

The Future of Federal Health Policy: What to Expect Under a Second Trump Administration

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Navigating Policy Shifts Under a Second Trump Administration

As we look ahead to a new political landscape, join us for a series of webinars that will offer insights into the key regulatory and policy changes expected under a second Trump presidency.

We'll explore how leadership transitions, executive actions, and congressional dynamics will shape the future of industries that include, among others, healthcare, financial services, energy, and trade.

Each session will feature analysis from Venable attorneys and senior policy advisors, providing actionable guidance on how businesses and organizations can navigate the evolving policy landscape. Join us for a comprehensive look at the changes coming to Washington in 2025 and beyond.

Unfinished healthcare agenda from lame duck

Addressing the cuts to Medicare physician reimbursement

Extending the COVID-19-era Medicare policy waivers for telehealth and programs like Hospital at Home

Using Medicare site-neutral payment to cover other healthcare costs

Reforming pharmacy benefit managers

Funding community health centers

Outcome of final healthcare regulations from the Biden administration



How the Congressional Review Act Works



Items still pending at the Office of Management and Budget (OMB)



Regulations finalized since August 2024

Medicare payment regulations are not subject to CRA
Non-annual Medicare payment regulations are subject to CRA



Regulations finalized prior to August 2024

Example: Nursing home staffing requirements



Regulatory Freeze Memo – January 20, 2025

Impact on items at OMB
Effect on items not yet at OMB

What Is the Congressional Review Act (CRA)?

The Congressional Review Act is a way for Congress to repeal or block agency actions.

Agency actions subject to the CRA are usually final rules that have gone through the formal rulemaking process, but the CRA is broad in its scope, covering anything “of general or particular applicability and future effect designed to implement, interpret, or prescribe law or policy” (5 U.S.C. §551).

- Exceptions include executive orders, rules affecting agency personnel, and rules affecting how an agency operates that do not affect non-agency parties.

The CRA is a blunt instrument, applying to final rules in their entirety. The CRA cannot be used to block parts of rules.

Agencies cannot issue a new rule in “substantially the same form” if a CRA resolution is successful. What constitutes “substantially the same” is not defined.

Rules disapproved of under the CRA cease to have effect immediately or never go into effect if the CRA resolution becomes law before the rule’s start date.

The Basic CRA Process

Agency Rule

Federal agencies must submit rules to Congress and the Government Accountability Office (GAO) and publish them in the *Federal Register*

Introduction

Any lawmaker can introduce a joint resolution of disapproval within 60 “continuous session” days of Congress receiving a rule; includes all calendar days except when chamber adjourns for more than three days

[Note: The 60-day window is slightly different at the end of a congressional session. See next slides.]

Committee

Senate: Disapproval resolution can be removed from committee, or discharged, to the floor after 20 calendar days with a petition signed by 30 senators

House: No explicit procedures for committee consideration

Floor Action

Senate: Any senator can force a vote on a discharged CRA resolution; **only a simple majority is needed for passage, as CRA resolutions cannot be filibustered** (i.e., no 60-vote threshold)

House: No explicit procedures for initial floor consideration; can pass resolutions with a simple majority under terms set by Rules Committee at any time

President

The president can sign, veto, or take no action on a disapproval resolution

Two-thirds majority needed in both chambers to override a veto, as with a regular bill

CRA Timing

The CRA can be used at almost any time during a Congress.

- A Congress in this context refers to the two years between elections to the House, which is usually split into two sessions (e.g., 118th Congress, 2nd Session; 117th Congress, 1st Session; etc.)

Members have 60 days of continuous session to submit a CRA resolution from the date the rule or major action is officially noticed in the Executive Communications section of the *Congressional Record*.

- Sometimes, agencies do not consider an action to be covered by the CRA, but members of Congress do.
- In those cases, if the Government Accountability Office (GAO) issues an opinion that the action is subject to the CRA, common practice is to start the 60-day window from the date that the GAO opinion appears in the *Congressional Record*.

Continuous session includes every calendar day, including weekends and holidays, unless one or both chambers adjourn for more than three days.

CRA Timing (cont.)

Using the CRA in the middle of a Congress rarely makes political sense.

Successfully using the CRA requires either support from the President, or, failing that, two-thirds support in each chamber. Two-thirds majorities are exceedingly rare in today's political climate, and it would be similarly unlikely for a President to want to use the CRA to overturn one of their own agency's actions. The Trump administration, did, however, use the CRA twice to overturn Consumer Financial Protection Bureau rules issued during his presidency.

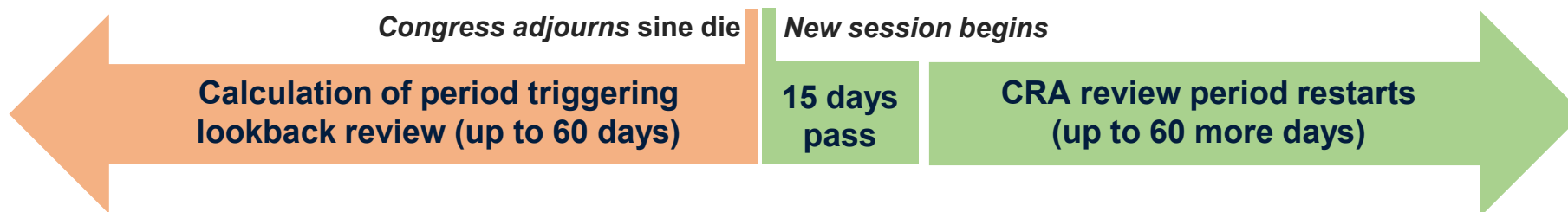
Congressional Republicans have been able to pass nine CRA resolutions in the current Congress with the support of a few Democrats in the Senate. But all have been vetoed by President Biden.

Vetoed Resolution	Rule Description
H. J. Res. 30	Labor Department rule allowing employers to consider ESG factors when choosing investments for retirement plans
H. J. Res. 27	Environmental Protection Agency and Army Corps of Engineers rule expanding protection for additional bodies of water
H. J. Res. 39	Commerce Department rule suspending tariffs on solar panels from Southeast Asia for two years
H. J. Res. 45	Education Department student loan rule to cancel federal student loan debt for certain borrowers
S. J. Res. 11	EPA rule establishing new emission standards for heavy-duty engines and vehicles
S. J. Res. 9	Fish and Wildlife Service rule listing two populations of the lesser prairie chicken under the Endangered Species Act
S. J. Res. 24	FWS rule designating the northern long-eared bat as an endangered species
S. J. Res. 32	Consumer Financial Protection Bureau rule requiring lenders to collect data on small business loan applicants
S. J. Res. 38	Federal Highway Administration rule temporarily waiving Buy America rules for material used in electric vehicle chargers

The CRA Lookback Window

CRA timing is calculated differently at the end of a Congress and the start of a new one.

The new Congress can use the CRA to overturn rules issued during the previous Congress if those rules were issued in a certain “lookback window,” which restarts the CRA clock.



Any rule finalized in the last 60 days of a congressional session can be subject to a new 60-day window in the next Congress. ***The House calculates using legislative days, the Senate uses session days.*** A rule can therefore be subject to different lookback windows in each chamber simultaneously.

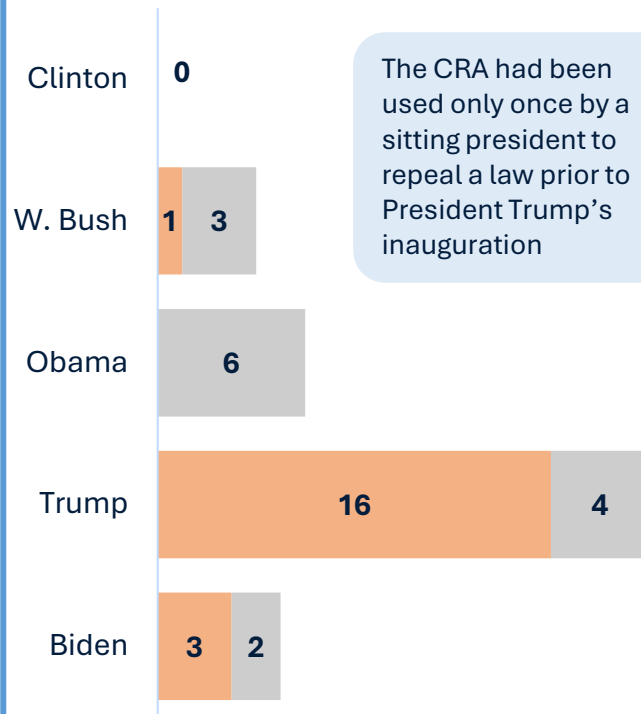
- Legislative days refer to a daily session between gaveling in and adjourning. If there is no adjournment at the end of the calendar day, the legislative day continues into the next calendar day until there is an adjournment.
- At the other extreme, there could be multiple adjournments in the same calendar day, leading to multiple legislative days passing.

Regulations finalized during the lookback period are treated as having been submitted on the 15th legislative day of the new session and restart the regular 60-day CRA review period.

Successful Uses of the CRA

Uses of the CRA since 1996

■ Rule repealed ■ Repeal attempt vetoed



Biden administration uses of the CRA

President Biden and congressional Democrats passed three CRA resolutions in 2021 to reverse Trump-era rules, taking advantage of the lookback window.

S.J.Res. 13 (117th Congress)

- 1 Nullified an EEOC rule amending conciliation procedures for charges violating Title VII of the Civil Rights Act of 1964

S.J.Res. 14 (117th Congress)

- 2 Nullified an EPA rule downscaling which pollutants are regulated under new source performance standards finalized in 2012 and 2016

S.J.Res. 15 (117th Congress)

- 3 Nullified a Comptroller of the Currency rule amending guidelines determining when a national bank or federal savings association bank is considered a “true lender”

Trump administration uses of the CRA

President Trump holds the record for successful CRA uses, at 16. Those resolutions applied to:

- SEC payment disclosure regulation
- The “Stream Protection Rule”
- Social Security Administration data provided for gun background checks
- Fair pay in defense contracting
- An Interior land use plans rule
- Every Student Succeeds Act accountability
- A teacher preparation rule
- Drug testing for unemployment benefits
- Wildlife Refuges in Alaska
- On-the-job injuries recordkeeping
- FCC broadband provider privacy requirements
- Title X family planning project recipients
- State-run savings plans
- County/city-run savings plans
- EPA emissions standards for oil and natural gas
- Lending by banks and savings associations

Calculating the Lookback Window for 2024-2025

A new Congress took office on January 3, 2025.

As of July 2024, the Congressional Research Service (CRS) unofficially estimates that rules finalized and noticed in the *Congressional Record* on August 1 or later will be subject to CRA disapproval in 2025.

This date can change; for example, House leadership added an additional week of recess after CRS made its estimate, potentially leading to fewer legislative days in 2024, which would push the House CRA lookback period into July.

The “starting point” for the lookback is likely January 3, 2025, because Congress usually officially adjourns the same day that the new Congress is sworn in. In other words, the 2024 session of Congress spills over slightly into 2025.

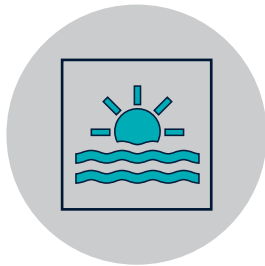
CRA

The Congressional Review Act could be used in 2025 to block Biden administration rules finalized from August 2024 on.

If Republicans sweep the November elections or control the House and presidency with a closely divided Senate, the Biden administration's regulatory agenda is in jeopardy.

Absent those results, however, it would take time for a second Trump administration to issue new rules or repeal Biden-era rules through the regular rulemaking process. Likewise, Republicans in Congress would have to find a different way to get legislation blocking, repealing, or changing Biden-era rules into law.

Rules and processes to evaluate current policies



DEREGULATION/SUNSET
RULE – RESCINDING BIDEN
REGULATIONS



USE OF CONGRESSIONAL
REVIEW ACT



EXECUTIVE ORDERS – NEW
AND RESCINDING BIDEN
REGULATIONS



BUDGET RECONCILIATION –
AFFORDABLE CARE ACT,
MEDICARE, MEDICAID,
INFLATION REEDUCATION
ACT

Medicare and Medicaid policy areas to watch

- Medicaid waivers and impact on states
 - Block granting
 - Work requirements
 - Change the match – reduce the match rate for the expansion population
 - IGT – intergovernmental transfers
 - Return of the MFAR regulation, which could impact state provider taxes
- Medicare Advantage
 - Dr. Oz is a fan
 - Possibility auto-enroll into Medicare Advantage as a default
 - Overturning accountability and ratings systems promulgated by Biden administration
- Value-Based Care – Medicare Shared Savings Program and Center for Medicare and Medicaid Innovation
 - Continued push toward VBC
 - Bullish on models that have proved to save money

Access and cost of care policy areas to watch



Price transparency/No Surprises Act



Site-neutral policies



Rural health



Telehealth and digital health innovation



340B drug pricing



Pharmacy benefit manager reform



Behavioral health



Taxes

Anticipated key Republican health policy players

Administration

- Secretary of HHS, RFK, Jr.
- Dep. Sec. of HHS – Jim O’Neill
- CMS Administrator – Dr. Oz
- FDA Commissioner – Dr. Makary
- CDC Director – Dr. Weldon
- NIH Director – Dr. Bhattacharya
- Transition Lead – Hannah Anderson
- Project 2025 / Heritage Foundation Staff
- America First Policy Institute Staff
- Paragon Health Institute Staff
- Some Trump 1.0 Administration Alumni

Congress

- Sen. Bill Cassidy (R-LA), Chair, Health, Education, Labor and Pensions Committee
- Sen. Mike Crapo (R-ID), Chair, Senate Finance Committee
- Jason Smith (R-MO), Chair, House Ways & Means Committee
- Vern Buchanan (R-FL), Chair, Health Subcommittee Ways & Means
- Brett Guthrie (R-KY), Chair, House Energy & Commerce Committee
- Buddy Carter (R-GA), Chair, Health Subcommittee House Energy & Commerce Committee
- Tim Walberg (R-MN), Chair, House Education & Workforce Committee

DOJ Healthcare Enforcement

Old Guard

Merrick Garland, U.S.
Attorney General
2021-2024



Lisa Monaco, Deputy U.S.
Attorney General
2021-2024



New Guard

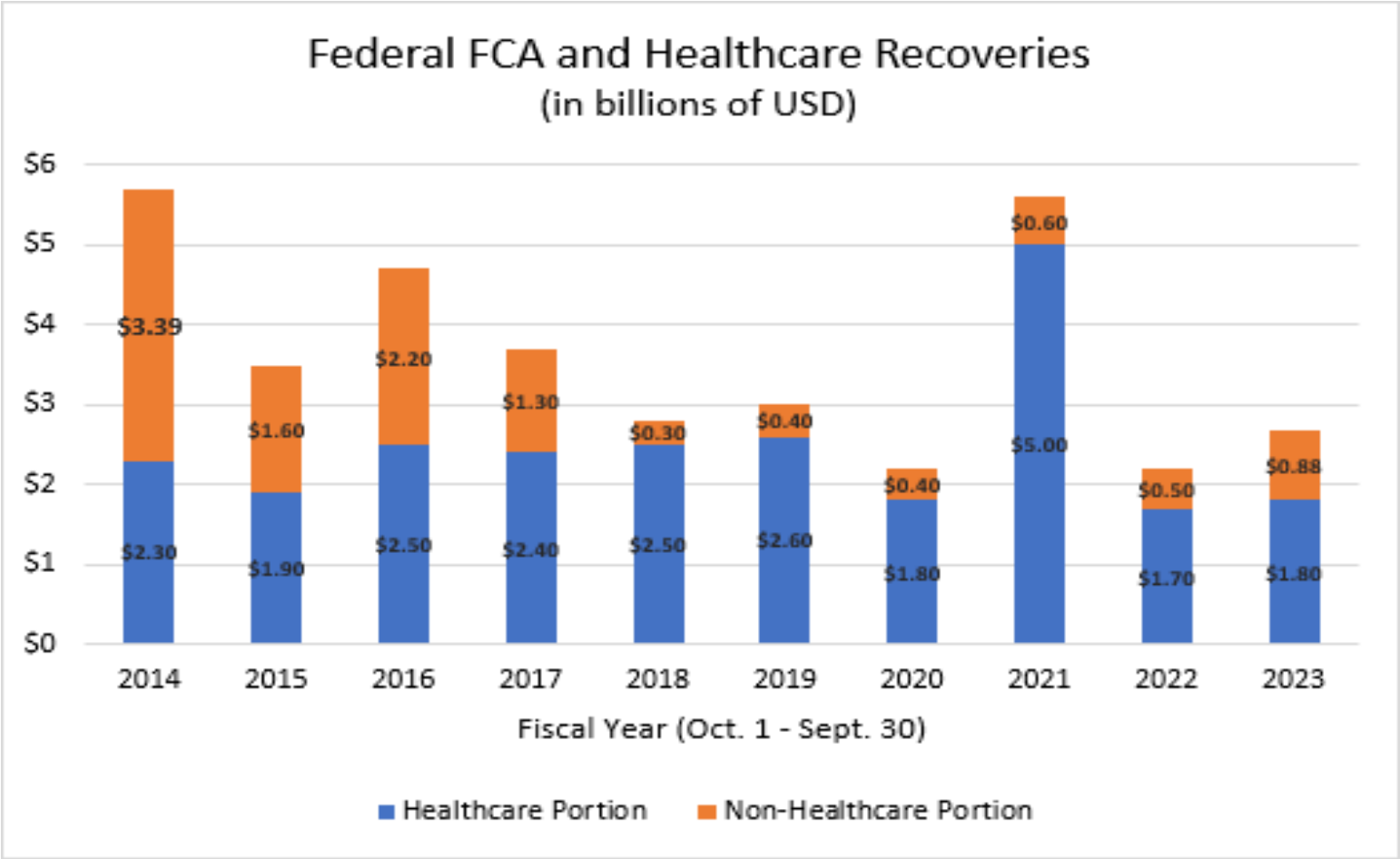
Pam Bondi, U.S.
Attorney General
2025-



Todd Blanche, Deputy U.S.
Attorney General
2025-



DOJ Healthcare Enforcement Recoveries 2014-2023

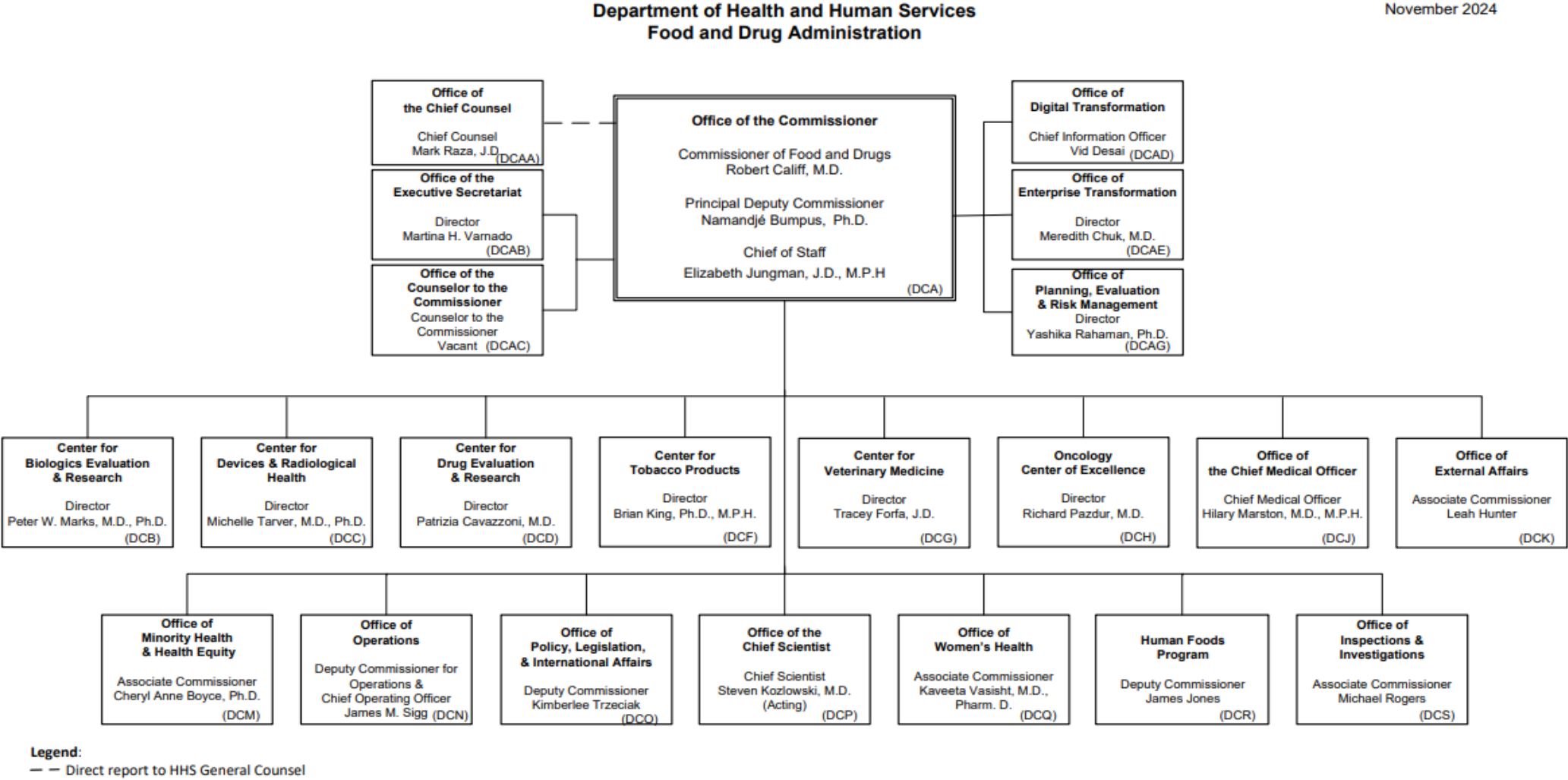


Source: DOJ Press Releases 2014-2024, available at <https://www.justice.gov>

Key Considerations for FDA in 2025

1. New Faces in New Positions at the U.S. Food and Drug Administration (FDA)
 - New FDA commissioner subject to confirmation by the U.S. Senate
 - Retirements of CDER and CDRH directors usher in a new regulatory environment for drugs and devices
2. Improbability of Radical Change
 - Appointed staff have the potential to impact significant policy trajectories, but the regulatory framework applied to medical products will remain constant, resulting in continued predictable regulatory pathways
 - Significant impact at the Office of the Commissioner level vs. limited impact at the Center-level
 - The sky is not falling
3. Some Key Areas of Significant Movement
 - Commissioner's background indicates potential movement in targeted policy areas (e.g., compounding, inspection and enforcement, patient-focused drug development)
 - Administration change could impact key areas (e.g., Laboratory-Developed Tests, compounding, etc.)

FDA Structure



Medical Product Centers: CDER, CBER, CDRH



Center for Drug Evaluation
and Research (CDER)

- Primarily Drugs (NDA)
- Some (Tx) biologics (BLA)



Center for Biologics
Evaluation and Research
(CBER)

- Biologics (BLA)



Center for Devices and
Radiological Health (CDRH)

- Devices (PMA, 510(k), De Novo)

Changing FDA Leadership



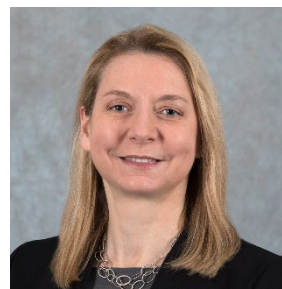
ROBERT CALIFF
COMMISSIONER OF FOOD
AND DRUGS



NAMANDJE BUMPUS
PRINCIPAL DEPUTY
COMMISSIONER



MARK RAZA
CHIEF COUNSEL



PATRICIA CAVAZZONI, MD
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OFFICE OF WOMEN'S
HEALTH



VIDYUT DESAI
CHIEF INFORMATION
OFFICER



Richard Pazdur
ONCOLOGY CENTER
OF EXCELLENT



BRIAN KING
DIRECTOR – CENTER
FOR TOBACCO
PRODUCTS



MICHAEL RODGERS, MS
ASSOCIATE
COMMISSIONER FOR
REGULATORY AFFAIRS



Dr. Martin Makary
COMMISSIONER OF FOOD
AND DRUGS (Nominee)



JANET WOODCOCK
FORMER PRINCIPAL
DEPUTY COMMISSIONER /
CDER Director

Recently Retired



JEFFREY SHUREN, MD
DIRECTOR – CENTER FOR
DEVICES & RADIOLOGICAL
HEALTH

Join Our Next Post-Election Webinar

January 15, 2024: The Future of Tax Policy: What's Next for the TCJA and Beyond | 2:00 - 3:00 p.m. ET

Join us next Wednesday, January 15, for a timely discussion on evolving tax policy in 2025, as we approach the expiration of key provisions of the 2017 Tax Cuts and Jobs Act (TCJA). Tax policy is expected to remain a central focus in the 119th Congress, and this webinar will explore anticipated tax priorities and potential legislative and regulatory developments, as well as how the reconciliation process may be leveraged. Our speakers will share insights to help you gain a deeper understanding of the critical tax policy issues businesses and organizations should anticipate navigating in 2025 and beyond.

Upcoming Webinars:

- January 22, 2024: Shake-up at the NLRB: What Employers Can Expect Under Trump's Second Administration | 2:00 - 3:00 p.m. ET
- January 29, 2024: A Discussion of the Trump Administration's Anticipated Priorities for Higher Education | 2:00 - 3:00 p.m. ET



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