THE ASPEN INSTITUTE

Health, Medicine and Society Program

WHITE PAPER

SEVEN FORMER FDA COMMISSIONERS RECOMMEND: FDA SHOULD BE AN INDEPENDENT FEDERAL AGENCY

Context and Deliberations

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From 2016 to 2018, the Health, Medicine and Society (HMS) Program, the domestic health policy unit of the Aspen Institute, supported the deliberations of seven former Food and Drug Administration (FDA) Commissioners who called for restructuring the FDA as an independent federal agency. Ruth J. Katz, JD, MPH, HMS program director, and Karyn Feiden, HMS communications consultant, led the effort, with funding from the Laura and John Arnold Foundation.

Research!America, which advocates for funding and policies that accelerate medical progress, conducted the background research, with support from Ellie Dehoney, MPH, vice president of policy and advocacy. William Hubbard, MPA, who served as policy advisor to numerous FDA commissioners, was a content expert for the project. David Vladeck, JD, an expert in administrative law at Georgetown Law School, educated the commissioners on the options for becoming an independent federal agency.

The terms of the seven FDA Commissioners who reached consensus on the recommendations presented here: Robert Califf, MD (2016-17); Margaret Hamburg, MD (2009-15); Andrew von Eschenbach, MD (2006-09); Mark McClellan, MD, PhD (2002-04); Jane Henney, MD (1999-2001); David A. Kessler, MD, JD (1990-97); Frank Young, MD, PhD (1984-89).

The January edition of *Health Affairs* includes a companion piece to this report, authored by the seven former commissioners, which can be accessed here.

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Contents

Overview

The goal of independence is to accommodate efficient, science-based decisionmaking by reengineering the processes through which FDA regulations and guidances flow from proposal to final form.

Seven former Commissioners of the U.S. Food and Drug Administration (FDA), physician scientists who together served in both Republican and Democrat Administrations for more than 30 years, believe the FDA should be reconfigured as an independent federal agency.

The goal is to accommodate efficient, science-based decisionmaking by reengineering the processes through which FDA regulations, guidances, and an array of communications flow from proposal to final form. Given its vast responsibilities for overseeing more than $2.5 trillion in products, the Agency needs to have every advantage to ensure its ability to promote and protect the public health, contribute its expertise to policy discussions, and bring more responsive and predictable decision making to its stakeholders.

Independence would not avoid accountability, nor exempt FDA from executive-branch input.

Independence would not avoid accountability, nor exempt FDA from executive-branch input. Rather, it would allow the FDA to operate within a more efficient administrative structure that roots action firmly in scientific evidence and encourages substantive external input. The intent is to build on the FDA's track record of success, support its core mission, and strengthen the capacity to keep pace with rapidly evolving knowledge. A more streamlined approach would also ensure transparency and create a framework that safeguards the Agency's contributions to the nation's health and economy in a competitive global environment.

FDA legislation has traditionally attracted broad bipartisan support, as illustrated by the 21st Century Cures Act. Passed in 2016 by a vote of 94-5 in the Senate and 392-26 in the House, the legislation grants the Agency significant new authority and responsibility and authorizes a modest, temporary boost in funding.[1] Other efforts to improve the processes by which FDA

[1] P.L. 114-255, *21st Century Cures Act* (114th Congress).

responds to evolving scientific knowledge and creates clarity for patients and industry have also garnered support from both sides of the political aisle. There is likewise every reason to believe that the call for an independent FDA can attract a broad base of support.

Greater independence can further FDA's ability to meet the following objectives:

- Promote and protect the public health.
- Ensure predictable decisionmaking, firmly grounded in scientific evidence, that allows safe and effective products to reach the market in timely fashion.
- Speed the development of biomedical innovations.
- Enhance the transparency of the Agency and sustain public confidence.
- Ensure the safety of FDA-regulated imports, including foods and cosmetics.
- Foster the development and availability of medical products that respond to deliberate and naturally emerging public health threats.
- Promote the capacity to act swiftly in an emergency.
- Design a legal and enforcement framework that is efficient and accountable.
- Improve access to external scientific advice from a wide range of sources.
- Ensure stakeholders, including patients, health professional groups, consumer groups and industry, have ample opportunity to inform FDA decisionmaking.

About this Paper

In June 2016, six former Commissioners of the Food and Drug Administration convened at Aspen Ideas: Health (previously Spotlight Health), the opening event of the Aspen Ideas Festival in Aspen, Colorado, to talk about the challenges facing the FDA, an agency that regulates roughly 20 cents of every dollar spent by American consumers each year. On that occasion, they publicly announced their consensus view that the FDA should be transformed into an independent federal agency.

Independence, free from administrative bottlenecks, will put the FDA in the strongest possible position to meet the challenges of the 21st century.

This paper advances that idea, explains the rationale for it, and suggests a path forward. It is built on an 18-month series of discussions organized by the Health, Medicine and Society Program of the Aspen Institute for the Commissioners (including a seventh, who joined the group in 2017), and presents evidence to support their shared view that independence free from administrative bottlenecks will put the FDA in the strongest possible position to meet the challenges of the 21st century, as science rapidly evolves, products become increasingly complex, and the economy grows ever more globalized.

FDA: Promoting and Protecting the Nation's Health

The Food and Drug Administration resides within the U.S. Department of Health and Human Services (HHS). It was established under the Pure Food and Drug Act, passed in 1906 in response to the recognition that misbranded and adulterated food and drugs were being sold to consumers. The Federal Food, Drug and Cosmetic Act of 1938 created rigorous safety standards and in 1962, an effectiveness standard was added – only then did a manufacturer have to prove that, in addition to being safe, drugs actually worked before they could be sold.

The FDA is recognized globally as setting the "gold standard" in its use of the best available scientific evidence to establish the safety and effectiveness of prescription and over-the-counter pharmaceuticals, biologics, vaccines, cosmetics, dietary supplements, medical devices, and other technologies. Nineteen thousand FDA-regulated prescription drugs are on the market and the Agency oversees 6,000 categories of medical devices. The FDA also regulates about 75 percent of the nation's food supply and more than 85,000 tobacco products, monitors the entry into the United States of 12 percent of all imported goods (valued at $273 billion), and has responsibility for radiological health; veterinary and livestock products; vital aspects of the emergency response system; and blood-related products.[2]

With its use of cutting-edge analytical tools and techniques, and rigorous data, the FDA helps keep the U.S. at the epicenter of developing new products and technologies. The Agency approves more drugs, and approves them faster, than its counterparts in Europe or Canada.[3] In 2016, for example, two-thirds of significant new pharmaceutical advances that were approved anywhere in the world were approved first by FDA.[4] The majority of those therapies were designated as suitable for some category of "expedited review," a rigorous system that hastens their journey to the market without compromising safety.

With its use of cutting-edge analytical tools and techniques, and rigorous data, the FDA helps keep the U.S. at the epicenter of developing new products and technologies.

The industries that FDA regulates are highly productive and well-positioned for growth. Public and private sector investments in biomedical research and innovation, one of America's greatest

[2] *Fact Sheet: FDA at a Glance*, August 2018.

[3] Downing NS, Aminawung JA, Shah ND, et al. "*Regulatory Review of Novel Therapeutics – Comparison of Three Regulatory Agencies*." New England Journal of Medicine: 2012;366:2284-93.

[4] Jenkins, J, US Food and Drug Administration. "*A Review of CDER's Novel Drug Approach for 2016*." FDA Voice: January 4, 2017.

scientific and economic success stories, have grown steadily for decades. Hubs of innovations that hold the promise of still more advances are springing up across the country. The market for the resulting therapeutic advances is flourishing and the impressive stock performance of the pharmaceutical, biotechnology and life sciences sector indicates high investor confidence in the industry's ability to thrive.

That sector is also a powerful job creator, even during the last economic downturn, when two million manufacturing jobs were lost to the American economy. According to the Pharmaceutical Research and Manufacturers of America (PhRMA), the industry trade association, the biopharmaceutical sector employs almost 854,000 workers and supports some 4.5 million jobs across the country, many of them well-paying.[5] The industry also contributes to a remarkable number of new business startups, a positive trade balance, and the "virtuous cycle" of new discoveries that provide resources to pursue still more discoveries.

FDA requirements promote the well-being of the American public and save lives; they also clarify the landscape for industry.

All of that is made possible in part by FDA's fundamental role as a regulatory agency. While regulations are sometimes assumed to be little more than an intrusive government burden, FDA requirements promote the well-being of the American public and save lives. Many of FDA's legally enforceable rules also clarify the landscape for industry, support their expeditious development of safe and effective new products, protect them from the necessity of costly recalls (such as when contaminants are identified in produce or other food), and, by keeping the unproven products of less rigorous competitors off the market, allow companies to meet their own high standards.

Meeting 21st Century Demands

In recent years, the Agency's responsibilities for promoting and protecting American interests have grown exponentially, but especially over the past two decades, when new authorities over drugs, devices, tobacco and food safety have been added, generally without concomitant resource allocations *(Chart 1: Legislation Adding to FDA's Responsibilities).* Among numerous other data points, the increased workload is reflected in the rising number of comments and documents submitted to the FDA, generally in response to proposed rules or notices (*Chart 2: Number of*

[5] Pharmaceutical Research and Manufacturers of America. "*The Economic Impact of the U.S. Biopharmaceutical Industry: National and State Estimates*" May 2016.

Comments and Newly Submitted Documents). The skyrocketing volume of FDA-regulated imports, which have more than doubled from 15 million lines subject to inspection in 2006 to some 37.5 million by 2016, also underscores the demands on the Agency *(Chart 3: Imports Subject to FDA Regulation)*.[6]

Remarkable advances in science and medicine, and the new generations of breakthrough therapies they are expected to produce, further highlight the need for a dexterous, decisive and scientifically exacting FDA. Among the emerging avenues of research likely to speed the pace of medical progress and transform the ability of physicians to diagnose, treat, or prevent disease:

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- Gene editing to modify disease risks
- Immunology
- Pharmaceutical compounds comprised of nanoparticles
- Precision medicine
- Preclinical tools, such as "organs on a chip"
- Robotic surgical tools
- Stem cell treatments that make it possible to regenerate human tissue
- Therapeutic imaging techniques

The passage of the 21st-Century Cures Act in the fall of 2016 reflected, at least in part, the urgent opportunity to bring these and other powerful technologies and therapeutics swiftly to people who need them. To fulfill the vision of the Cures Act, FDA is expected to carry out almost 100 specific additional activities, ranging from promulgating new regulations to developing guidance for drug developers to crafting planning documents and policy statements.

For example, the 2016 law requires that FDA develop 17 new guidances, with various deadlines over the next few years, including issues related to clinical trial design, novel combination products, criteria for priority review, and more. The FDA is also working with researchers on a cascade of projects aimed at enhancing data-gathering and developing analytic tools to assess the risks and benefits of new discoveries more quickly.

[6] FDA Office of Regulatory Affairs. "Narrative of Field Activities" FY 2017 budget request.

Under the FDA's current administrative structure, essential opportunities to reduce the time and costs associated with moving safe and effective products through the discovery, development and delivery pipeline are being lost.

Beyond the development of medical products, the FDA needs to respond to numerous other challenges within its jurisdiction. Its toxicology capabilities must be modernized to assess consumer product safety. The explosion of new food components, combined with the emergence of new contaminants in food, dictates the need for expensive and complex tracking of consumer exposure over time. Strengthened surveillance of foodborne disease, the use of next-generation DNA sequences to assure the safety of vaccines, and access to new technologies to monitor trends and mechanisms of antibiotic resistance are also essential.

Under the FDA's current administrative structure, essential opportunities to reduce the time and costs associated with moving safe and effective products through the discovery, development and delivery pipeline are being lost.

Barriers to Responsive Decisionmaking

Unless administrative requirements are streamlined, the FDA's capacity to make efficient scientific decisions, and thus ensure timely access to medical breakthroughs and safe foods, will become ever more compromised.

In addition to safeguarding the public health, effective FDA rules should provide consistency and predictability to industry, encouraging innovators to enter the marketplace and compete to meet consumers' needs. Regulation should also be able to respond rapidly and efficiently to new developments in the regulated space so that the benefit of new innovations to consumers is not unjustifiably delayed and a sector crucial to the nation's health retains its vibrancy. As well, an efficient structure is needed to support hubs of innovation across the country (*Chart 4: Innovation Hotspots*) and to sunset regulations that no longer serve their intended purpose.

FDA's position within the federal government, and its reporting relationships, are barriers to those objectives. As one of twelve arms of the Department of Health and Human Services, FDA is part of a huge organization responsible for a budget that exceeds a trillion dollars

(*Chart 5: Organizational Chart of HHS*). FDA issues are not always a priority for a department that is charged with a vast and complex range of other equally vital functions. A further complication of its position within HHS is the fact that FDA has regulatory authority over some activities of "sister" agencies within HHS, including the Centers for Disease Control and Prevention (CDC) and the National Institutes of Health (NIH).

Layers of oversight requirements within HHS and the White House also slow the FDA's capacity to fulfill its mission (*Chart 6: The Flow of Rulemaking Today*). Further impediments are Department protocols that give review authority to staff without any scientific background, and delays that result simply from the logistics of moving a review through so many hands. It is increasingly apparent that precious resources are being spent on bureaucracy, rather than on the expertise needed to keep pace with scientific advances.

The cumulative impact has been apparent during the tenure of every FDA Commissioner. Each one has cases to cite about decisions that were bogged down not for reasons of science, or even political sensitivities, but because of multiple levels of red tape. Often, a final document has wound up with few substantive changes despite delays that consumed months or years.[7] Moreover, the duplicative nature of HHS review has spread the Department itself thinner than necessary at a time when its other responsibilities have grown substantially.

Those trends underscore the importance of process improvements that would minimize the burden of administration requirements and ensure a responsive pace. If the FDA is forced to channel its finite resources into endless cycles of review and revision that do not add benefit to an action or communication, other responsibilities of much greater value to its core mission will inevitably suffer.

Existing procedural impediments represent a significant break from past practices. For most of FDA's existence, Commissioners were delegated authority to carry out their public health functions with limited interference from other officials within the executive branch. Because the Agency's scientific pursuits were often very technical in nature, staff expertise was recognized, deference in decisionmaking provided, and the flow from draft regulation to final rule had just a few speedy steps (*Chart 7: The Flow of Rulemaking Before 1981*).

That began to shift in the early 1980s, when the HHS Secretary revoked the delegation of authority to the Commissioner for major rules, and President Ronald Reagan signed Executive Order 12291 requiring the Office of Information and Regulatory Affairs (OIRA) to review "economically

[7] Interviews conducted with seven FDA Commissioners as part of this project.

significant rules."[8] (OIRA sits within the Office of Management and Budget [OMB].) Through successive presidents and HHS secretaries, that concept has been applied ever more broadly, and an increasing number of executive-branch agencies and lower-level HHS staff have inserted themselves in FDA's day-to-day work.[9]

The result is illustrated by the delayed implementation of the Food Safety Modernization Act (FSMA).[10] This legislation was enacted with overwhelming bipartisan congressional support at the urging of both consumer and industry groups, including the Grocery Manufacturers of America, and signed into law in 2011. The Act's intention was to reduce both the heavy toll of illness from contaminated food and the multi-billion dollar annual costs to the food industry when contamination occurred.

Much of the enforcement responsibility fell to the FDA, which began a carefully coordinated process of working with farmers and food producers to develop the necessary implementing rules. Despite an efficient response aimed at meeting strict congressional deadlines, a sometimes-byzantine sequence of reviews outside FDA prevented food safety problems from being adequately addressed for many years, resulting in illnesses, deaths, and significant losses to the American economy. The promised opportunities in the law are still being translated into regulations and guidances, and FDA's position within HHS makes it hard to get the full attention and resources necessary to ensure their full implementation.

That has become an all-too-common story (*Chart 8: Avoidable Costs: Health and Financial Consequences of Delays in FDA Regulation*). Senior FDA staffers believe that issuing a new rule should in general be expected to take less than two years.[11] In fact, the median time to finalize rules is 7.3 years, according to a recent analysis in *Health Affairs*.[12] For example, a proposed rule to require labeling for oral over-the-counter drugs was published in April 1996, and finalized in March 2004.

Senior FDA staffers believe that issuing a new rule should take less than two years. In fact, the median time to finalize rules is 7.3 years.

[8] Exec. Order No. 12291, 46 Fed. Reg. 13193 (Feb. 17, 1981). "Economically significant" rules are defined principally as those "likely to have an annual effect on the economy of $100 million or more, or adversely affect in a material way the economy, a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, Local, or tribal governments or communities."

[9] Gladwell M. "Breaking Bureaucratic Grip on FDA: Is Independence the Answer? *Washington Post:* July 17, 1990. More recent challenges with micromanagement were reported in interviews conducted with seven FDA Commissioners and nine external stakeholders as part of this project.

[10] P.L. 111-353, *Food Safety Modernization Act* (111th Congress).

[11] Personal communication with FDA staffers as part of this project.

[12] Hwang TJ, Avorn J, Carpenter D, Kesselheim AS. "*Quantifying the Food and Drug Administration's Rulemaking Delays Highlights the Need for Transparency*" *Health Affairs*: February 2014;33(2):309-15.

A rule to require a toll-free number for reporting adverse events, proposed in April 2004, was not finalized until October 2008.[13]

This pace stands in dramatic contrast to the process of approving drugs, which now proceeds with great efficiency in part because there is little interference from other layers of government. The FDA acts on more than 95% of the new drug applications it receives within the time frame negotiated with pharmaceutical developers.[14]

With rulemaking embedded in layers of review, the FDA has increased its use of guidance documents, especially over the past decade *(Chart 9: Increase in FDA Guidances and Rules).* While guidances reflect current Agency thinking on a topic, they do not have the weight of law. Obtaining clearance for guidances is somewhat less cumbersome, but bureaucratic roadblocks still regularly slow their completion. Even press releases must be reviewed by HHS and routine replies to Congressional correspondence and technical assistance intended to inform proposed legislation are also increasingly delayed.[15]

These are counterproductive barriers to timely Agency action. The FDA performs its job in a highly dynamic space where fast-evolving science, technological innovation, market competition, and consumer demand converge in a stream of new products. Unless administrative requirements are streamlined, the efficient operation of core FDA functions and its capacity to make decisions, and thus access to medical breakthroughs and safe foods, will become ever more compromised.

Pathway to an Independent Federal Agency

Structuring the FDA as an independent federal agency would reengineer the processes by which the Agency takes action, giving it more control over its budget, greater stature in dealing with counterparts around the globe and within the executive and legislative branches of the federal government, more participation in executive-branch policy discussions, and the capacity to determine its own priorities. Truly economically significant rules would still be subject to OIRA review, but many other interim steps would be eliminated *(Chart 10: Simplified Approach to Rulemaking).* With less unproductive "churn" of documents moving through the hands of non-scientists outside the FDA, Americans can feel more confident that rigorous evidence, not bureaucracy or partisanship, is the determining factor in Agency decisionmaking.

[13] Food and Drug Administration. "*Rulemaking History of General Labeling Requirements for OTC Drug Products*"

[14] FDA. *Annual Report to Congress* 2016.

[15] Personal communication with FDA staffers as part of this project.

If, for example, an independent FDA determined that an antiquated information technology system is impeding its ability to monitor manufacturing plants or share data on medical devices, it could redirect resources to IT on its own authority, rather than waiting for outside approval. If concerns arise about contaminated food imports, the Agency could work more directly with customs officials or State Department representatives who focus on trade policy. When Congress hands the FDA extraordinarily ambitious new responsibilities, as it has with the 21st Century Cures Act, an independent FDA freed from current administrative layers of review is far more likely to be able to get the work done.

Recognizing the compelling need to assure timely and responsive decisionmaking and promote regulatory certainty, the Commissioners are proposing a two-step process to foster greater independence for the FDA:

- The optimal goal, which requires statutory changes, is to remove FDA from the Department of Health and Human Services, and reconstitute it as an independent federal agency reporting to the President.
- Recognizing that enacting this major policy shift is likely to take time, the interim goal is for the HHS Secretary and the FDA Commissioner to identify and implement steps to streamline HHS staff review of FDA work products.

Vision for a More Independent FDA

As part of their information-gathering process, the Commissioners studied the structure of other federal agencies, including independent regulatory commissions, such as the Federal Trade Commission, and executive-branch agencies that report directly to the President, such as the Small Business Administration and the Environmental Protection Agency (*Chart 11: Agency Models within the Federal Government*).

They also looked at the rationale that drove earlier organizational overhauls within the federal government. Of particular interest was the decision by Congress to carve the Social Security Administration (SSA) out of HHS and reconfigure it as an independent agency. The Congressional Record reflects a view that the SSA was suffering from a diminished profile inside HHS and identified the goal of independence as "improving the quality of its service to the public… insulating its operations from short-term political pressure, and stabilizing

agency management." During the legislative debate, Republican Congressman Bill Archer said "freeing Social Security from the layers of bureaucracy imposed upon it by its current structure within HHS will go a long way in making it less political and both more responsive and more accountable."[16]

With overwhelming bipartisan support (unanimity in the House), SSA became independent in 1994, governed by a three-member Board, appointed by the President for six-year terms and removable only with cause. SSA now submits an annual budget to the President, who is mandated to send it to Congress without revision.

Ultimately, the Commissioners concluded that no single model for an independent agency could be replicated exactly, but instead identified key attributes that suited FDA's unique public health mission. There was little appetite for an agency headed by a multi-member board, such as the Federal Trade Commission or Federal Communications Commission, rather than a single leader. The group was interested in having the authority to make budget requests directly to the Office of Management and Budget, with simultaneous review by Congress, but concluded that the experience of other federal agencies suggested this would not be feasible.

Among the characteristics they considered key:

- Leadership by one individual, appointed by the President, confirmed by the Senate.
- Rulemaking authority in accordance with congressional enabling legislation and intent, with appropriate, but judicious, input from the executive branch of government.
- Oversight by the Office of Management and Budget (OMB limited to significant regulations and policy development, with transparency embedded and limitations clearly defined.
- Litigation authority, in coordination with the U.S. Department of Justice.

While the overarching recommendation for FDA independence is firmly held among the Commissioners, the structural specifics could appropriately change as other players weigh in and Congress considers the options. For example, other approaches to ensuring continuity of leadership may merit consideration, such as appointing a Commissioner for a specific term, removable only for cause. Another fungible question is whether the line for budget requests should go directly from an independent FDA to Congress or be reviewed first by OMB. These and

[16] Social Security Administration. *Legislative History of Public Law 103-296: Social Security Independence and Program Improvements Act of 1994*.

other issues will be more fully addressed as the proposal makes its way through congressional subcommittees, stakeholders weigh in with testimony and comment, and legislation is drafted.

In the interim, the HHS Secretary and FDA Commissioner should jointly determine a more efficient administrative path for the Agency by examining current processes with an eye toward assessing the flow of reviews and the number of offices that can conduct them, eliminating redundancy, and ensuring timeliness. While the Secretary will certainly remain involved in the development of regulations and policies, HHS staff should not micromanage the FDA's routine work. This would save time and costs both at the FDA and HHS, privilege scientific evidence as the key decisionmaking variable, foster consistency, and ease HHS's obligations to handle responsibilities that are somewhat removed from its other fundamental, and mostly non-regulatory, functions in the health and human service arenas.

Strategies for greater independence within HHS include:

- Identify, in consultation with the Commissioner, opportunities to streamline the current system of multi-layered executive branch oversight of FDA decisionmaking.
- Formalize more direct communication between the Secretary and Commissioner so that timely decisions can be made on high-priority issues.
- Define the criteria for determining which regulations should be subject to OMB review, and discontinue OMB review of guidances and communication with Congress.
- Allow the FDA full recruitment and hiring authority.
- Enhance the independence and robustness of the scientific advisory system.

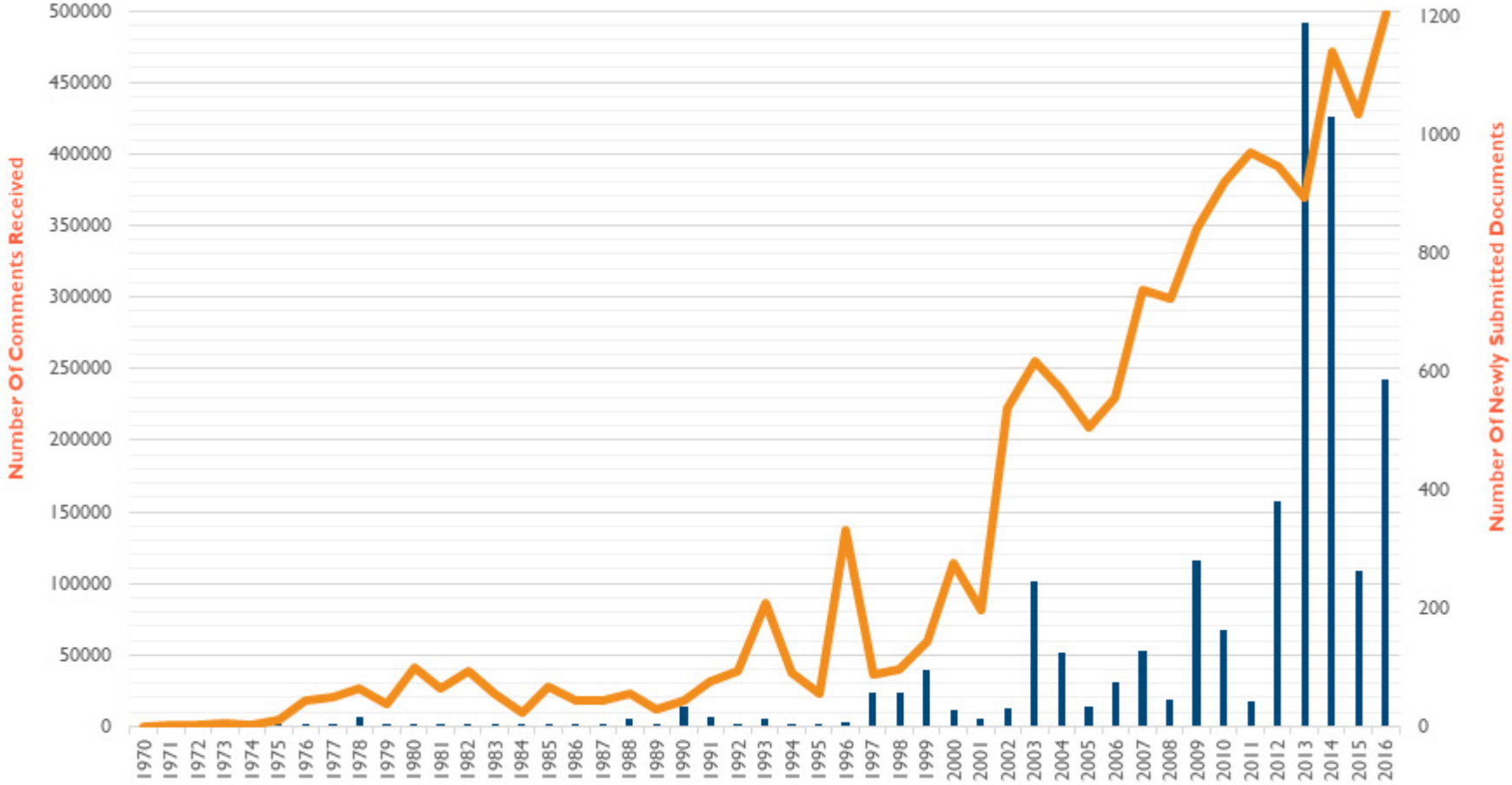
America and Americans would be well-served by an independent FDA prepared to meet the scientific challenges of the 21st century, direct more of its resources to promoting its public health and safety mission, and responsibly bring innovations more swiftly to patients. This two-step pathway holds the promise of making all of that possible.

Appendices

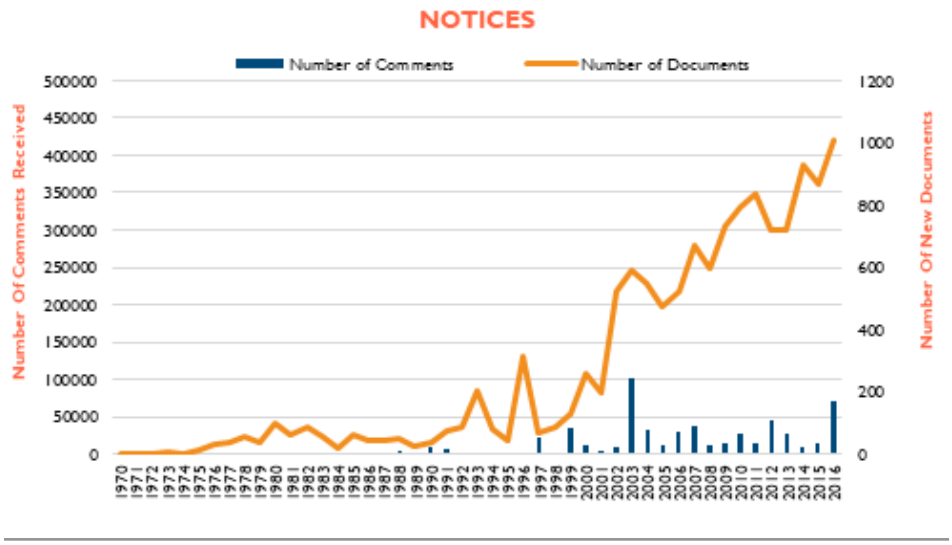
Chart 1: Legislation Adding to FDA's Responsibilities

- 1906 Pure Food and Drug Act
- 1907 Federal Meat Inspection Act
- 1914 Federal Trade Commission Act
- 1923 Filled Milk Act
- 1927 Import Milk Act
- 1938 FD&C Act
- 1944 Public Health Service Act
- 1946 Trademark Act of 1946
- 1951 Durham-Humphrey Amendments
- 1953 Reorganization Plan 1
- 1957 Poultry Products Inspection Act
- 1958 Food Additives Amendments
- 1962 Kefauver-Harris Amendments
- 1966 Fair Packaging and Labeling Act
- 1968 Radiation Control for Health & Safety Act (RCHSA)
- 1970 The National Environmental Policy Act
- Controlled Substances Act
- Controlled Substances Import and Export Act
- Egg Products Inspection Act
- 1971 Lead-Based Paint Poisoning Prevention Act
- 1972 Federal Advisory Committee Act
- 1976 Government in the Sunshine Act
- Food, Drug and Cosmetic Act (FD&C)
- 1980 Infant Formula Act
- Government Patent Policy Act of 1980
- 1983 Federal Anti-Tampering Act
- Orphan Drug Act
- 1984 Drug Price Competition and Patent Term Restoration Act (Hatch–Waxman Act)
- 1987 Prescription Drug Marketing Act (PDMA)
- 1988 Generic Animal Drug and Patent Term Restoration Act
- 1990 Safe Medical Devices Act (SMDA)
- Nutritional Labeling and Education Act (NLEA)
- 1992 Mammography Quality Standards Act (MQSA)
- Medical Device Amendments
- Prescription Drug User Fee Act
- 1994 Animal Medicinal Drug Use Clarification Act
- Dietary Supplement Health and Education Act
- 1995 Federal Reports Elimination and Sunset Act
- Unfunded Mandates Reform Act
- The Paperwork Reduction Act
- 1996 Animal Drug Availability Act
- Food Quality Protection Ac
- Freedom on Information Act
- Safe Drinking Water Act Amendments
- Animal Drug Availability Act
- Food Quality Protection Act
- Economic Espionage Act of 1996
- Electronic Freedom of Information Improvement Act
- Comprehensive Methamphetamine Control Act
- Health Insurance Portability and Accountability Act (HIPAA)
- Drug-Induced Rape Prevention Punishment Act
- 1997 Food & Drug Administration Modernization Act (FDAMA)
- Better Pharmaceuticals for Children Act
- PDUFA II
- 1998 Antimicrobial Regulation Technical Corrections Act
- Sec. 615 Ag. Research, Extension and Education Reform Act
- MQSA Reauthorization
- Sec. 654, Omnibus Approps. (Family Impact Assessments)
- 1999 Government Employees Training Act
- Fed. Financial Assistance Management Improvement Act
- 2000 Clinical Lab Improvement Amendments (CLIA)
- Approps Act (FDA) - FY 2001
- Medicine Equity and Drug Safety Act
- Prescription Drug Import Fairness Act
- Approps. Act (HHS) Sec. 516, HPV-Condom Labeling Review
- Ryan White AIDS Care Act
- Date Rape Drug Prohibition Act
- Children's Health Act
- Technology Transfer Commercialization Act
- 2001 Animal Disease Risk Assessment
- 2002 Medical Device User Fee and Modernization Act (MDUFMA)
- Hatch-Waxman-Amendments
- Drug Importation Report
- Farm Security & Rural Investment Act
- Bioterrorism Act
- PDUFA III
- Best Pharmaceuticals for Children Act
- Rare Diseases – Orphan Product Development
- E-Government Act
- 2003 Mosquito Abatement for Safety and Health Act
- Animal Drug User Fee Act
- Pediatric Research Equity Act (PREA)
- Medicare Prescription Drug and Modernization Act
- 2004 Minor Use and Minor Species Animal Health Act
- Food Allergen Labeling and Consumer Protection Act
- Medical Devices Technical Corrections Act
- National Defense Authorization Act
- AIDS (PEPFAR)
- Project BioShield
- Anabolic Steroid Control Act
- MQSA Reauthorization
- Homeland Security Presidential Directive (HSPD) #12, Identification Standard
- 2005 Protecting America in the War on Terror Act
- Patient Safety & Quality Improvement Act
- Medical Device User Fee Stabilization Act (MDUFSA)
- Stem Cell Therapeutic and Research Act
- 2006 Combat Meth Act
- 2007 FDAAA
- 2009 Family Smoking Prevention & Tobacco Control Act
- 2010 Food Safety Modernization Act
- Patient Protection & Affordable Care Act
- 2012 Food and Drug Administration Safety and Improvement Act (FDASIA)
- Generic Drug User Fee Act
- PDUFA V
- MDUFA III
- 2013 Pandemic and All-Hazards Preparedness Act
- Drug Quality and Security Act
- ADUFA/AGDUFA Reauthorization Act
- 2014 Sunscreen Innovation Act
- 2015 Microbead Free Waters Act
- Regulatory Transparency for New Medical Therapies Act
- 2016 Twenty-First Century Cures
- 2018 ADUFA/AGDUFA Amendments of 2018

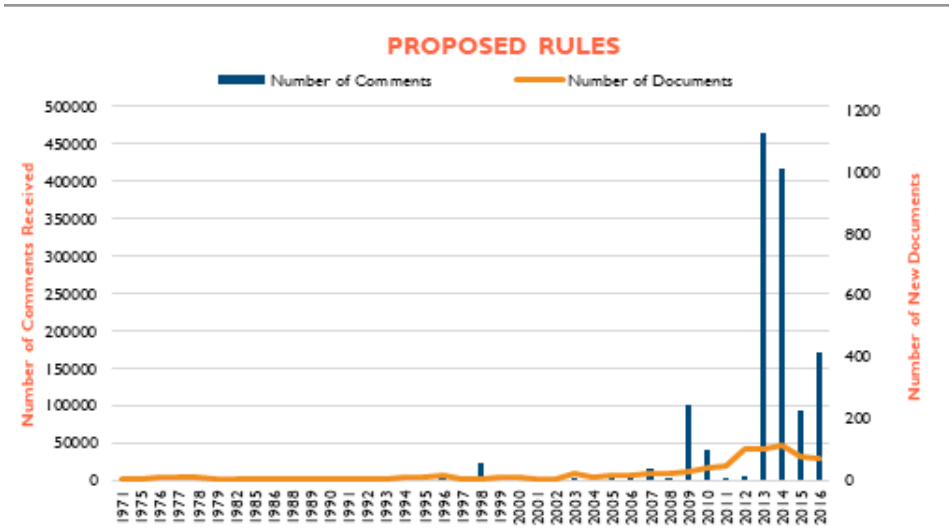
Chart 2: Number of Comments and Newly Submitted Documents



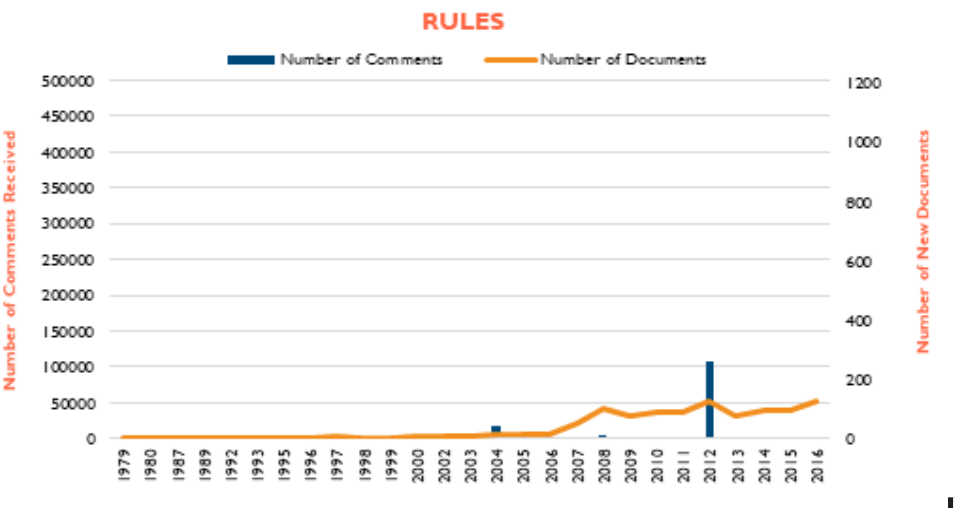
These data, gathered from regulations.gov, illustrate the growing volume of information that the FDA must contend with in executing its regulatory mission. They show the number of comments received and submitted documents filed relating to rules, proposed rules, or notices issued by the FDA. Documents include the FDA's own submissions, as well as written comments, supporting studies, and other information placed in the docket of a given regulatory action. Undated comments and documents are not included here.



The majority of newly submitted documents each year are related to notices issued by the FDA; the number of corresponding comments remains relatively low.

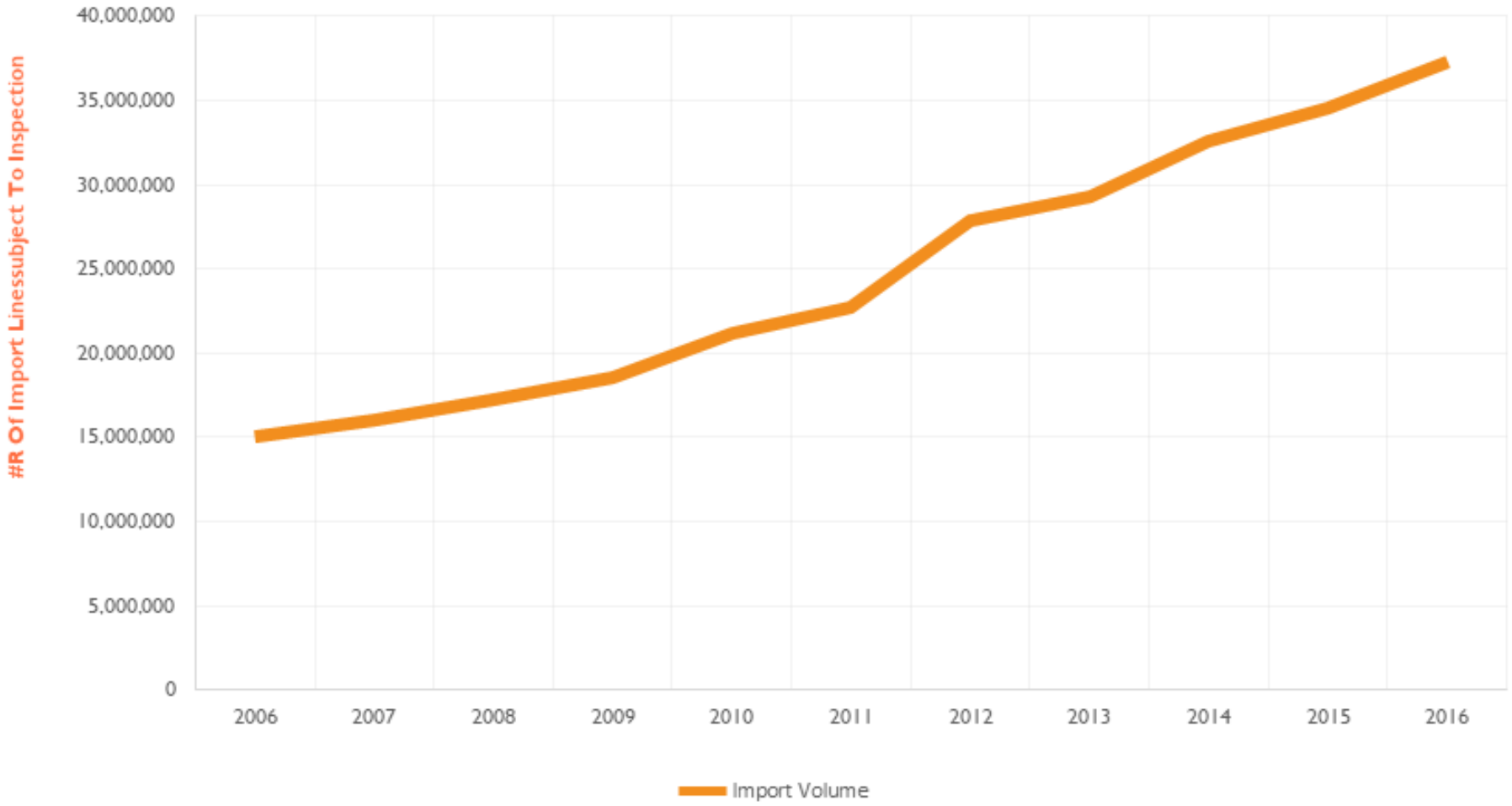


Proposed rules account for a fairly low number of submitted documents, but represent the greatest number of comments received by the FDA.



Final rules receive sparse comment. They represent a slightly higher proportion of the number of new documents than do proposed rules.

Chart 3: Imports Subject to FDA Regulation

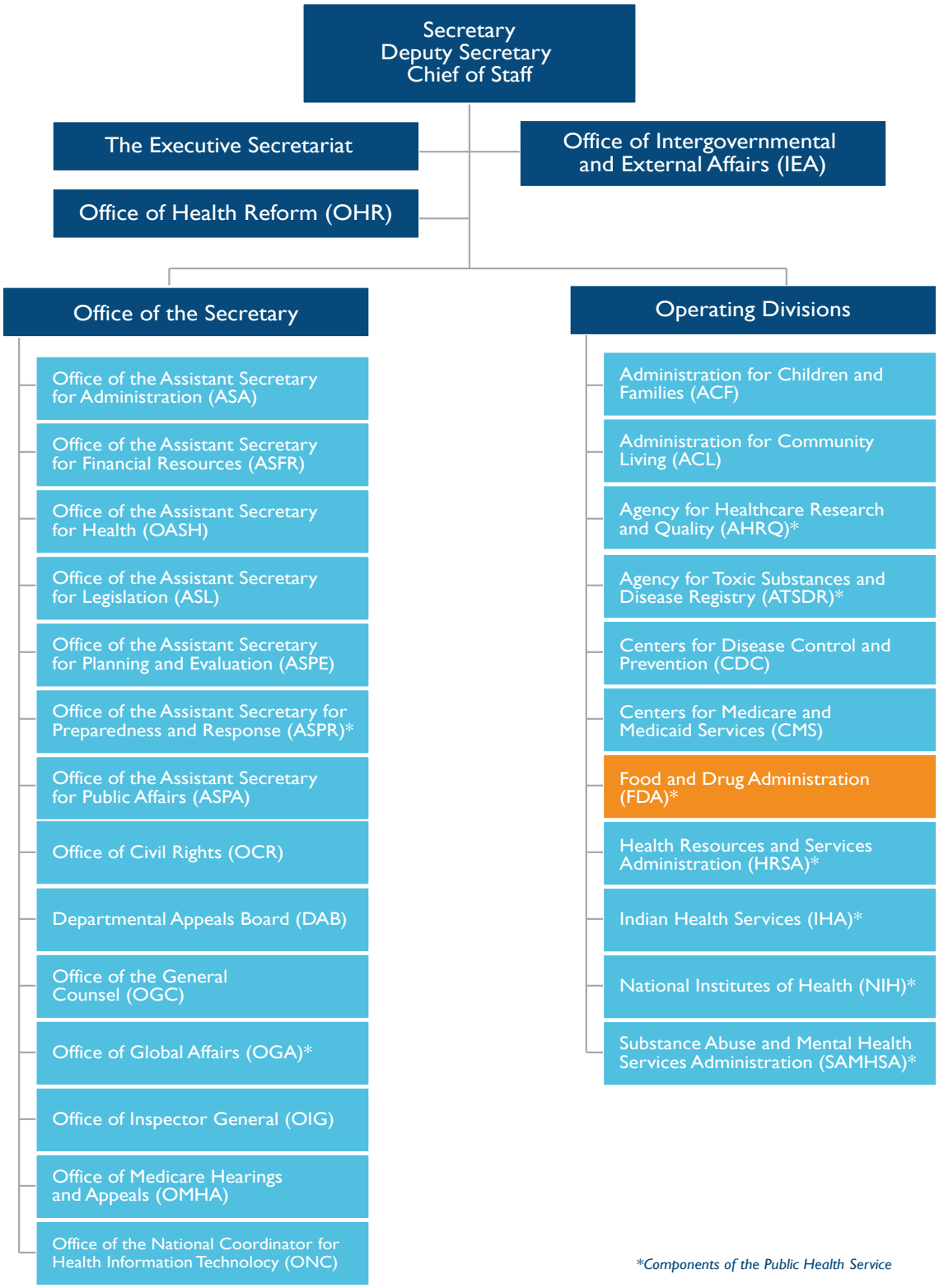


Data represent the volume of FDA-regulated product shipments subject to inspection at US ports of entry. The import volume data was drawn from the FDA's FY 2017 Budget Request, Office of Regulatory Affairs Narrative of Field Activities.

Chart 4: Innovation Hotspots

Innovation hotspots are defined in the report, *Battelle/ BIO State Bioscience Jobs, Investments and Innovation 2014,* as large, medium and small Metropolitan Statistical Areas that have the largest employment levels and location quotient (measure of job concentration within region compared to nation) in the following sectors: Drugs and Pharmaceuticals; Medical Devices and Equipment; Research, Testing, and Medical Laboratories; and Bioscience-Related Distribution.

Chart 5: Organizational Chart of HHS



*Components of the Public Health Service

Chart 6: The Flow of Rulemaking Today

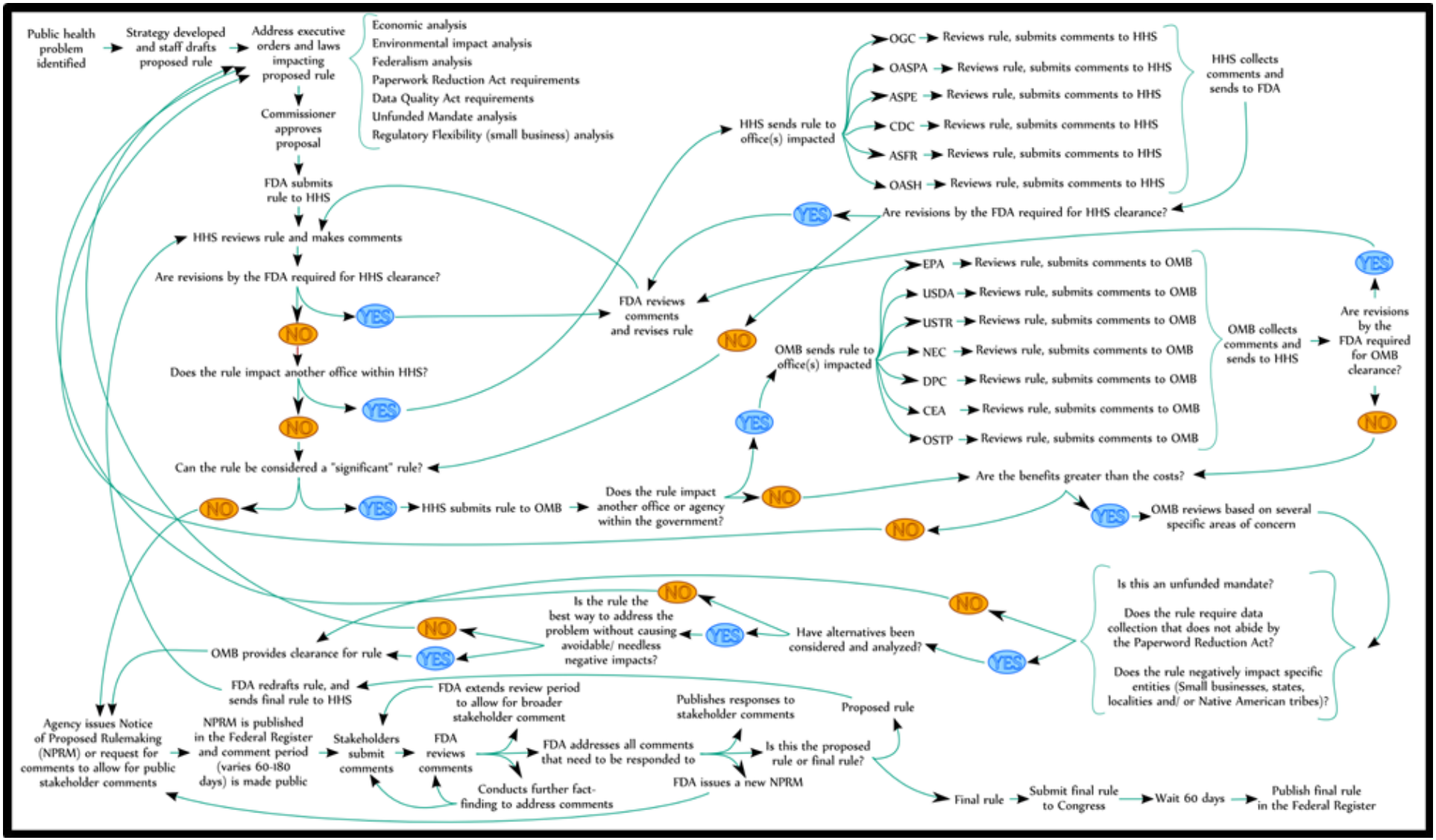


Chart 7: The Flow of Rulemaking Before 1981

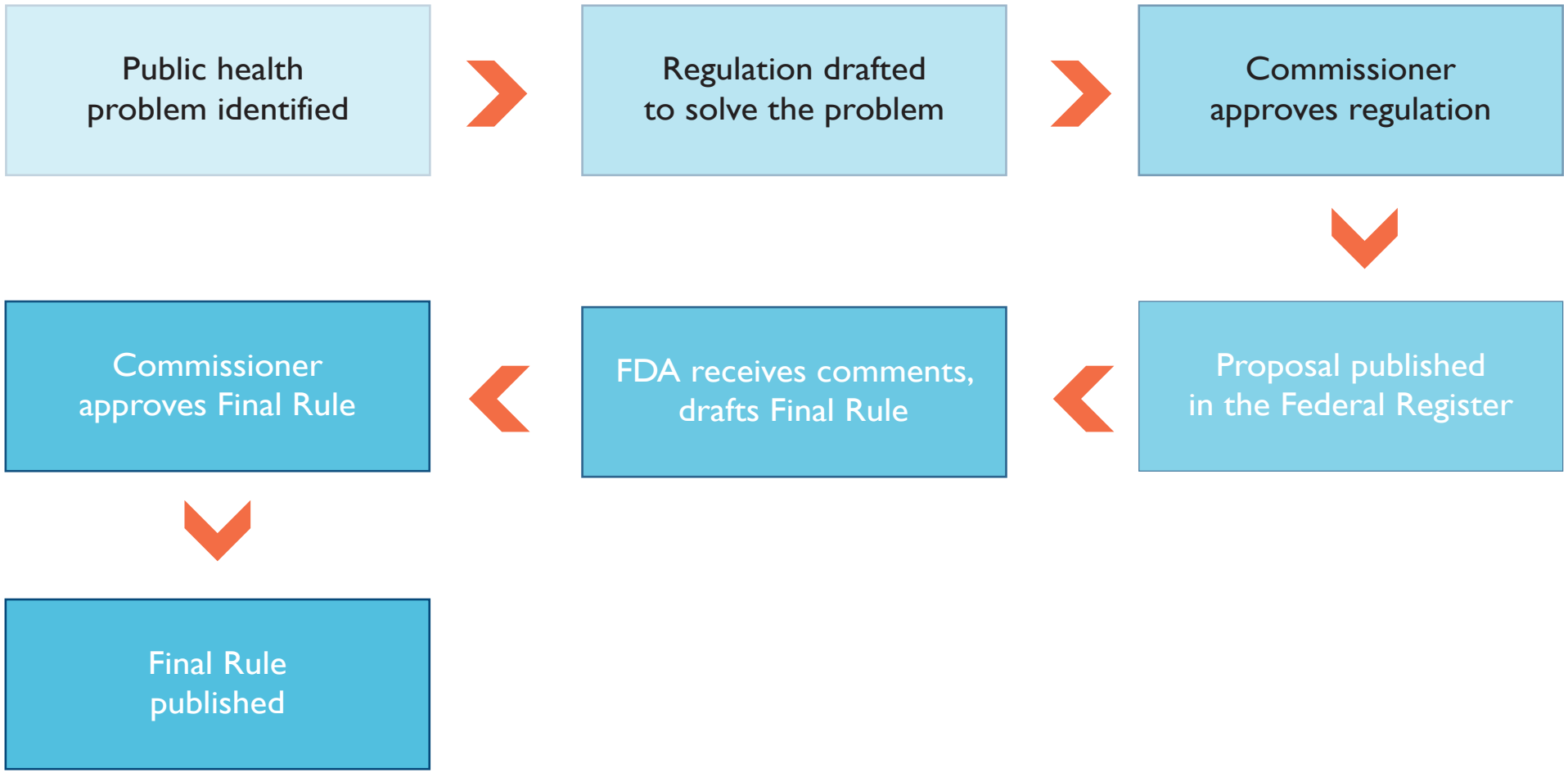


Chart 8: Avoidable Costs: Health and Financial Consequences of Delays in FDA Regulation

REGULATION	FIRST NPRM	EXPECTED COMPLETION	FINAL RULE	ANNUAL COSTS TO THE PUBLIC	COSTS TO THE PUBLIC OF DELAY
Infant Formula	July 9, 1996	January 9, 1998	June 10, 2014	$10 million	$164 million
Transfat Labeling	November 16, 1999	May 16, 2001	July 11, 2003	1,200 heart attacks; 480 deaths; $8.3 billion	2,600 heart attacks; 1,040 deaths; $18 billion
Dietary Supplements	March 13, 2003	September 13, 2004	June 25, 2007	48,000 illnesses; $44 million	132,000 illnesses; $123 million
Salmonella in Eggs	September 22, 2004	March 22, 2006	July 9, 2009	79,170 illnesses; $1,4 billion	263,920 illnesses; $4.7 billion
Produce for Human Consumption	January 16, 2013	July 16, 2014	November 27, 2015	1,750,000 illnesses; $925 million	291,666 illnesses; $1.3 billion
Blood Products and Transfusions	November 8, 2007	May 8, 2009	May 22, 2015	$95 million	$573 million
Labeling Requirements for Prescription Drugs and Biologics	December 22, 2000	June 22, 2002	January 24, 2006	$48 million	$172 million
Gluten-Free Labeling	January 23, 2007	July 23, 2008	August 5, 2013	$110 million	$554 million
Acetaminophen Warning Labeling	December 26, 2006	June 26, 2008	April 29, 2009	$17 million	$14 million
Antibiotics Labeling	September 19, 2000	March 19, 2002	February 6, 2003	$16 million	$14 million
Ephedra Ban	June 4, 1997	December 4, 1998	February 11, 2004	$132 million	$685 million
Juice Hazard Analysis Critical Control Point	April 24, 1998	October 24, 1999	January 19, 2001	$151 million	$188 million
Hepatitis-C Virus Lookback	November 16, 2000	May 16, 2002	August 24, 2007	$144 million	$759 million

METHODOLOGY FOR CHART 8

- Regulation: Sample drawn from a comprehensive list of regulations promulgated by the FDA since 1986. Rules selected as examples: 1) had clear cost/benefit language available; 2) had delays of 18 months or longer from First Notice of Proposed Rulemaking (NPRM) to Final Rule; 3) had significant health and cost impact on a large number of Americans.

- First NPRM: Date of publication in the Federal Register; Advance NPRMs are not included.

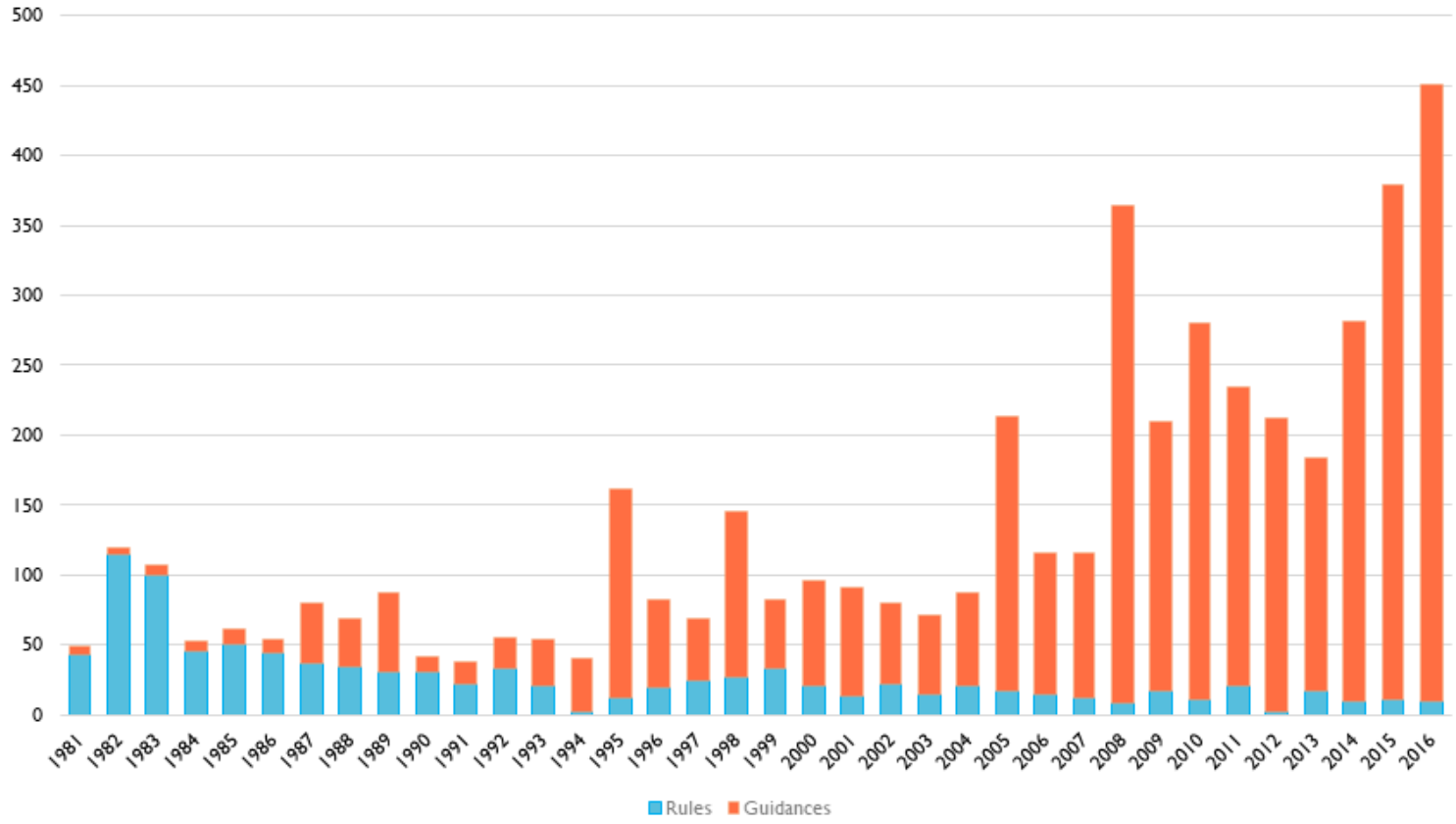
- Expected Completion: Assumes any regulation promulgated by the FDA should take 18 months to move from the NPRM stage to the Final Rule stage; these dates reflect that idealized 18-month completion period.

- Final Rule: Publication date of the Final Rule in the Federal Register.

- Annual Costs to the Public: Drawn from the Regulatory Impact Analyses published in the Federal Register for each Final Rule. Costs to the Public is defined as the annualized benefit(s) reported in the Federal Register. For purposes of this chart, any unrealized benefit, such as illness that could have been avoided, is defined as a cost.

- Costs to the Public of Delay: Calculated by dividing the Annual Costs to the Public by 365 to derive a daily average, then multiplied by the number of days between the Expected Completion date and the Final Rule publication date.

Chart 9: Increase in FDA Guidance and Rules



Data represent the number of guidance documents promulgated by the FDA and the number of FDA rules concluded in each calendar year. Data were drawn from the FDA's Guidance Document search tool and OIRA's regulatory action search.

The last twenty years, and especially the last decade, have seen an explosion in the mountain of regulation that the FDA has promulgated. Since the advent of OIRA and the greater intra-agency review of FDA regulatory action, the role of rules has diminished in comparison to guidances. We have not distinguished in this chart between the rules and guidances that arise "organically" within the FDA and those that are promulgated in response to legislative requirements.

Chart 10: Simplified Approach to Rulemaking

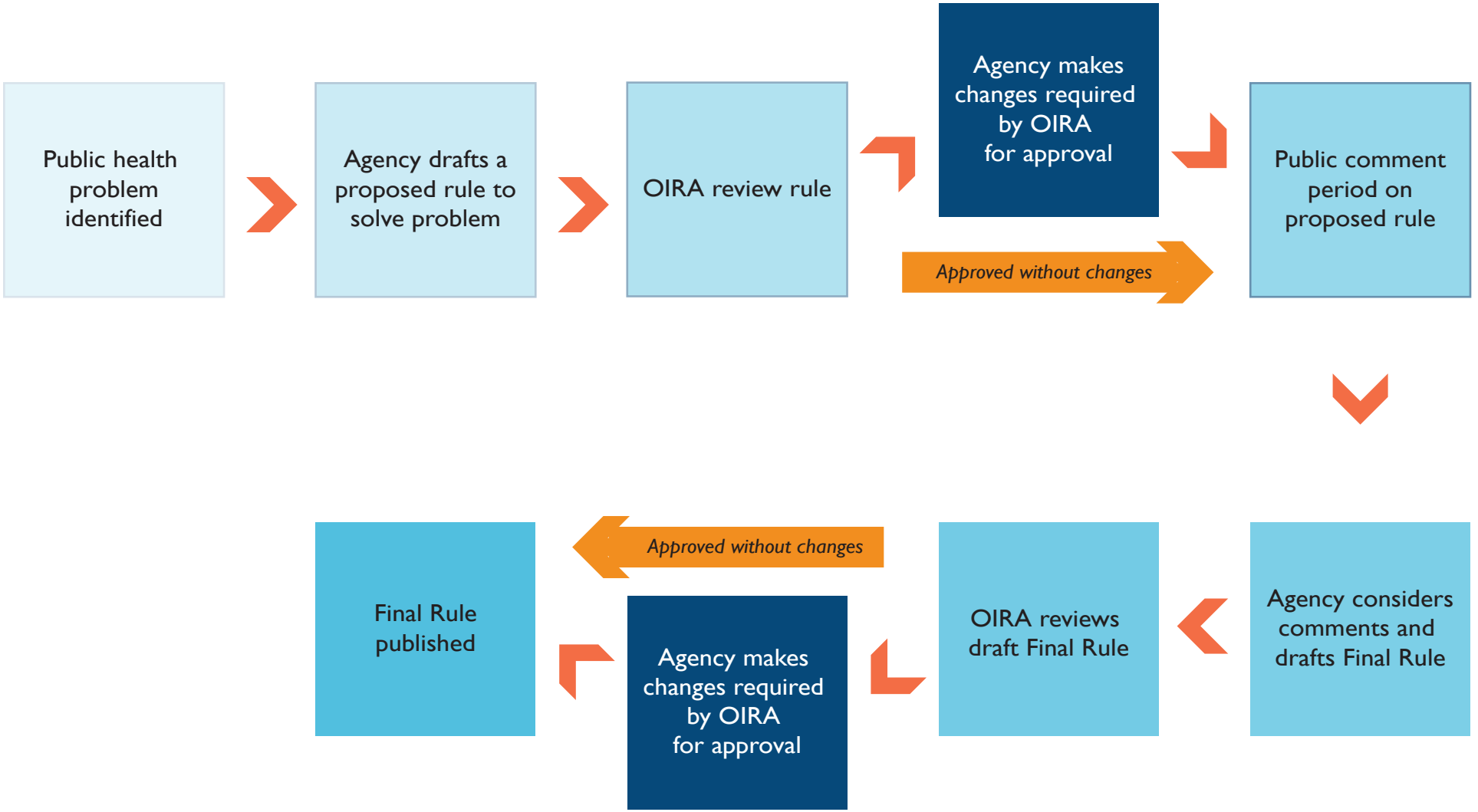


Chart 11: Agency Models within the Federal Government

	INDEPENDENT COMMISSION (REGULATORY)	EXECUTIVE AGENCY	FDA'S CURRENT STRUCTURE
Organization within the Government	An independent regulatory agency technically within the executive branch but operationally outside the reach of the executive and legislative branches. (e.g., FCC)	An independent agency with a mix of regulatory and non-regulatory functions within the executive branch of the U.S. government. (e.g., EPA)	A regulatory agency within the Health and Human Services Department.
Top Leadership	A bipartisan commission or board with the majority appointed by the President and confirmed with advice and consent of the Senate.	A single director, appointed by the President and confirmed by the Senate, who reports directly to the President.	A single Commissioner, appointed by the President and confirmed by the Senate, whose power and authority derives from the Secretary of HHS.
Term Limits	Staggered, 5-year terms	None, serves at the pleasure of the President	None, serves at the pleasure of the President
Removal without Cause	No	Yes	Yes
Funding Source	Fees and/or Appropriations	Appropriations (and fees in some cases)	Appropriations and fees
Appropriations Request	Submitted directly to Congress	Reviewed by OMB and submitted to Congress in the President's Budget	Reviewed by HHS then OMB before submission to Congress in the President's Budget
Rulemaking Authority	Governed by the strictures of the Administrative Procedure Act (APA) (Notice of Proposed Rulemaking, comment period, etc.). Limited external oversight in discrete situations (regulations impacting small businesses, regulations greatly impacting economic stability, etc.).	Governed by the strictures of the APA and constrained by the agency's enabling legislation, as well as by subsequent Executive directions and memoranda.	Rulemaking authority derived from the Secretary of HHS. Must conform with the APA and go through normal agency oversight procedures (OMB OIRA review, etc.).
OMB Oversight	No	Yes	Yes
Litigation Authority	Some independent commissions have independent litigation authority; these commissions generally partner with DoJ in substantive actions in federal court.	Executive agencies generally must rely on DoJ's legal staff to conduct litigation. Some agencies have limited powers to litigate administrative matters in-house.	Devolves to HHS and then to DoJ.

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