Amicus CEO Bradley Campbell.

ON THE HORIZON

- FTC PBM 6B study final report **(TBD)**
- President’s Budget **(March 2026)**
- MedPAC meeting **(March 2-3, 2026)**

- CMS proposed FY27 Inpatient Hospital/LTCH, Psych, IRF, SNF, & Hospice rules **(April 2026)**
- Final MA & Part D Rule (comments due Jan. 26) **(April 2026)**
- CMS MA Final Rates '27 **(by April 6, 2026)**
- MedPAC meeting **(April 9-10, 2026)**
- CMS IRA drug negotiation (2028) town hall **(April 22-23, 2026)**
- CMS launch of BALANCE model in Medicaid **(May 2026)**
- Sec. 232 report on medical devices due to White House **(May 30, 2026)**
- Deadline for CMS to send an initial offer for 2028 selected drug **(June 1, 2026)**
- CMS proposed CY27 Outpatient Hospital/ASC, PFS, Home Health, & ESRD rules **(Early July 2026)**
- USMCA joint review **(July 1, 2026)**
- CMS final FY27 Inpatient Hospital/LTCH, Psych, IRF, SNF, & Hospice rules **(August 2026)**
- Start of FY 2027 **(Oct. 1, 2026)**
- CMS launch of GLOBE model in Medicare Part B **(Oct. 1, 2026)**
- CMS final CY27 Outpatient Hospital/ASC, PFS, Home Health, & ESRD rules **(Early-Nov, 2026)**
- Deadline for CMS to publish 2028 negotiated maximum fair prices **(November 30, 2026)**
- CMS CY2027 Clinical Lab Fee Schedule **(Late-December 2026)**
- CMS launch of BALANCE model in Medicare Part D **(January 2027)**
- CMS launch of GUARD model in Medicare Part D **(Jan. 1, 2027)**
- CMS MFP Effective for Selected Drugs **(Jan. 1, 2027)**
- FDA PDUFA and MDUFA reauthorization deadline **(Oct. 1, 2027)**

CMS Coverage Decisions

- CMS Draft NCD on Biomarker Tests for Colorectal Cancer Screening **(March 10, 2026)**
- CMS Final NCD on Biomarker Tests for Colorectal Cancer Screening **(June 8, 2026)**
- CMS Draft NCD on TAVR for Asymptomatic Patients (EW) **(June 15, 2026)**
- CMS Final NCD on TAVR for Asymptomatic Patients (EW) **(Sept. 13, 2026)**

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