



U.S. Election Implications for Health

Following the U.S. elections, President-elect Donald Trump is consolidating power with Republican control of both branches of the U.S. Congress. Trump is swiftly naming his cabinet nominees, while Congress is orienting new members and electing its leadership.

The nomination of Robert F. Kennedy (RFK) Jr. as Secretary for the Department of Health and Human Services (HHS) presents a radical shift in federal priorities. Kennedy, who has a history of pushing debunked claims about vaccines, has spearheaded the public health agenda Make America Healthy Again (MAHA). He has proposed overhauling the health system, including firing employees, eliminating certain U.S. Food & Drug Administration (FDA) centers and shifting National Institutes of Health (NIH) research focus from infectious diseases to chronic diseases. However, given HHS's size, its status as the largest federal agency by spending, and its strong constituencies in Congress and nationwide, the extent of change he can implement is uncertain.

What you should do now

With nominees being named and policies being considered, multinational health care companies and organizations should develop 2025 U.S. engagement and business plans with initial advocacy priorities, a refreshed stakeholder mapping session and a revised policy landscape analysis.

APCO is a bipartisan firm with deep experience helping global health care companies navigate complex political and regulatory issues at global, federal and state levels. We have relationships with the executive branch transition team, elected (new and current) officials and staff across all levels of government and are counselling clients on what comes next. APCO has the expertise and connections to garner meaningful insights and fast intel into changes in Washington, D.C., advising through the noise and chaos. Our global, One APCO approach, also means this counsel is always shared through a multinational perspective, connecting dots for global public affairs strategies and providing specific in-market analysis.

Our team is ready to facilitate insightful discussions with experts who can provide both current and historical perspectives on potential policy changes and business implications.

Key health priorities

Here are the top issues to consider as your teams plan for a Trump administration and Republican-controlled Senate and House of Representatives:

Health priorities expected to continue:

- An aggressive push for reshoring the medical supply chain and moving away from "countries of concern."
- Addressing drug shortages and lowering health care costs, impacting drug prices, hospital, and insurance fees.
- State regulations and advocacy to maintain existing health coverage and federal funding opportunities for key policy initiatives like combatting the opioid epidemic, lowering drug prices and addressing medical debt.

Health priorities set to change:

- A revised approach to engaging with global health institutions and partnerships (e.g., the World Health Organization [WHO], Pan American Health Organization [PAHO]).
- Reducing funds for NIH research and shifting funds away from vaccine and drug development, infectious disease and pandemic preparedness to alternative therapies and chronic health conditions.

Domestic issues with global consequences:

building un/common ground...





- Cuts to health programs like Medicaid and the Affordable Care Act (ACA), resulting in fewer insured Americans and restricted access to health care, including preventive, reproductive care and medicine.
- Deregulation and less oversight of mergers and acquisitions across the health industry.

Beyond health, all global businesses must consider several policy positions that will be center to Trump and Congress's initial actions in 2025:

- An "America-first" agenda prioritizing reshoring industries to the U.S. over friend-shoring.
- Threats of tariffs (60% on China and 10-20% across the board on other countries).
- Extension of the 2017 tax cuts for corporations and individuals, which are set to expire in 2025.
- New positions towards global agreements and participation in multilateral engagements.

What we're watching closely

There is considerable uncertainty regarding the 2025 policy priorities of the HHS and its health agencies, particularly the FDA, NIH and Centers for Disease Control and Prevention (CDC). This ambiguity is compounded by differing agendas: Senate and House Republicans aim to reverse Biden's health policies and challenge the ACA, while Kennedy and Trump advocate for a MAHA agenda, emphasizing vaccine skepticism and food ingredient (including dye) concerns.

There is speculation about the NIH budget and whether the administration will seek to cut it and direct funding to certain Institutes or diseases. This would likely create a significant fight with Congress as members have their own priorities for NIH, which includes research grants to influential groups in their states like academic hospitals. The CDC is also likely to see funding cuts, which could impact their work with states. To try and avoid these battles, congressional Republicans and the Trump administration will seek to work out compromises before advancing legislation, which will also require bipartisan support to pass the Senate.

For more on potential changes at the FDA read: <u>10 observations on the FDA and health/regulatory policy</u> under Trump 2.0 by Former FDA Associate Commissioner and APCO colleague Wayne Pines.

Pharma, biotech, and med device industries

- Drug Approval Processes: The Trump administration is likely to continue advocating for faster FDA approval
 processes, benefiting companies developing innovative therapies, particularly in areas like oncology, rare
 diseases and gene therapy. Trump's previous support for the "Right to Try" law, which allows terminally ill
 patients to access experimental treatments, may continue or expand. However, Kennedy has said FDA
 cannot be in the pocket of pharmaceutical companies, so he is expected to exercise more scrutiny, which
 could slow approvals.
- Drug Pricing and Reimbursement: Republicans in Congress will attempt to roll back the Inflation Reduction Act (IRA), but it remains to be seen if Trump will overturn the Medicare drug negotiation provisions. Trump has previously advocated for aligning U.S. drug prices with those in other developed nations, aiming to reduce domestic costs. This approach, known as the "Most Favored Nation" rule, could pressure pharmaceutical companies to lower prices and significantly alter how Medicare pays for certain prescription drugs. He may also try and accelerate state efforts to import drugs from Canada. Together, these new regulations and policies could affect market dynamics, including safety and quality concerns, ability to make a profit in the U.S. and create more competition for domestic drug manufacturers.
- Supply Chain Security & Geopolitical Relationships: Trump's "America First" policy is expected to promote
 domestic manufacturing of pharmaceuticals (including Active Pharmaceutical Ingredients [APIs]) and
 medical devices to reduce reliance on international supply chains. There is broad bipartisan support for
 onshoring the medical supply chain, especially shifting API supply away from China and India, which could
 include incentives for U.S.-based production. The proposed 20% tariff on all imports and the 60% tariff on
 Chinese goods would affect medical supplies and equipment, potentially increasing costs for hospitals and





health care providers, as well as changing supply chain strategies for multinational pharmaceutical companies.

• *Essential Medicines and Devices:* Trump may build on his executive order from 2020 to ensure essential medicines and medical devices are made in the U.S. Such efforts would require federal agencies to prioritize purchasing domestically produced medical devices, creating opportunities for U.S. manufacturers but also posing challenges for companies relying on global supply chains.

Public health

- Pandemic and Public Health Crisis Preparedness: Expect substantial changes. During the campaign, Trump indicated that he would shut down the White House Office of Pandemic Preparedness and Response, describing it as unnecessary and suggesting the government would respond when an outbreak happens. Other international programs and health cooperation could be at risk, including the WHO's Pandemic Treaty, of which negotiations have been extended into 2025. In the coming months, uncertainty surrounding the HHS agenda is likely to be disruptive for pharma and biopharma company pipelines as well as public health organizations committed to preventing outbreaks.
- Global Health Organizations and Programs: Trump may attempt to withdraw the U.S. from the WHO early in his term, which would undercut the WHO as the U.S. is its second-largest funder and could lead to other countries stepping in like China. In July of 2020, Trump tried withdrawing the U.S. but by law it takes a year, and the Biden administration reversed the decision upon taking office. Countries that fill the void left by the U.S. could have greater influence on global health programs. Another international health program (falling under the U.S. State Department, however) that could see changes is the President's Emergency Plan for AIDS Relief (PEPFAR), which has saved the lives of millions of people, primarily in Africa. Normally a bi-partisan program, in 2024 it was reauthorized for only one year instead of the usual five years due to objections from abortion opponents who claimed the program was supporting the procedure. Expect this issue to be raised again when reauthorization is debated in 2025. Trump is also expected to restore the Mexico City Policy under executive order, which requires NGOs receiving U.S. funds to certify they are not providing or referring for abortions even if those services are funded separately.
- International Aid: Congress is likely to cut foreign aid dramatically. However, with Senator Marco Rubio nominated as Secretary of State, foreign aid groups may find a partner they can work with. Expect competing messages and confusion regarding foreign health aid and the diseases prevented or managed because of such aid.

An integrated strategy forward

Major party changes in the U.S. often create disruption, and the expected policy shifts in the health sector could be more pronounced than in previous transitions. APCO is supporting clients with our U.S. and global health experts to provide specific market implications for diverse regions, shape policy agendas across countries that respond to a Trump administration and provide specific recommendations for clients.

While Trump and his nominees may propose significant changes and immense uncertainty, not all will be enacted swiftly, many will need support from Congress, and quick engagement can influence policy. Reach out to APCO for an integrated approach that centers advocacy and communications to be prepared to engage on business-critical issues.