



BUT WHO RULES THE RULEMAKERS?

A STUDY OF ILLEGALLY ISSUED REGULATIONS AT HHS

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EXECUTIVE SUMMARY

An endless expansion of federal agency rules threatens American prosperity, which once was the envy of the world. A thicket of red tape undermines economic growth, job creation, individual liberty, and, in some ways, the rule of law itself.

Most regulations seek to better protect people or the environment, but only a tiny fraction of the rules issued have reliable cost estimates, and those costs often exceed the projected benefits. A 2016 study by the Mercatus Center at George Mason University estimated that burdensome regulations cost Americans \$4 trillion in economic growth from 1980 through 2012, resulting in a loss of nearly \$13,000 per American. The public bears these costs directly and indirectly through higher prices for goods and services, reduced consumer choices, stagnant wages, lost jobs, and limitations on their freedoms. Businesses don't "absorb" these losses—people do.

Researchers and government officials are increasingly concerned about the growth of the regulatory state and its drag on American prosperity. Besides exploding costs, binding rules issued by countless agency bureaus and departments dwarf the laws passed by Congress. The rule of law is severely strained when hundreds of offices are issuing thousands of rules that no one can possibly read.

To fix these deep-seated problems, policymakers and the public need to understand what's driving the increase in regulation. One possible culprit has never been studied before: a large expansion of rulemakers who are not democratically accountable. These unaccountable rulemakers are not constitutionally authorized to issue final rules that have the force of law. But, as this study shows, that hasn't stopped them.

The Appointments Clause: Making Our Rulers Accountable to the People

The U.S. Constitution requires executive branch officials who exercise significant authority and discretion to be formally appointed in a manner the Appointments Clause specifies in Article II, Section 2. All principal officers must be nominated by the President and confirmed by the Senate before they are appointed. Inferior officers must undergo the same process unless Congress by law authorizes their appointment by the President or a department head. The Framers specified these appointment rules to ensure that all high government officials who exercise significant power over us would be accountable to the people in a meaningful way. The Supreme Court established 43 years ago that rulemaking was one of those significant powers that only democratically accountable officers appointed in this manner could exercise. Rightly so.

Permanent career staff in regulatory agencies have important jobs, but they are not democratically accountable to the people in this manner. They shouldn't be issuing regulatory law that governs us. Their rules simply aren't valid.

Study Findings: Unconstitutional Rulemaking Procedures Are Rife at HHS, Especially at the FDA

Pacific Legal Foundation (PLF) analyzed the rulemaking practices of one executive department over several administrations. In a first-of-its-kind study, the researchers examined every regulation issued by the Department of Health and Human Services (HHS) from 2001 through 2017 (2,952 rules). The study focused on who issued each final rule, the rulemaker's authority, and the rule's significance.

The study found that a majority of HHS regulations were illegally issued by low-level officials or career employees who had no authority to do so. The Food and Drug Administration (FDA) was the most frequent and clear-cut violator. The FDA's illegal rules were so numerous that they skewed the results for the rest of HHS.

Nearly three-fourths (71%) of HHS rules are unconstitutional based on who finalized and issued them.

KEY FINDINGS:

- Nearly three-fourths (71%) of HHS rules are unconstitutional based on who finalized and issued them.
- The majority of unconstitutional rules at HHS (89%) were issued by the FDA. Among FDA final rules, 98% were issued by career employees who have no constitutional authority to do so.

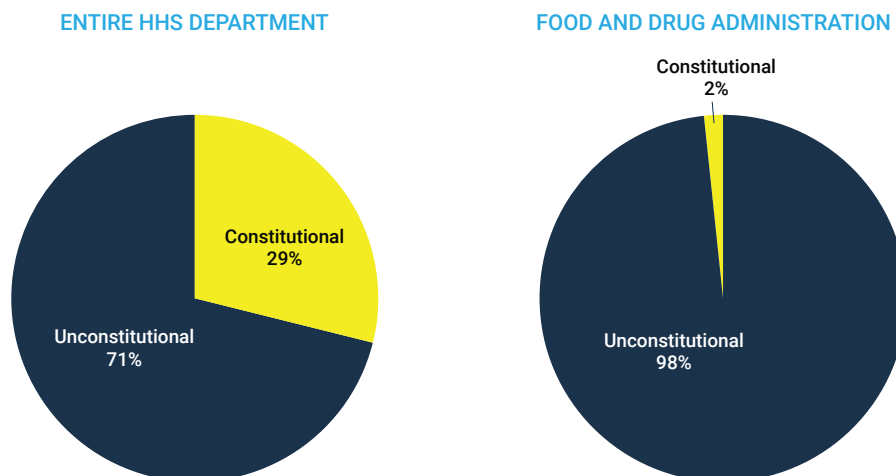
- In contrast, only 25% of Centers for Medicaid and Medicare Services rules were issued by someone other than a Senate-confirmed officer of the United States.
- Among substantive final rules considered to have a significant regulatory impact by the Office of Management and Budget, 80 from the FDA were unconstitutional—93% of all substantive and significant HHS rules. Twenty-five of those rules had an economic impact of over \$100 million each.

Examples of Illegal Rules Uncovered

Ample evidence shows that HHS's unconstitutional rulemaking has real and serious effects on Americans who live and work under a regulatory regime that is increasingly unrestrained and unaccountable.

Vaping store retailer Steve Green of California cannot share his story of quitting a 30-year smoking habit and recovering from early signs of emphysema without first obtaining government permission, thanks to an FDA rule that affects him and other entrepreneurs.

Figure 1: Percentage of Constitutional and Unconstitutional Final Rules, 2001–2017



Under FDA rules, dairy farmers such as Randy Sowers of Frederick County, MD, cannot call their skim milk “skim milk” without first adding artificial vitamins.

Even rules with beneficial impacts are at risk if they were illegally issued. Tens of millions of patients who rely on low-cost generic drugs may find their treatment options limited in the future due to slowed approvals of new generics, if courts strike down a helpful FDA rule issued by an FDA employee.

What Can Courts, Congress, and the White House Do?

Regardless of the precise cost of illegal regulations, the existing unconstitutional rules should be struck down by the courts when individually challenged. Rules can then be reissued using constitutional means. The agencies, litigants, and courts can also devise interim regulatory solutions on a rule-by-rule basis.

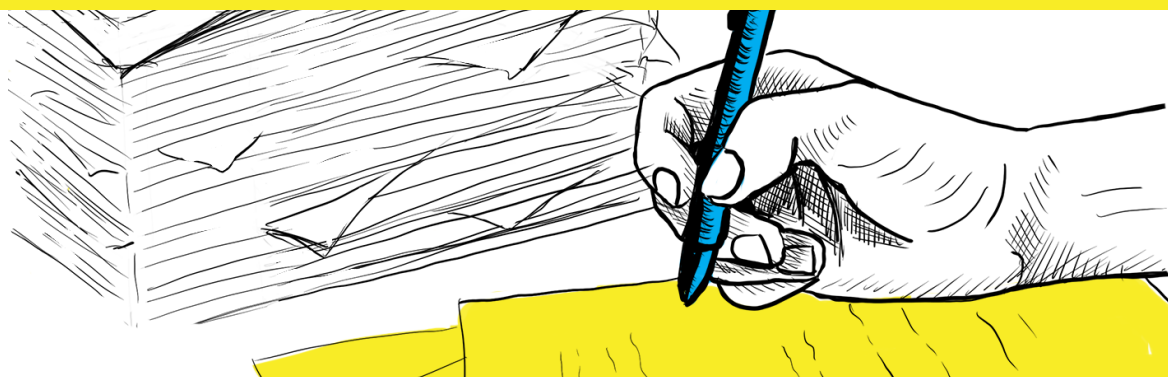
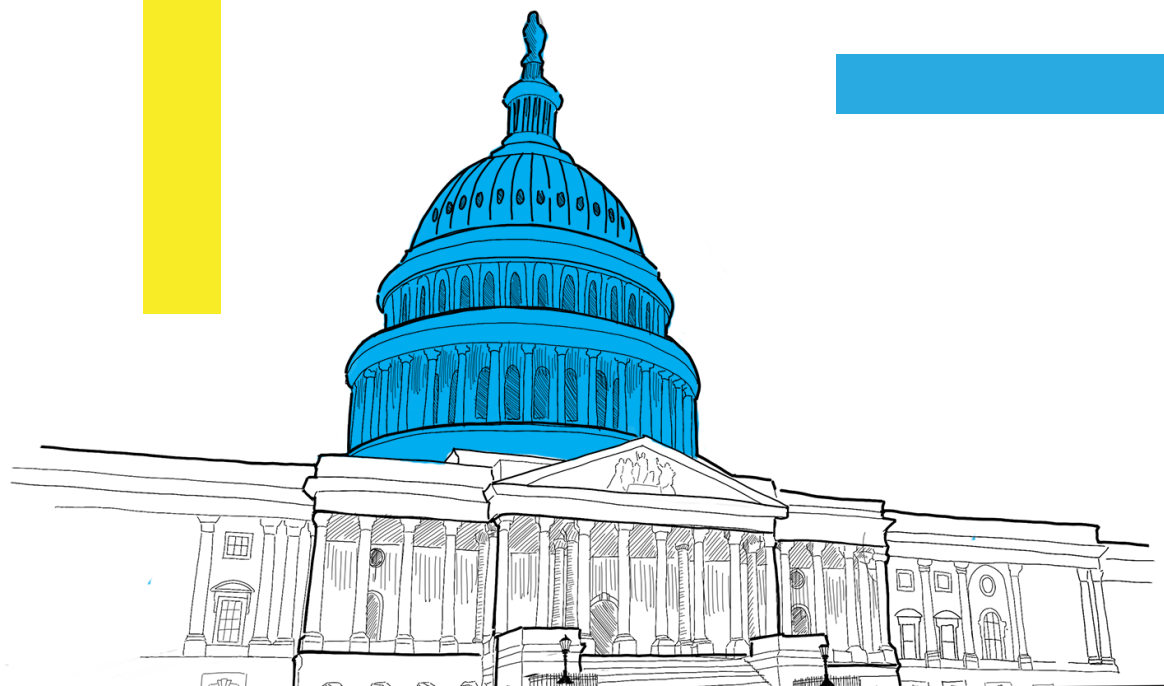
To restore democratic accountability to the regulatory process in the future, the following reforms should be implemented:

- Congress needs to ensure that rulemaking under statutes it enacts is exercised solely by democratically accountable officers—principal officers nominated by the President and confirmed by the U.S. Senate. It can do so by using confirmation hearings, appropriations bills, and regulatory reform legislation. Congress also needs to expressly prohibit delegations of rulemaking authority from Senate-confirmed officials to career bureaucrats.
- The President can act on his own. With a stroke of his pen, he can and should order his senior appointees to take personal responsibility for regulations issued during his administration.

The current administration made a serious commitment to reduce the regulatory burden, and numerous members of Congress from both parties share this goal. For these reform-minded leaders, ending the unconstitutional practice of delegating authority for issuing final rules should be a top priority.

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INTRODUCTION

American democracy is built on the separation of powers. No branch of government has absolute power, and each serves as a check on the others. For example, although Supreme Court Justices may invalidate the laws passed by Congress and signed by the President, they can take office only after securing a presidential nomination and Senate confirmation. Only Justices who have gone through this vetting

process by the other branches are eligible to issue opinions binding on all Americans.

But suppose that a Supreme Court Justice authorized his law clerks to issue opinions in their own names? What if this went on for 17 years, and no one noticed? The Constitution would not have been ratified if the Framers proposed that *employees* of the federal

judiciary—neither appointed by the President nor confirmed by the Senate—could issue opinions that are legally binding on the public. Such a practice would render the carefully designed system of interbranch checks and balances pointless.

By the same token, the Constitution would not have been ratified if career employees in the executive branch—employees neither appointed by the President nor confirmed by the Senate—could issue final and irreversible regulations that would be legally binding on the public. Yet unlike our law clerk hypothetical, this violation of checks and balances is actually happening: Career employees in some agencies are purporting to issue binding regulations under their own name and authority.

This method of rulemaking is unconstitutional. It is unconstitutional for career employees—instead of democratically accountable officers

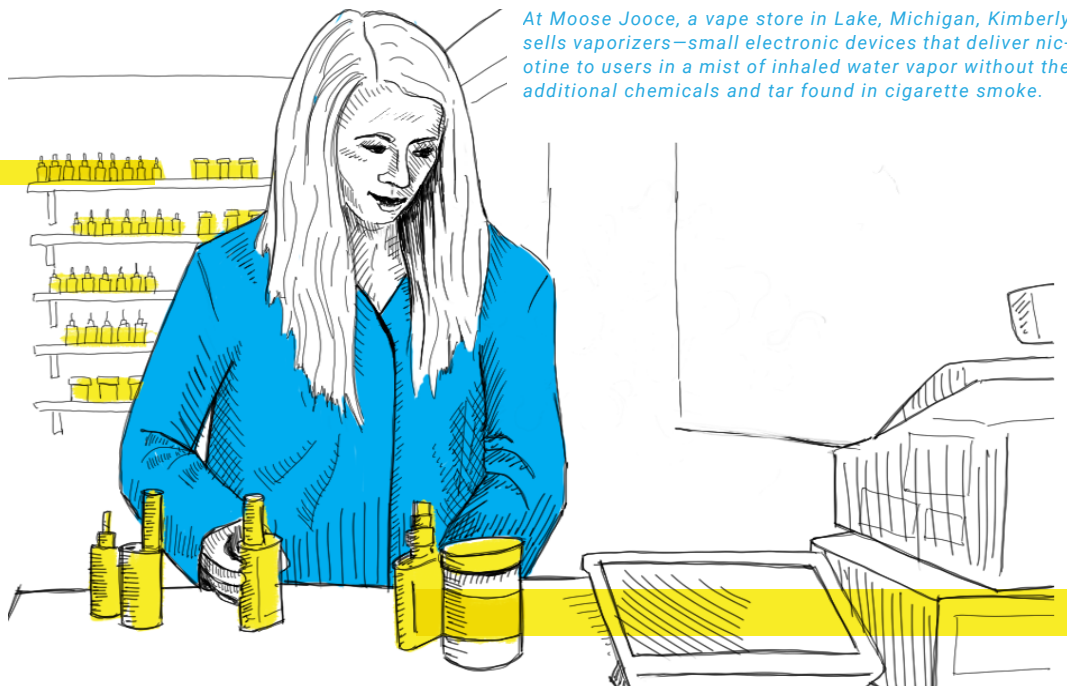
of the United States—to establish the rules that govern us. The Supreme Court has already held that the power to set national policy through regulations must be exercised solely by *officers*. Subsequent cases and the original meaning of the Appointments Clause lead strongly

to the conclusion that only Senate-confirmed *principal officers* may issue rules. There is no doubt that career employees may not do so.

This study is the first to examine and present the facts regarding rulemaking by career agency employ-

ees. Those facts inform both the legality of their rulemaking and many policy issues surrounding the practice. When these facts are known, Americans can insist that the courts, the President, and Congress prohibit this type of lawmaking by unelected regulators. We hope this study will also spark a broader debate about holding regulatory agencies accountable to the constitutional rules for rulemaking.

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At Moose Jooce, a vape store in Lake, Michigan, Kimberly sells vaporizers—small electronic devices that deliver nicotine to users in a mist of inhaled water vapor without the additional chemicals and tar found in cigarette smoke.

WHAT'S AT STAKE?

The growing thicket of red tape created by countless federal regulations stifles American economic growth, wages, and job creation. It raises prices, limits consumer choice, and restricts individual liberty. The toll on economic growth alone is significant. From 1980 through 2012, regulations cost Americans \$4 trillion in economic growth—\$13,000 per person.¹

The goals of most regulations are worthy—to better protect individuals and the environment—yet only a tiny fraction of regulations are issued with reliable cost estimates.² And even then, many regulations have projected costs that exceed the agencies' estimates of public benefits.³ Despite recent Supreme Court rulings that encourage or require cost-benefit analysis,⁴ many regulatory agencies still interpret ambiguous statutes they administer as prohibiting the consideration of costs in their regulatory decisions. Ignoring the costs of regulation allows agency regulators greater discretion to impose massive costs on the public with minor benefits.

The cumulative regulatory costs all Americans suffer are troubling, but the impact of many regulations falls especially hard on particular individuals. For regulations that are unwarranted or illegal, such personal hardships are unjust. This study uncovers hundreds of HHS rules issued in an illegal manner. Many of these rules are also onerous and problematic for other reasons, as the following examples highlight.

After her husband passed away from lung cancer, Kimberly Manor started an innovative business to help longtime smokers quit. At Moose Jooce, a vape store in Lake, Michigan, Kimberly sells vaporizers—small electronic devices that deliver nicotine to users in a mist of inhaled water vapor without the additional chemicals and tar found in cigarette smoke. Kimberly's business prospered, and she has helped hundreds of people in her small town to quit smoking.⁵

Unfortunately, the Food and Drug Administration (FDA) threw a wrench in Kimberly's business model. In 2016, the FDA created a rule deeming vaping products—vaporizers and the liquid used in them—to be subject to the same restrictions placed on cigarettes under the Tobacco Control Act of 2009, even though vaping products contain no tobacco.⁶

Vaping allows people to obtain nicotine and mimic the experience of smoking without the major causes of cancer—combustion gases, smoke, and tar. Nicotine is extracted from a plant in the tobacco family or from synthetic tobacco. Because vaping can be customized for the user, former smokers can gradually reduce their nicotine intake by using liquids with declining nicotine levels and eventually no nicotine at all. For example, vaping helped Steve Green, the owner of Mountain Vapors in Sonora, California, quit smoking after 30 years and recover from early signs of emphysema.⁷

The Deeming Rule, as the FDA's regulation of vaping devices is called, imposes years of regulatory hurdles and hundreds of thousands of dollars in costs per product, which is stifling innovation and harming small shop owners across the country. The rule's mandates take effect in stages. In 2021, it will require "premarket" approval to keep existing vapor products on the market, which means each liquid with a different flavor or different level of nicotine, including liquids with no nicotine, will have to be approved individually through a lengthy process at a cost of up to \$466,000 (by the FDA's own estimation).⁸ And any product introduced after the Deeming Rule went into effect in 2016 must go through this process *immediately*, which has effectively halted innovation.

Steve notes that the "restrictions stop me from sharing my personal story."

For Kimberly and Steve, this rule also means they are no longer able to repair products for their customers. This premarket approval process will be prohibitively expensive for small business owners across the country, while big companies can better afford the approval process for their few vaping products.⁹

In addition to stifling Kimberly's and Steve's ability to sell vaping products, the Deeming Rule also limits their free speech. No matter how accurate their product descriptions and ingredient lists are, they must secure FDA approval for them. In addition, they are severely restricted in their ability to advertise or educate consumers about how they can quit smoking using vaping products without FDA approval for their speech.

Steve notes that the "restrictions stop me from sharing my personal story." As he explains, "For years, I smoked 2-1/2 packs of cigarettes a day, and it nearly gave me emphysema. Vaping freed me from my addiction, and the doctor says I've recovered."¹⁰

Beyond making it expensive and onerous for entrepreneurs, vapers, and cigarette smokers who want to quit, the Deeming Rule has a more fundamental problem: The rule was issued by a career employee. While the employee has been with the FDA for 30 years and was promoted to a senior career position, she was never nominated by any President or confirmed by the Senate for any democratically accountable office. For that basic reason, the rule was illegal the moment it hit the books. Tenure does not confer constitutional authority.

The Constitution requires regulations to be issued by appointed officials subject to the democratic process, not by unelected public servants. The career employee who issued the Deeming Rule, Leslie Kux, probably didn't know that the rulemaking power she was asked to exercise was unconstitutional. But good intentions can't transform an illegal rule into a legal one.

Kimberly and Steve have teamed up with Pacific Legal Foundation to sue the FDA over this unconstitutional practice of using career bureaucrats to issue rules binding on Americans. In early 2018, PLF attorneys challenged the Deeming Rule with three lawsuits, representing eight small vaping businesses and the non-profit Tobacco Harm Reduction 4 Life.¹¹ In these and other lawsuits, PLF's clients seek to enforce the constitutional separation of powers and the democratic accountability that the Founding generation established in the Constitution.

Vaping store retailers are only one example of those harmed by illegal regulations uncovered by our research—regulations that restrict individuals and small businesses across the

country. In another example, dairy farmer Randy Sowers is required to call the milk produced by his cows "imitation skim milk" for the sole reason that he skims the fat off it and does not add synthetic vitamins.¹² He is not allowed to call it what it is, skim milk, because of a rule signed by an unelected public servant.¹³

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Even the rules that do effectively promote the health and safety of Americans are at risk of being invalidated if they were issued in an illegal manner. For example, Congress passed a law authorizing an expedited approval process for generic drugs,¹⁴ and the FDA subsequently issued a regulation governing what that new approval process would be.¹⁵ The new process essentially eliminated the wait for generic drug approvals—

what had been a list of 2,800 applications was slashed to around 100 applications.¹⁶ The lower prices resulting from new approvals during an 18-month period were estimated to save Americans \$26 billion.¹⁷ But the FDA rule that established the new process was issued by a career employee. The rule is therefore unconstitutional, despite its benefits.

STUDY OBJECTIVES AND ORGANIZATION

This report is the first to systematically review whether final rules published in the *Federal Register* are constitutional based on who signed and issued them. The next section provides the context for the factual findings that follow, explaining both *how* such subdelegation of rulemaking authority violates the Constitution and *why* it is a serious problem for both democracy and liberty.

The report then presents the research on how common it is for HHS agencies to rely on unconstitutional rulemaking by low-level officials and employees. We analyzed all the final rules issued by HHS during the past 17 years, focusing on the individuals who actually made each final decision to enact a rule binding on the public. Unfortunately, the practice of having

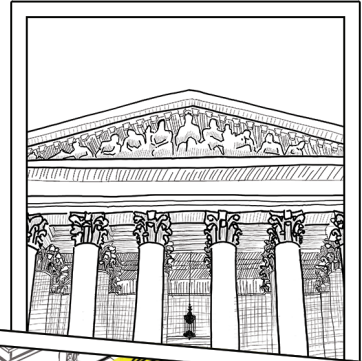
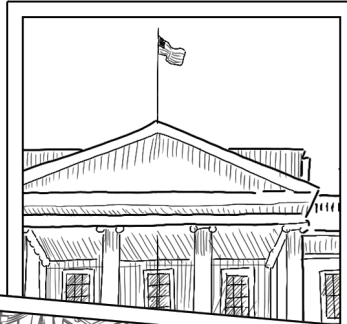
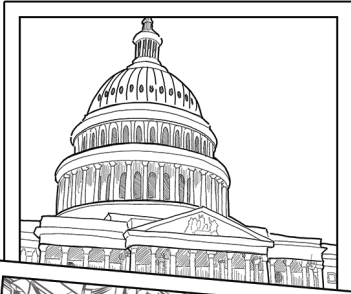
career staff sign final rules such as the Deeming Rule is especially common for FDA rules. Our results show that the FDA is an outlier among the various units of HHS, though it is not the only unit to impose rules without democratic controls.¹⁸

By examining, in detail, the frequency and variability with which each HHS agency has complied (or not complied) with the Appointments Clause in its rulemaking activities, this study also suggests the need to evaluate the problem across the federal government. The report's final section sets forth possible solutions to end unconstitutional rulemaking procedures.

Legislative

Executive

Judicial



Administrative



CONSTITUTIONAL AND UNCONSTITUTIONAL RULEMAKING

Separation of Powers

The U.S. Constitution established a republic with a unique design for the separation of governmental powers. The effective division of government powers was the most important point of agreement among the Framers and ratifiers of the Constitution, and its refinement was *and* has remained the most important innovation in constitutional democracy since 1689.¹⁹

The Constitution requires the President to faithfully execute the laws passed by Congress.²⁰ The Framers knew, however, that the President alone could not carry out all executive functions. The Constitution therefore created a process for appointing executive-branch department heads and other senior government officials (including those in the judiciary) who may serve as “officers of the United States.” Governed by the Constitution’s Appointments Clause, this process ensures that even unelected officers are democratically accountable

in a particular manner. The Appointments Clause specifies the acceptable methods to fill senior executive- and judicial-branch officers. Only these officers may be granted significant decision-making authority.

The text of the Appointments Clause recognizes two levels of officers and specifies how each may be appointed:²¹

- All “principal officers” are nominated by the President, and the Senate must consent before the President appoints them. Ambassadors, Supreme Court Justices, and certain other public ministers must follow this route. Department heads also fall in this category by implication since they are not inferior officers.
- “Inferior officers” must be appointed in this same manner unless Congress enacts a law making an exception to Senate confirmation. Even then, the alternative methods of appointment are limited. Congress may by law vest the appointment of an inferior officer in the President alone, in the heads of the executive departments, or in the courts of law.²²

The Appointments Clause ensures that the Senate will vote on the appointment of every significant federal official unless Congress makes an exception by law for specified lesser officers—whose appointments are still politically controlled. In this manner, all officers are politically responsible to the executive and legislative branches either directly, in the case of all principal officers, or indirectly, in the case of inferior officers. These officers can, in effect, be voted out when administrations change. As an organization, the executive branch is largely

composed of departments headed by department secretaries. All department heads are principal officers. They must be nominated by the President and confirmed by the Senate. Congress may give them authority to appoint constitutional inferior officers.

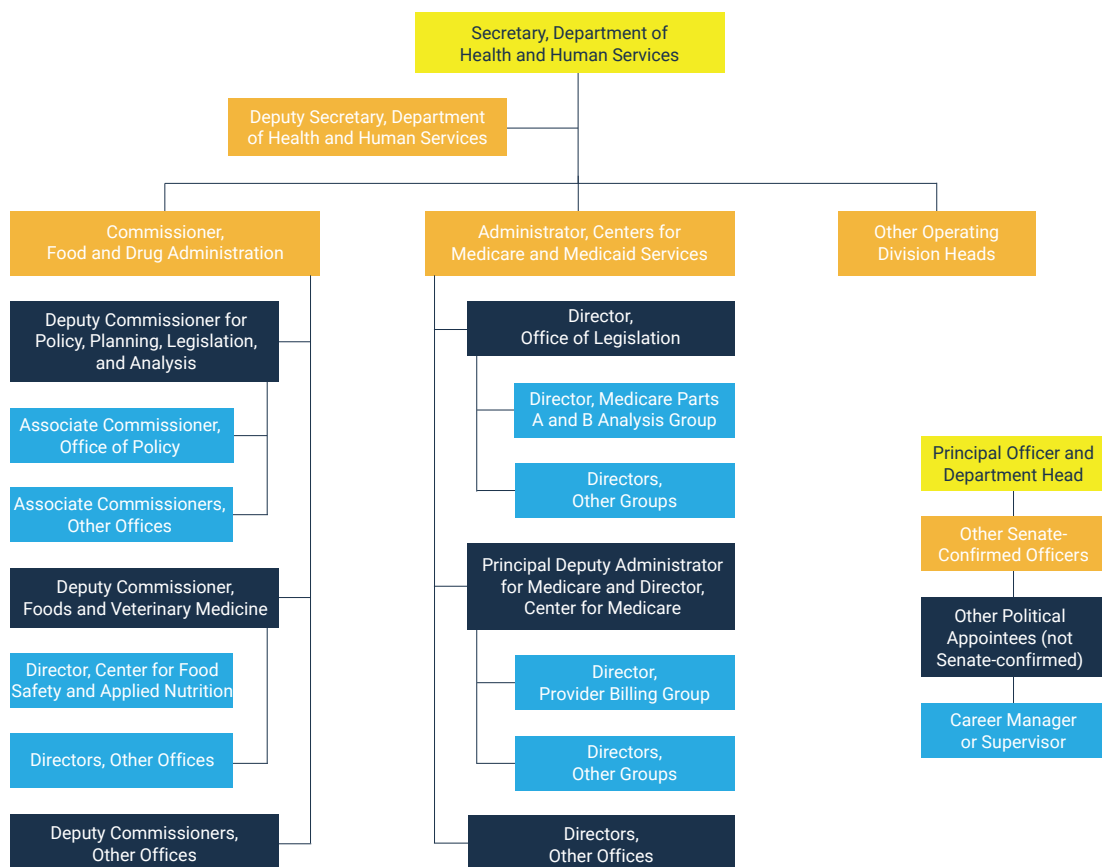
In large departments and agencies, the undersecretaries, assistant secretaries, and directors of large bureaus manage major divisions within the department. The FDA, which is headed by a commissioner, is one of the bureaus within HHS. Congress normally requires Senate confirmation for such senior division or bureau chiefs. Senate-confirmed division heads are “officers of the United States.” Some may even be principal officers, depending on the degree of independence conferred on their office and, especially, whether their duties are reviewable by others besides the President. (Appendix A provides a further explanation, but as an example, all U.S. ambassadors are designated as principal officers in the Constitution even though they serve under the Secretary of State in the State Department.)

Below the assistant secretaries and bureau chiefs, deputy assistant secretaries and deputy bureau chiefs often supervise distinct offices. However, only those appointed by the President or a department head may exercise the duties of an inferior officer. Perhaps for this reason, Congress often confers the appointment of deputy assistant secretaries and deputy bureau chiefs on the department head, and not on the division chief to whom they will report. Regardless, assistant secretaries and bureau chiefs may also be permitted to hire noncareer special assistants and other deputies to help manage the division—as long as those hires do not exercise the duties of “officers of the United States.”

Thus, large departments are typically managed by several layers of democratically accountable officers and senior political appointees: the department head and division heads (all are usually Senate-confirmed officers), deputy assistant secretaries or deputy bureau chiefs (some of whom may be inferior officers), and certain other political appointees. Together, they direct the work of career employees, including career managers and career supervisors. Career managers and supervisors, however, are not “officers of the United States” in the constitutional sense.

Figure 2 shows an abridged version of the Department of Health and Human Services’s organizational structure, with some of its constitutional officers, other political appointees, and career managers. For illustration purposes, the chart focuses on the FDA and the Centers for Medicare and Medicaid Services (CMS), which are comparable divisions of HHS in many respects.

Figure 2: Abridged Organizational Chart of HHS, Featuring the FDA and CMS



Note: HHS’s complete organizational chart is at <https://www.hhs.gov/about/agencies/orgchart/index.html>.

Executive Rulemaking

Executive agencies must fill in any gaps left by Congress in the regulatory laws they administer. Although agency rulemaking is not the only means to specify how laws will be implemented, it is often required by the underlying statute to fill in the basic details of a regulatory scheme.

Lawful final rules issued through agency notice-and-comment procedures are binding on the public. So long as they are in effect, they have little functional distinction from the statutes passed by Congress. And their importance has only increased since the Supreme Court required courts to defer in many instances to these rules in their interpretation of relevant statutes.²³

Congress's tendency in recent decades to enact laws with broad mandates and few regulatory details has left enormous discretionary gaps for agencies to fill. Such broad congressional delegations have led to an explosion of agency regulations that dwarf the number of congressional statutes passed every year—an average of 28 rules for every statute passed.²⁴ The rule of law is strained since no one can possibly know the tens of thousands of rules churned out by regulatory agencies. That makes democratic accountability of the regulatory decisionmakers even more important.

To be sure, many voices can contribute to a rule's content, including those of agency staffers and policy experts. Further, many significant rules go through internal review processes before they are issued, including at the Office of Information

and Regulatory Affairs. But no matter how many people influence a rule, one official ultimately determines its final content and whether to issue it and bind the public. That official issues the rule in his or her own name.

The significance of this executive rulemaking power led the Supreme Court to correctly conclude—over 43 years ago—that the power to issue final rules can only be exercised by a constitutional officer of the United States appointed according to the Appointments Clause.²⁵

Though it is clear that nonofficers may not issue rules binding on the public, an authoritative court has not yet ruled directly on whether an inferior

officer may do so. Even so, the rationale of several recent rulings discussed in Appendix A casts serious doubt on whether inferior officers can issue final rules since no higher official can alter a final rule without another rulemaking. In sum, a published rule is a final, unreview-

able, and unalterable executive action.

Elected members of Congress should care about how the laws they pass are interpreted and implemented and who is responsible for doing so. This may be one reason why Senate confirmation is a grueling process, and many officer nominees are either rejected or never receive a vote.²⁶ Through this process, the Senate carefully evaluates and tests potential officers who will exercise significant power. In some cases, the Senate may even secure commitments from the nominee that may later lead him or her to resign if the President demands an action that would violate that commitment.²⁷

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The confirmation process also constrains the President, who won't nominate and can't appoint someone who doesn't survive Senate confirmation. Though appointees are primarily accountable to the President after appointment, they will rarely serve him well if they don't maintain a good relationship with Congress. The departments and agencies that appointees run may be starved of funds and checked in other ways if appointees frustrate elected representatives in Congress. Principal officers are also expected to periodically testify before Congress on the statutes they administer and issue a stream of reports on various topics, including whether new legislation may be justified.

Even inferior officers who are appointed without Senate confirmation owe their office to a congressional statute granting an exception to Senate confirmation, and their political appointment makes them either directly responsible to the President or indirectly responsible through the department head. Inferior officers are also frequently called before Congress to testify or provide written reports and other information. Moreover, they are generally swept in and out of office with the change of administrations (even within the same party) or even the change of an individual department head. They too essentially owe their continued appointment to the voters.

Though Congress has some means to enforce the Appointments Clause, it does not protect congressional interests alone. As such, Congress cannot lawfully consent to or acquiesce in its violation. Like other separation of powers principles, the Appointments Clause ultimately protects the liberties of the American people. As the Supreme Court has explained, the Appointments Clause "is a bulwark against one branch aggrandizing its

power at the expense of another branch, but it is more: it 'preserves another aspect of the Constitution's structural integrity by preventing the diffusion of the appointment power.'"²⁸ Whether Congress has abdicated its role knowingly or unknowingly is ultimately irrelevant because, as the High Court explained, "the separation of powers does not depend on ... whether 'the encroached-upon branch approves the encroachment.'"²⁹

The Proper Role of the Career Civil Service

Civil servants are consciously employed outside of the political or electoral process. Neither the President nor an elected member of Congress exercises meaningful control over the views, biases, and opinions of career civil service employees. Such employees are by statute required (with few exceptions) to be hired solely based on merit and can be removed from office only for limited reasons. They also enjoy administrative appeals and potential judicial review of any dismissal. Career civil servants do important work, but they are not hired or fired based on their policy views or political judgment.

That limitation is by design in the civil service system, and it was regarded as an important reform against political patronage and the politicization of lower-level government employees when Congress instituted it in the early twentieth century. The corresponding trade-off is that such nonpolitical employees cannot exercise meaningful policy or political discretion. Rulemaking is the quintessential policy and political function.

Congress's broad grants of rulemaking authority to regulatory agencies—with little or no statutory guidance except the regulatory subject matter (e.g., establishing worker safety standards

that are “appropriate,” ensuring food safety, establishing communications policy “in the public interest”)—are themselves constitutionally questionable. But the constitutional problem is magnified if the grant of rulemaking power to a cabinet secretary or other principal officer is redelegated to inferior officers and especially to nonofficers.

Our research uncovered a plainly illegal subdelegation of authority that occurred within HHS and the FDA more than 25 years ago, establishing a practice that continues to the present day. Publicly available documents show a series of purported delegations to issue final FDA rules. The first delegation is from the secretary of HHS to the FDA commissioner—who is also nominated by the President and confirmed by the Senate. The most questionable delegation is from the FDA commissioner to the occupant of the career position referred to as the associate commissioner for policy at the FDA (see Figure 2, page 14).³⁰

Thus, the FDA’s Deeming Rule and hundreds of others were signed and issued by Leslie Kux, an attorney and associate commissioner for policy in the FDA. Kux issued the most rules during the study period, but she was never a constitutional officer—she was a career FDA employee.³¹

While at the FDA, Kux typified the normal path of lifetime employees. In 1988, she started working for the FDA, initially in litigation and counseling on a wide variety of subjects.³² By serving in the FDA continuously for 30 years in various roles, and under both Republican and Democratic presidents and congresses, Kux was not subject to any meaningful electoral control.

Kux’s hiring, work performance, and subsequent promotions were dictated by other career FDA staff with an allegiance to the agency’s long-term power and bureaucratic influence. And most importantly, her promotion to associate commissioner for policy was not through the political process required for a constitutional officer. Civil servants like Kux perform vital staff work, but they are unresponsive and unaccountable to changes in presidential administrations, new cabinet secretaries, or other democratic controls.

Yet with the stroke of a former FDA commissioner’s pen, Kux found herself wielding a power granted by Congress to the Secretary of Health and Human Services: the power to issue final and binding regulations interpreting and implementing all aspects of the Food and Drug Act, the Tobacco Control Act, and other FDA laws.

Beyond HHS, which is the subject of this study, it is unknown how common these democratically unaccountable subdelegations may be,³³ but they cannot serve as legitimate alternatives to Senate confirmation for officers exercising significant and final agency actions. If there were no constitutional limit on the powers that can be subdelegated by Senate-confirmed officers, then whether many nominees actually win Senate confirmation for positions below the cabinet level would be rendered virtually meaningless. Cabinet secretaries could simply subdelegate to failed nominees precisely the powers that the Senate declined to grant. That is one reason why an exercise of rulemaking power by an employee is always unconstitutional, regardless of whether a superior has purported to subdelegate that authority.

RESEARCH METHODOLOGY

Data

To examine whether divisions within HHS issue final rulings that are constitutional or unconstitutional under the Appointments Clause, we created and analyzed a database of final rules in the *Federal Register* obtained through Westlaw and the *Federal Register* website.³⁴

We collected all HHS rules going back two full administrations and including the first year of the Trump administration—specifically, those rules published from January 20, 2001, through January 19, 2018. During that time, HHS and its divisions issued 2,952 final rules. The information we collected from each final rule included the final rule number, issuing division in HHS, rule title, publication date, type of action the rule took, and each signer and their title. We also counted the number of words for each final rule.

Rules that had no Senate-confirmed signers are counted as “unconstitutional” because non-Senate-confirmed signers cannot be principal officers, whether they are inferior officers or career employees.

Classification of Signers

Once we obtained the names of each rule’s signers, we used three sources to determine whether those signers were Senate-confirmed officers.

1. We looked up the signers’ titles in the Plum Book, which contains a complete list of policymaking positions in the federal government, including information on how each position is filled.
2. We consulted an exhaustive list published by the Congressional Research Service in 2017 of every executive branch position requiring Senate confirmation.
3. We searched for the names of signers in Congress’ online database of every nomination submitted to the Senate for confirmation.

Appendix B provides more detail on these three sources. In this report, we have counted all rules signed by at least one Senate-confirmed officer as “constitutional” even if that may arguably overstate the number.

Rules that had no Senate-confirmed signers are counted as “unconstitutional” because non-Senate-confirmed signers cannot be principal officers, whether they are inferior officers or career employees. And thus, with one significant exception, we did not determine whether non-Senate-confirmed issuers were

validly appointed as inferior officers or, instead, were career employees. The exception is the FDA, which had the highest number of questionably issued rules. For the FDA, we determined that no signers were validly appointed as inferior officers, as explained further below. In sum, all FDA rule issuers other than the commissioner were career employees.

Analysis

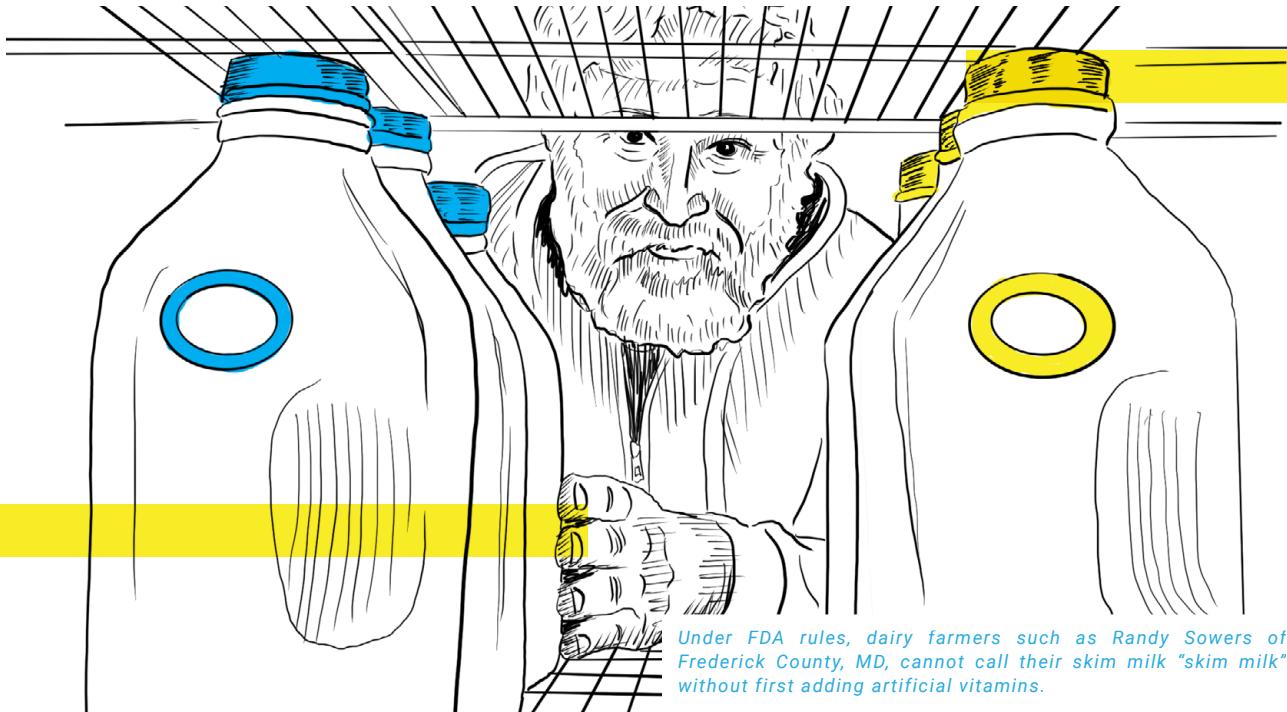
To determine how common unconstitutional final rules are within HHS, we calculated the percentage of final rules signed by Senate-confirmed officers for each division of HHS.

We also calculated these numbers for two types of final rules:

- Substantive—All rules are considered substantive unless they make small changes. Rules with small changes include corrections, technical amendments, and date changes. We also reclassified final rules that included “change of sponsor’s address/name” in the title as rules with small changes. (A list of substantive actions can be found in Appendix B.)
- Significant—According to Executive Order 12866, rules are deemed significant if they have an impact equal to or greater than \$100 million, conflict with another agency rule, have a budgetary impact, or raise a novel legal or policy issue.

A substantive rule may or may not be significant. A significant rule may be substantive or may be a small change.

Appendix B contains further details about the analysis.³⁵



Under FDA rules, dairy farmers such as Randy Sowers of Frederick County, MD, cannot call their skim milk "skim milk" without first adding artificial vitamins.

RESULTS

The majority of rules, more than two-thirds, issued by HHS during the last 17 years were not issued by Senate-confirmed officers and, thus, are unconstitutional. The FDA issued the majority of unconstitutional rules—almost all of which were issued by career employees—even after removing from our analysis rules with small changes or rules that do not have a significant impact. The FDA is operating in blatant violation of the Appointments Clause of the U.S. Constitution.

HHS'S OFFICES AND DIVISIONS (UNITS) INCLUDE THESE 10:

- Office of the Secretary
- Administration for Children and Families (ACF)
- Administration for Community Living (ACL)
- Centers for Disease Control and Prevention (CDC)

- Centers for Medicare and Medicaid Services (CMS)
- Food and Drug Administration (FDA)
- Health Resources and Services Administration (HRSA)
- Indian Health Service (IHS)
- National Institutes of Health (NIH)
- Substance Abuse and Mental Health Services Administration (SAMHSA)

Figure 3 illustrates the annual average number of final rules each unit published during the study period. With an average of 111.2 rules per year, the FDA published the most by far—approximately two rules every five business days.

Most authority to issue rules within HHS is initially conferred by Congress to the secretary.³⁶ The HHS secretary, who is undoubtedly a principal officer, sometimes signs rules for each

of the HHS offices and divisions, including, occasionally, the FDA. These rules are issued by an official with clear constitutional authority to act.

When authorized by express language or by implication in the relevant statute, the secretary’s subdelegation of rulemaking authority to other principal officers confirmed by the Senate is not constitutionally problematic. The FDA has one Senate-confirmed officer: the FDA commissioner, who might also be a principal officer (see discussion in Appendix A on what constitutes a principal officer).

The subsequent subdelegation to non-Senate-confirmed officials (inferior officers and career employees) implicates the Appointments Clause and democratic accountability.

Those subsequent subdelegations can occur decades after the original delegation from the department secretary. We regard subdelegations of rulemaking authority to inferior officers and employees as unconstitutional, but there is no doubt that such delegations to employees are unlawful.

More than two-thirds of the final rules issued by HHS and published in the *Federal Register* were issued by non-Senate-confirmed officials—including inferior officers and civil service employees. The constitutionality of all these rules is seriously in doubt, so much so that we label them unconstitutional. Those rules issued by civil service employees, like Leslie Kux, are certainly unconstitutional.

Figure 3: Average Number of Final Rules Published Annually by Each Unit of HHS, January 20, 2001–January 19, 2018

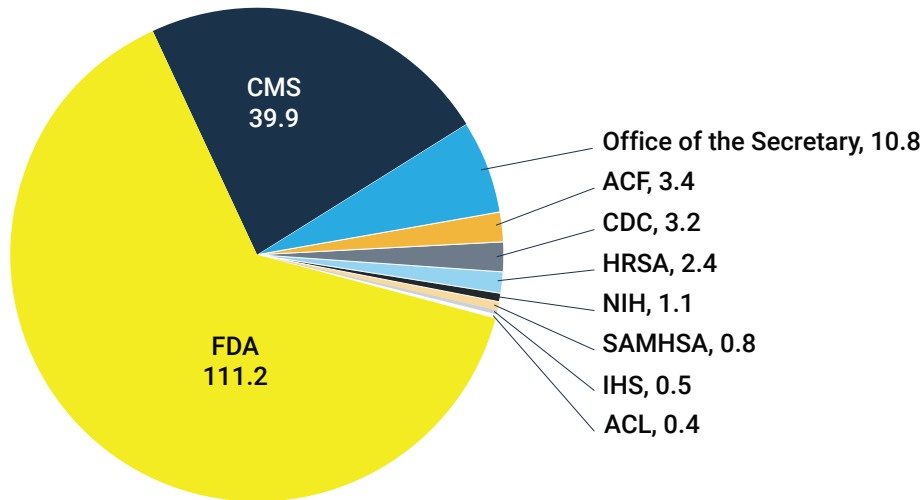
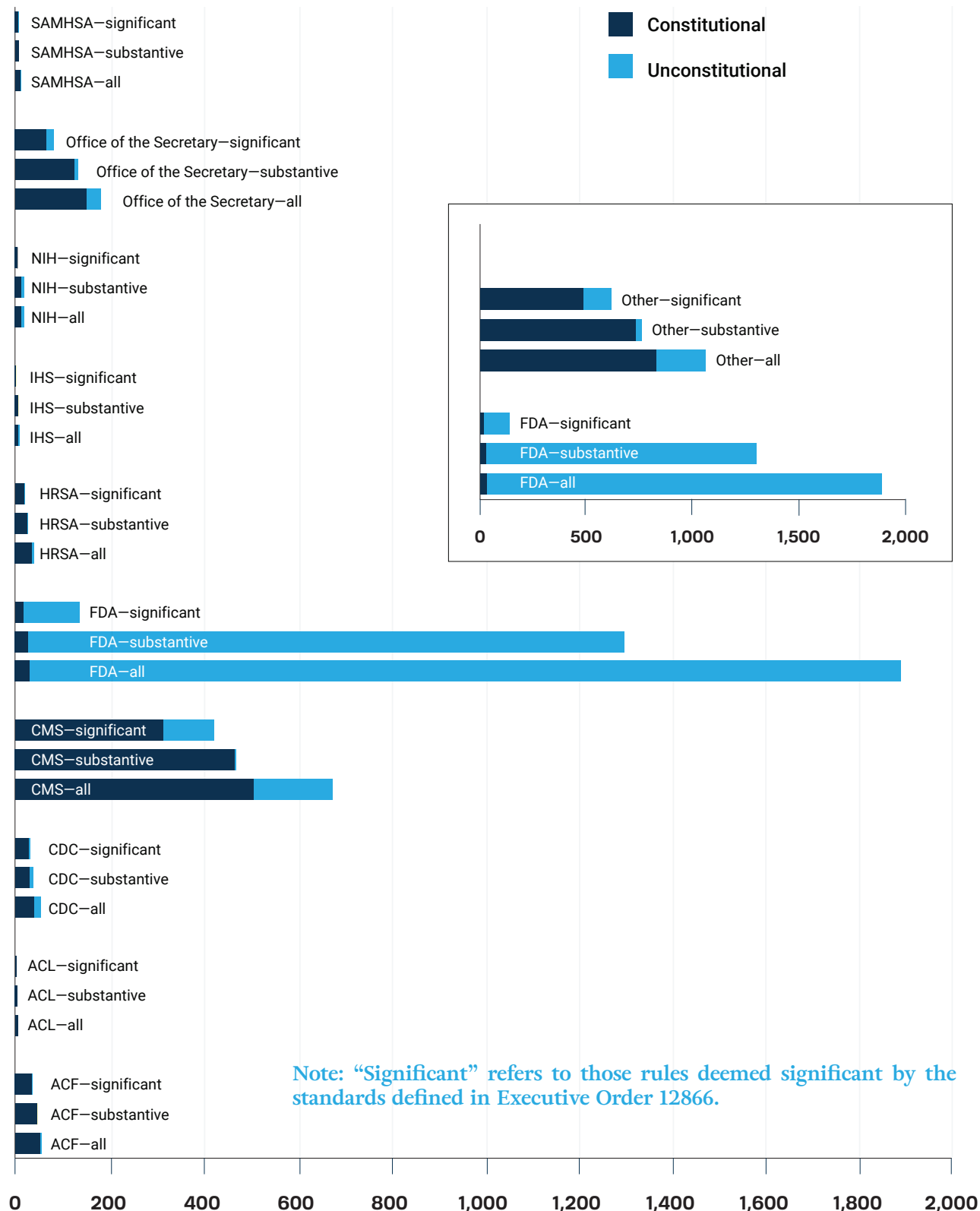


Figure 4: Number of Constitutional and Unconstitutional Final Rules by HHS Unit and Rule Type, January 20, 2001–January 19, 2018



The FDA issued a majority of the HHS’s unconstitutional rules from January 20, 2001, through January 19, 2018, and all of these fall in the category that is most clearly unconstitutional—signed by career employees. Though the FDA accounts for 64% of the rules issued by HHS, it accounts for:

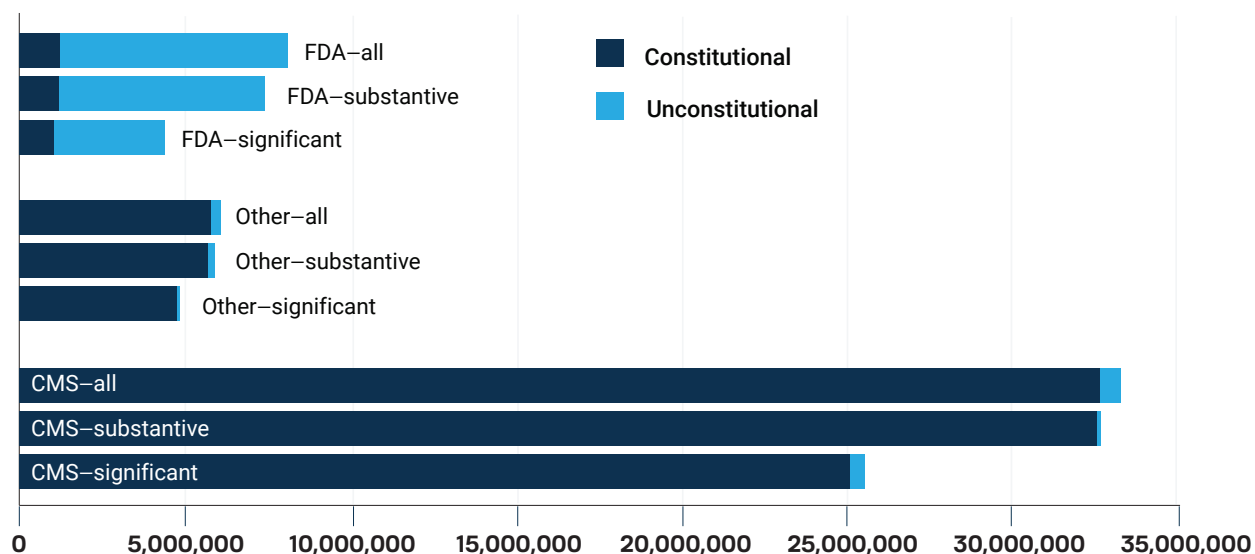
- 89% of all unconstitutional rules;
- 98% of unconstitutional substantive rules; and
- 93% of substantive and significant unconstitutional rules.

Even worse is the overlap of substantive and economically significant rules. The FDA issued 33 substantive rules with an economic impact of \$100 million or more, only seven of which

were signed by Senate-confirmed officials. Twenty-five rules were issued unconstitutionally with an economic impact of more than \$2.5 billion. Figure 4 (see page 22) shows the number of rules issued by each HHS unit, including how many are constitutional and unconstitutional by category of rule (see Appendix C for the data).

The FDA issues the most rules, which also make up the majority of clearly unconstitutional rules. But when looking at the length of rules, CMS issues the most extensive rules. Despite being much longer, these CMS rules were signed by Senate-confirmed officers. Most often, CMS rules were signed by both the CMS administrator and the HHS secretary. Figure 5 shows the total number of words in the issued rules by the FDA, CMS, and all other units of HHS.

Figure 5: Number of Constitutional and Unconstitutional Words in Final Rules by HHS Unit and Rule Type, January 20, 2001–January 19, 2018



Note: “Significant” refers to those rules deemed significant by the standards defined in Executive Order 12866.

CMS is the most comparable unit to the FDA in HHS. Yet nearly all of CMS's substantive rules were issued by a Senate-confirmed officer, whereas just a tiny fraction of FDA rules were issued by a Senate-confirmed officer.

In addition to the clear constitutional ruling that career employees may not issue rules binding on the public, recent court decisions strongly support our conclusion that those appointed as inferior officers may not issue final rules either. Final rules are lawfully binding, and without a new rulemaking procedure, no one may overrule or alter notice-and-comment rules once they have been issued. Thus, final rulemaking authority is the type of *unreviewable* and *unalterable* executive power that the Supreme Court has suggested must be reserved to principal officers.³⁷

While it is more difficult to ascertain from publicly available records whether a particular official may have been validly appointed as an *inferior* officer than it is to identify a Senate-confirmed officer, there is strong evidence that all of the non-Senate-confirmed officials who issued FDA rules during our study period were also not validly appointed as inferior officers.

Recall that all inferior officers must be appointed by either the President, a department head, or a court of law, and that such appointment power must be vested by statute. We found that none of these FDA signatories was appointed by the President.³⁸

Under the Constitution's Appointments Clause, Congress may, "by law," also give the HHS secretary the authority to appoint inferior officers within HHS since the secretary is the "head of a department." But Congress has not given such blanket hiring authority to the HHS secretary.

The statutes governing the FDA do define several specific FDA positions that may be filled by secretarial appointment—for example, each member of the Technical Electronic Product Radiation Safety Standards Committee.³⁹ None of these positions signed a rule in our database.

Nor could any appointment by someone below the HHS secretary satisfy the Constitution; the Appointments Clause does not allow Congress to confer the authority to appoint inferior officers on bureau or other subagency heads. Anyone hired by the FDA commissioner (who is subordinate to the HHS secretary) has not been validly appointed as an inferior officer.

Even if an FDA signer was officially hired by the HHS secretary, that hiring was not pursuant to an act of Congress. Therefore, such a signer would not have been a validly appointed inferior officer under the Appointments Clause. Other than the commissioner, every signer of an FDA rule since 2000 was an employee, constitutionally incapable of exercising significant final agency authority, including issuing final rules that are binding on the public.

Thus, it is clear that no one in the FDA who signed any of the questionable rules meets the constitutional requirements for being an inferior officer. That includes Leslie Kux, issuer of the most unconstitutional HHS rules (a total of 385) in our study, including the Deeming Rule (see Table 1).

During the 17 years covered by our study, four of the top five rule signers by volume were career staff from the FDA (see Table 1). Even when looking at signers' titles, three of the top five titles are career positions at the FDA. The FDA appears to have no regard for the Appointments Clause of the U.S. Constitution.

Table 1: The Top Five Individual Signers and Titles of Signers of HHS Rules, January 20, 2001–January 19, 2018

Individual Signers	Position	Rules
Leslie Kux (FDA employee)	Career staff	385
Jeffrey Shuren (FDA employee)	Career staff	275
Bernadette Dunham (FDA employee)	Career staff	267
Kathleen Sebelius (HHS Secretary)	Principal officer	231
Steven D. Vaughn (FDA employee)	Career staff	212
Title of Signers (includes acting appointments)		
Secretary of HHS	Principal officer	822
Assistant/Associate Commissioner for Policy (and Planning), FDA	Career staff	746
Administrator, CMS	Principal officer*	508
Director, Center for Veterinary Medicine (CVM), FDA	Career staff	464
Director, Office of New Animal Drug Evaluation, CVM, FDA	Career staff	284

*All department heads, such as the HHS secretary, are principal officers. The administrator of CMS is a Senate-confirmed position, and the occupant might be a principal officer based on factors we did not analyze. Appendix A contains a discussion of what constitutes a principal officer.

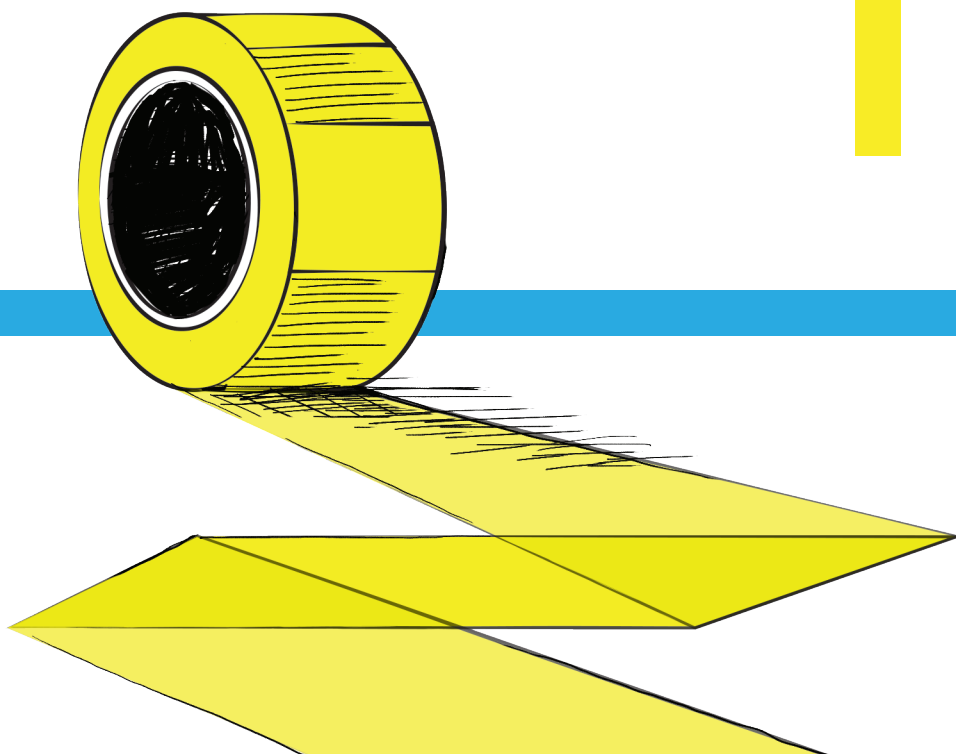
FUTURE RESEARCH

This is the first study to examine who a given department's rulemakers are and what their constitutional authority to act is. But it should not be the last. The public would benefit from a greater understanding of these and related issues throughout the federal government.

For example, we studied rulemaking only within HHS. Further studies could look at other or all departments and independent agencies in the executive branch. How common is rulemaking by democratically unaccountable individuals in other departments? Putting legal issues aside, do agencies with more final agency decisionmakers issue more final decisions? Do departments with more final rulemakers issue more rules? Conversely, does the number of rulemakers in a given department correlate with the number of rules a department must issue? Our study of HHS units suggests this is not necessarily the case, but constitutional rules may currently constrain some agencies more than others.

Research should also be done on the differences in the rules issued by constitutional officers compared to career employees or inferior officers. The Appointments Clause was added to the Constitution because centuries of experience had shown that government officials who are more directly accountable to the people are more sensitive to protecting the people's interests and liberties. Future scholars may seek to measure if differences exist in how burdensome or expensive rules are based on who issued them or if other differences exist related to rules' clarity or penalties.

Future research could also explore these issues at the state level.



APPROPRIATE JUDICIAL, LEGISLATIVE, AND ADMINISTRATIVE RESPONSES

On behalf of nine different individuals and small entities, Pacific Legal Foundation filed three lawsuits in early 2018 against the FDA for its unconstitutional practice of using career employees to issue rules affecting Americans. Those lawsuits target the Deeming Rule—just one of the 25 substantive rules with an impact of \$100 million or more issued by an FDA career bureaucrat in the last 17 years.

The FDA is not the only unit in HHS to issue rules without a Senate-confirmed officer's signature, even if it is the most frequent offender within HHS. If citizens directly harmed by other rules file suit, the courts should strike down any rule that was issued in an unconstitutional manner. Enforcing this constitutional principle will not bring the workings of government to a screeching halt. Courts can invalidate only one rule at a time, and only when an injured party with standing seeks to have a rule struck down. In such litigation with concrete

facts, the courts would resolve the statutory enforcement issues that arise with each invalidation on an individualized basis. In the meantime, the FDA and other affected agencies could reconsider such rules through constitutional means. Under other laws that govern rulemaking, these reconsiderations would have to include new information gained since the invalid rules were issued, which may improve them.

In addition, unconstitutional rules are one component of broader regulatory schemes that include, most importantly, the statute under which the rule is issued. These congressional statutes will still be in place, and other regulations may apply that don't suffer from the same defect. Agencies will be able to respond to the invalidation of rules by relying on their statutory authority or by reissuing similar rules via a constitutional procedure.

Regardless of individual court actions that will be largely retrospective, the political branches can and should ban the practice of employee rulemaking going forward. The problem with subdelegation to career employees is not solely a judicial or legal issue. It is also a practical and political issue. Democratic accountability leads to governmental decisions that are more attentive to individual liberties. That was true at the nation's founding and remains true today.

Congress should explore statutory solutions to prohibit the subdelegation of rulemaking power, including across-the-board prohibitions or specific disincentives, such as funding restrictions for agencies that don't enforce the constitutional rules for rulemaking. Likewise, the executive branch should look for ways to curtail the problem, including both presidential executive orders and individual departmental orders.

Such solutions adhere to constitutional norms of democratic accountability, but they are non-partisan responses that no one should oppose on ideological grounds. No President should hesitate to have his Senate-confirmed appointees take responsibility for the rules issued during his administration. Indeed, a presidential executive order would be durable for that very reason.

In sum, it is time for the courts, Congress, the White House, and the HHS secretary to rein in unconstitutional rulemaking.

Separation of Powers

The importance of the U.S. Constitution's design for the separation of governmental powers cannot be overstated. The effective division of government powers was the central goal for the Framers and ratifiers of the Constitution, and its refinement was the most important innovation in constitutional democracy in several hundred years. Justice Antonin Scalia explained why the separation of powers is the indispensable protection for our substantive freedoms:

The Framers ... viewed the principle of the separation of powers as the absolutely central guarantee of a just government. In [Federalist 47], Madison wrote that “[n]o political truth is certainly of greater intrinsic value, or is stamped with the authority of more enlightened patrons of liberty.” ... Without a secure structure of separated powers, our Bill of Rights would be worthless, as are the bills of rights of many nations of the world.⁴⁰

Yet some scholars mistakenly argue that government officials can devise new checks that substitute for the original design and still maintain an effective balance of power between the branches.⁴¹ That is wrong, even if such substitutions are constitutionally permissible. Our constitutional separation of powers was *not* for the benefit of government officials. It is not a power-sharing arrangement between oligarchs, such that their agreement on new terms is all that matters.

Instead, its purpose is to better protect the individual liberties of the governed, and the Framers knew that not just any system of separated powers would do that. For that reason, the Constitution does not allow government actors to reassign the original allocations of power or the checks on democratic accountability. Instead, the people who created the federal government decided that liberty is protected when particular powers are exercised by specific actors, with unique checks appropriate for each type of actor.

In our Constitution, the people vested the exclusive lawmaking power in Congress with a potential presidential veto so that the people could directly elect and control their lawmakers at regular intervals.⁴² There is a healthy debate—which the Supreme Court of the United States is revisiting in its current term—about the degree of regulatory authority that Congress is constitutionally permitted to delegate to executive-branch agencies to spell out in agency regulations. But whatever scope or level of regulatory power agencies may exercise through rulemaking, that power is currently substantial, and—of relevance to this report—it must be exercised by executive-branch officers who are themselves democratically accountable. It cannot be delegated further, even with nominal supervision.

The Origin of the Appointments Clause

The Constitution vests all executive power in a single President of the United States.⁴³ But the Framers of the Constitution knew that the President would necessarily be aided by executive-branch officers granted some decisionmaking authority under the President's direction. The Framers also recognized that, in practice, these executive officers would have significant power, so how they attain their offices should not be taken lightly.

For this reason, a serious debate occurred during the Constitutional Convention over the best method of appointing executive-branch officers. "One group of delegates, led by James Wilson, Nathaniel Gorham, Alexander Hamilton, and Gouverneur Morris, favored control of appointments by a strong executive. The opposing camp, led by Charles Pinckney, Luther Martin, George Mason, Roger Sherman, Oliver Ellsworth, and John Rutledge, favored legislative control of the appointment process."⁴⁴

Eventually, these two sides reached a compromise. The President would select each nominee for high office, but those nominees would be installed by the President only after obtaining the advice and consent of the Senate. Gouverneur Morris explained the strength of this dual-role system: "As the President was to nominate, there would be responsibility, and as the Senate was to concur, there would be security."⁴⁵

On September 17, 1787, the convention approved the final version of the Appointments Clause, giving us the system of executive-branch appointment we retain today:

*[The President] shall nominate, and by and with the Advice and Consent of the Senate, shall appoint Ambassadors, other public Ministers and Consuls, Judges of the supreme Court, and all other officers of the United States, whose Appointments are not herein otherwise provided for, and which shall be established by Law: but the Congress may by Law vest the Appointment of such inferior Officers, as they think proper, in the President alone, in the Courts of Law, or in the Heads of Departments.*⁴⁶

Thus, the default in the Constitution is that all officers, high or low, must receive Senate confirmation. The Constitution allows Congress as a whole to depart from Senate confirmation if three conditions are met:

- The position to be filled is for an "inferior" officer;
- Congress authorizes such exception to Senate confirmation in a law;
- Such inferior officer is appointed by the President, a court of law, or a department head (as the statute so provides).

For example, it is unclear what level of military or civilian officers Congress may by law allow the President or the secretaries of the Army, Navy, Marines, Air Force, and Defense to appoint alone, but Congress has generally not authorized many such appointments without Senate consent, including promotions of military officers. Nominations for military promotions are generally made in large batches. The Senate Committee on Armed Services considers approximately 50,000 such nominations per year, and it occasionally does withhold consent from individual promotions.⁴⁷

Applying the Appointments Clause

The Framers never explicitly defined the terms *officer* or *inferior officer* in the Constitution, meaning judges and scholars have interpreted these terms' meanings over the years since the Constitution's enactment. For ease of terminology and to clearly distinguish those officers who are not inferior (and who therefore must be confirmed by the Senate without exception), the term *principal officer* came into use.⁴⁸ And to further distinguish those millions of people who work for the federal government but are not officers (neither inferior nor principal) at all, the term *employee* became standard usage.⁴⁹ The result is a three-tiered hierarchy:

1. Principal officers (who must be confirmed by the Senate without exception);
2. Inferior officers (who must be confirmed by the Senate unless Congress grants an exception);
3. Employees (who may be hired by methods other than those laid out in the Constitution).

The hard work of constitutional interpretation draws the two dividing lines between these three tiers. Which powers are so important that the Framers would have expected them to only be exercised by principal officers? And which powers are important enough that they must be exercised by at least inferior officers, not employees?

These lines have slowly been fleshed out by the Supreme Court over the years. The key dividing line between officers and employees is that only officers may exercise "significant authority" pursuant to the laws of the United States.⁵⁰ And the key dividing line between

principal and inferior officers is that inferior officers "are officers whose work is directed and supervised at some level by others who were appointed by presidential nomination with the advice and consent of the Senate."⁵¹ For the purposes of this research report, these tests are most relevant for what they say about the power to issue final rules that are binding on the American people.

Rulemaking and the Appointments Clause

The Supreme Court has explicitly held that the power to issue final rules is a power that, at the least, must be exercised by an officer.⁵² This is uncontroversial. After all, rulemaking is virtually indistinguishable from William Blackstone's classic definition of the lawmaking power, since rulemakers have the power to impose a "rule of civil conduct prescribed by the supreme power in a state, commanding what is right and prohibiting what is wrong."⁵³ To the extent that executive-branch rulemaking is constitutionally legitimate at all, it is inconceivable that the Framers would have anticipated such a power being exercised by someone not even appointed an officer pursuant to the Constitution.

The more difficult question—and one the Supreme Court has not yet had an opportunity to answer—is whether rulemaking must further be limited only to *principal officers*. But research on the historical meaning of inferior officers, especially that by Jennifer Mascott, strongly supports the view that inferior officers were not anticipated to wield such a final and unreviewable power. As Mascott explains, "[i]n the Founding era, the term 'officer' was commonly understood to encompass any individual who had ongoing responsibility for a governmental duty."⁵⁴

The power held by executive-branch rulemakers today is virtually indistinguishable from what the Framers would have considered to be legislative power. Wielding such power in the executive branch was the exception, not the norm. The rulemaking power was so unusual and significant in the Framing era, it is implausible the Framers would have approved its dispersal among the many inferior officers. Mascott's convincing research as to how many positions were considered inferior officers supports this conclusion.

Further, this view is consistent with the Supreme Court's approach, which defines inferior officers by their relationship to a superior. The power to issue a final and unreviewable rule without the assent of a superior is incompatible with any realistic definition of being a true "subordinate." Consistent with that reasoning, the Court of Appeals for the DC Circuit recently held that arbitrators with the power to issue final and unreviewable rules were necessarily principal officers. As that court put it, an arbitrator was "inescapabl[y]" a principal officer because she held the power to take a "final agency action, the promulgation of metrics and standards," without "any procedure by which the arbitrator's decision is reviewable."⁵⁵

Although the level of supervision of any particular officer is necessarily a fact-specific inquiry, most career employees, including career members of the Senior Executive Service (such as Leslie Kux), can be removed from their jobs only for cause—not for policy disagreements.⁵⁶ This removal protection eliminates a "powerful tool for control" by a superior, which further supports the view that such rulemakers must be appointed as principal officers.⁵⁷

In sum, there is no doubt that a rule issued by an employee is unconstitutional as a violation of the Appointments Clause. A proper reading of the Constitution's structure makes clear that a rule issued by an inferior officer is unconstitutional as well.

Finally, there is little doubt that the officer whose signature appears on a rule is the officer who has issued it. Courts generally do not look into the mental steps or workflow of the signer of a regulation because such an inquiry would delve too deeply into the internal processes of a coordinate branch.⁵⁸ Absent exceptional circumstances, a constitutionally authorized signer will not have his signature called into question by delving into whether the rule was primarily drafted and reviewed by a nonsigning underling.⁵⁹ But by the same token, an unauthorized signer cannot justify the validity of a rule by claiming that it was reviewed and approved by a nonsigning superior. It is the authority of the signer and the signer alone that gives a rule its binding power.

APPENDIX B

RESEARCH METHODOLOGY

In addition to obtaining all the rules from Westlaw, we verified that we obtained the full population of HHS rules through a search on the *Federal Register* website. These rules were then labeled as small changes or substantive ones. Table B1 lists the simplified actions we considered substantive.

To classify signers, we started by consulting the official government publication known as the Plum Book (so named because it lists each of the “plum” federal government jobs), which the Office of Personnel Management publishes every four years. The Plum Book contains a complete list of policymaking positions in the federal government, including information on how each position is filled. In each of the last five editions (2000, 2004, 2008, 2012, and 2016), the Plum Book lists only one office in the FDA as “PAS,” the terminology for

positions requiring nomination by the President and confirmation by the Senate. This position is the FDA commissioner.⁶⁰

Next, we consulted an exhaustive list published by the Congressional Research Service in 2017 of every executive branch position requiring Senate confirmation. Likewise, this list contains only one Senate-confirmed position in the FDA: the commissioner.⁶¹

Finally, we reviewed a searchable online database maintained by Congress of every nomination (both confirmed and not confirmed) submitted to the Senate for confirmation going back to 1981. A search on this website for “food and drug” returns only eight results: the last eight nominations for FDA commissioner.⁶²

Table B1: List of Substantive Actions

Adoption of interim final rule as final rule with amendments	Interim final rule and request for comments
Direct final rule	Interim rule; adoption as final and response to public comments
Direct final rule and request for comments	Issuance of direct final rule and opportunity for comment
Final order	Proposed rule
Final regulation	Direct final rule; withdrawal
Final requirements	Final rule and final order; withdrawal
Final rule	Final rule; removal
Final rule and final order	Final rule; removal of regulatory provisions in response to court order
Final rule with comment period	Final rule; withdrawal
Final rule with comment period and interim final rule with comment period	Notification of withdrawal
Final rule, Interim final rule	Notification of withdrawal of approval
Final rule; implementation of court orders	Withdrawal of final rule with comment period
Final rules and interim final rule with comment period	Withdrawal of interim final rule and issuance of final rule
Interim and final rule with comment period	
Interim final rule	

Note: Actions are the “type of action” as published in the *Federal Register*.

Table C1: Number of Constitutional and Unconstitutional Rules by Type and HHS Unit, January 20, 2001–January 19, 2018

Rule Type	Unit	Constitutional	Unconstitutional	Total
All	ACF	53	4	57
	ACL	6	1	7
	CDC	40	15	55
	CMS	509	169	678
	FDA	31	1,860	1,891
	HRSA	36	4	40
	IHS	7	2	9
	NIH	13	6	19
	Office of the Secretary	152	31	183
	SAMHSA	11	2	13
	Total	858	2,094	2,952

Continued on p. 36

Table C1: Number of Constitutional and Unconstitutional Rules by Type and HHS Unit, January 20, 2001–January 19, 2018 (continued)

Rule Type	Unit	Constitutional	Unconstitutional	Total
Substantive New rules or large edits to existing rules	ACF	47	0	47
	ACL	5	0	5
	CDC	30	9	39
	CMS	469	2	471
	FDA	28	1,273	1,301
	HRSA	26	2	28
	IHS	7	0	7
	NIH	13	6	19
	Office of the Secretary	126	9	135
	SAMHSA	8	0	8
	Total	759	1,301	2,060
Significant According to OMB	ACF	36	1	37
	ACL	3	1	4
	CDC	29	3	32
	CMS	316	109	425
	FDA	17	121	138
	HRSA	19	2	21
	IHS	2	0	2
	NIH	5	0	5
	Office of the Secretary	67	16	83
	SAMHSA	7	1	8
	Total	501	254	755

ENDNOTES

- ¹ Bentley Coffey, Patrick A. McLaughlin, and Pietro Peretto, “The Cumulative Cost of Regulations,” Mercatus Working Paper (Arlington, VA: Mercatus Center at George Mason University, April 2016), <https://www.mercatus.org/publication/cumulative-cost-regulations>.
- ² Richard Williams, “Comparison of Final Rules with Monetized Benefits and Costs” (Arlington, VA: Mercatus Center at George Mason University, April 23, 2012), <http://mercatus.org/publication/comparison-final-rules-monetized-benefits-and-costs>.
- ³ Cass R. Sunstein and Robert W. Hahn, “A New Executive Order for Improving Federal Regulation? Deeper and Wider Cost–Benefit Analysis,” Working Paper No. 150 (Charlottesville, VA: John M. Olin Program in Law and Economics, 2002), <https://dash.harvard.edu/handle/1/12795538>; Robert W. Hahn, “Regulatory Reform: Assessing the Government’s Numbers,” Working Paper No. 99-6 (Washington, DC: AEI-Brookings Joint Center for Regulatory Studies, 1999), <https://ssrn.com/abstract=269630>; Robert W. Hahn and Robert E. Litan, “An Analysis of the Third Government Report on the Benefits and Costs of Federal Regulations,” Regulatory Analysis 00-1 (Washington, DC: AEI-Brookings Joint Center, 2000), <https://ssrn.com/abstract=243534>.
- ⁴ In 2015, the Supreme Court struck down one Environmental Protection Agency rule after rejecting the EPA’s position that it couldn’t consider costs in its decision to set hazardous air pollutant standards. *Michigan v. EPA*, 135 S. Ct. 2699, 2708–10 (2015). The EPA maintained it was required to impose many billions in costs for minimal direct benefits. Writing for the Court, Justice Scalia declared that “the phrase ‘appropriate and necessary’ [in the relevant EPA statute] requires at least some attention to cost. One would not say that it is even rational, never mind ‘appropriate,’ to impose billions of dollars in economic costs in return for a few dollars in health or environmental benefits.” *Id.* at 2707; see also *Entergy Corp. v. Riverkeeper*, 556 U.S. 208 (2009). Sadly, many federal agencies continue to interpret their regulatory authority in a similarly irrational manner.
- ⁵ See Complaint at 3, *Moose Jooce v. FDA*, No. 1:18-cv-0203 (D.D.C. Jan. 30, 2018).
- ⁶ Deeming Tobacco Products to Be Subject to the Federal Food, Drug, and Cosmetic Act, as Amended by the Family Smoking Prevention and Tobacco Control Act; Restrictions on the Sale and Distribution of Tobacco Products and Required Warning Statements for Tobacco Products, 81 Fed. Reg. 28,974 (May 10, 2016).
- ⁷ See Complaint, *supra* note 5, at 3.
- ⁸ Center for Tobacco Products, “Commonly Asked Questions: About the Center for Tobacco Products,” U.S. Food and Drug Administration, questions 1 and 2, accessed February 4, 2019, <https://www.fda.gov/tobaccoproducts/aboutctp/ucm378205.htm>.
- ⁹ “These regulations have already damaged my business and my customers,” said Steve. “For example, some popular liquids are no longer available because small manufacturers and retailers can’t afford to navigate the regulatory process. I’ve also had to stop helping customers build or repair their vape pens. I stopped because it could classify me as a manufacturer and bury me under regulations.”

¹⁰ “Arbitrary Federal Vaping Regulations Threaten Businesses, Consumers—and Constitutional Rights” (Pacific Legal Foundation, January 30, 2018), <https://pacificlegal.org/press-release/arbitrary-federal-vaping-regulations-threaten-businesses-consumers-and-constitutional-rights/>.

¹¹ Based on the government’s procedural motions and rulings on them, two of the cases were transferred to the district court in the District of Columbia, where the third suit was filed. Consideration of the substance of the challenges is in its early stages in that court at the time of this publication. The FDA demonstrated its fear that the Deeming Rule is in legal jeopardy by purporting to cure the constitutional problem with a “ratification” letter by outgoing FDA Commissioner Gottlieb dated April 3, 2019—almost three years after Kux issued the rule. Gottlieb’s letter denies that there is any constitutional defect that needs to be cured. But, the highly unusual intervention during litigation speaks louder than his denial that there is no problem to cure. Plaintiffs will contest the validity of this attempted ratification of one rule. As to the many other unconstitutional rules, if ratification by a new official can ever be lawful, it must, at the very least, be based on a knowing review of each rulemaking record. An attempted mass ratification of over two thousand HHS rules would be unprecedented and even more questionable than ratification of any one rule.

¹² “Family-Run Farm Sues FDA for Right to Say Skim Milk Is Skim Milk” (Institute for Justice, April 5, 2018), <http://ij.org/press-release/family-run-farm-sues-fda-right-say-skim-milk-skim-milk/>.

¹³ Lowfat and Skim Milk Products, Lowfat and Nonfat Yogurt Products, Lowfat Cottage Cheese: Revocation of Standards of Identity; Food Labeling, Nutrient Content Claims for Fat, Fatty Acids, and Cholesterol Content of Food, 61 Fed. Reg. 58,991-01 (Nov. 20, 1996).

¹⁴ Food and Drug Administration Safety and Innovation Act, 126 Stat. 993 (2012).

¹⁵ Abbreviated New Drug Applications and 505(b)(2), 81 Fed. Reg. 69,580-01 (Oct. 6, 2016).

¹⁶ Raymond J. March, “FDA Approves Record Number of Generic Drugs in 2018,” *The Beacon*, January 9, 2019, <http://blog.independent.org/2019/01/09/fda-approves-record-number-of-generic-drugs-in-2018/>.

¹⁷ “FDA in Brief: FDA Highlights Record-Breaking Number of Generic Drug Approvals in October,” U.S. Food and Drug Administration, November 9, 2018, <https://www.fda.gov/NewsEvents/Newsroom/FDAInBrief/ucm625627.htm>.

¹⁸ Through 2018 and early 2019, Leslie Kux continued to issue final FDA rules. See 83 Fed. Reg. 54,006, 54,007, 54,665, 54,869, 54,873, 54,875. As of March 2019, career employees in the FDA continue to issue final rules. See 84 Fed. Reg. 8,967, 9,226, 9,228. We hope outgoing FDA Commissioner Gottlieb’s attempted ratification of the Deeming Rule on April 3, 2019, (see note 11) signals serious reexamination of the practice of career employees issuing final rules. But the ratification was more likely made solely as an attempt to thwart litigation over that one rule. Moreover, a law or executive order is still needed to prevent thousands of more rules from being illegally issued at FDA and other agencies.

¹⁹ Appendix A to this report describes relevant constitutional principles and their historical development, including the centrality of the separation of powers design in the U.S. Constitution.

²⁰ U.S. Const. art. II, § 1, cl. 1.

²¹ The relevant portion of Article II, Section 2, Clause 2 provides that:

[The President] shall nominate, and by and with the Advice and Consent of the Senate, shall appoint Ambassadors, other public Ministers and Consuls, Judges of the supreme

Court, and all other Officers of the United States, whose Appointments are not herein otherwise provided for, and which shall be established by Law: but the Congress may by Law vest the Appointment of such inferior Officers, as they think proper, in the President alone, in the Courts of Law, or in the Heads of Departments.

²² U.S. Const. art. II, § 2, cl. 2. The head of a small agency probably may not be vested with the appointment power, but the constitutional line between a small agency and a great department is not clear. For an early attempt to define the word *department*, see *United States v. Germaine*, 99 U.S. 508, 510–11 (1878).

²³ See *Chevron U.S.A., Inc. v. Natural Resources Defense Council*, 467 U.S. 837 (1984).

²⁴ Clyde Wayne Crews Jr., *Ten Thousand Commandments: An Annual Snapshot of the Federal Regulatory State* (Washington, DC: Competitive Enterprise Institute, 2018), 4.

²⁵ *Buckley v. Valeo*, 424 U.S. 1, 140–41 (1976) (“[R]ulemaking represents the performance of a significant governmental duty exercised pursuant to a public law [This function] may therefore be exercised only by persons who are ‘Officers of the United States.’”).

²⁶ For example, at the end of their respective first calendar years in office, Presidents George W. Bush, Barack Obama, and Donald Trump had seen only 1,245 of their combined 1,901 nominees confirmed by the Senate. Jay Diehm, Sergio Hernandez, Aaron Kessler, Tal Kopan, Curt Merrill, and Sean O’Key, “Tracking Trump’s Nominations,” CNN, last modified December 31, 2017, <https://www.cnn.com/interactive/2017/politics/trump-nominations/>.

²⁷ For example, Attorney General Elliot Richardson and Deputy Attorney General William French Smith, in turn, refused President Nixon’s order to fire Watergate special prosecutor Archibald Cox and resigned instead. Richardson had pledged in his Senate confirmation hearing that he would not dismiss the Watergate special prosecutor except for cause. Stanley I. Kutler, *The Wars of Watergate: The Last Crisis of Richard Nixon* (New York: W.W. Norton, 1990), 407.

²⁸ *Ryder v. United States*, 515 U.S. 177, 182 (1995) (quoting *Freytag v. Commissioner*, 501 U.S. 868, 878 (1991)).

²⁹ *Free Enterprise Fund v. Public Co. Accounting Oversight Bd.*, 561 U.S. 477, 497 (2010) (quoting *New York v. United States*, 505 U.S. 144, 182 (1992)).

³⁰ FDA Staff Manual Guide 1410.21.1.G.1 (authorizing the associate commissioner for policy “[t]o perform any of the functions of the Commissioner with respect to the issuance of FR notices and proposed and final regulations of the Food and Drug Administration”), <https://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/StaffManual%20Guides/UCM273783.pdf>.

³¹ FDA rules are currently being issued by the Principal Associate Commissioner for Policy Lowell J. Schiller, another career employee of the FDA. See also note 18.

³² “Meet Leslie Kux, Associate Commissioner for Policy,” U.S. Food and Drug Administration, accessed February 4, 2019, <https://www.fda.gov/AboutFDA/CentersOffices/ucm304642.htm>.

³³ Not all subdelegations are constitutionally problematic. Preliminary or nonfinal agency actions, for example, may be subdelegated from principal to inferior officers without the same concerns as delegations of final agency actions. Jennifer Nou, “Subdelegating Powers,” *Columbia Law Review* 116 (2017): 473.

³⁴ In addition to final rules, agencies produce guidance documents (that are not publicly available unless they are posted on the agencies’ websites) that are enforced like final rules in the *Federal Register*. This study was unable to collect or analyze the constitutional nature of these types of documents.

³⁵ These raw numbers are useful but may not tell the full story. To control for the additional factors that could affect comparisons between divisions, we ran a regression analysis. The difference in how the FDA and other units of HHS use Senate-confirmed officer signatures is statistically significant, even when accounting for substantive rules, significant rules, word count, and who the secretary was when the rule was published. The analysis and results are available upon request.

³⁶ See, e.g., 21 U.S.C. § 387a (granting regulatory powers under the Tobacco Control Act to the HHS secretary).

³⁷ See *Edmond v. United States*, 520 U.S. 651, 662–63 (1997); see also *DOT v. Ass’n of Am. R.R.*, 135 Ct. 1225, 1239 (2015) (Alito, J., concurring) (“[N]othing final should appear in the *Federal Register* unless a presidential appointee has at least signed off on it.”).

³⁸ The Plum Book indicates those officers who were appointed by the President alone (designated as PA).

³⁹ See, e.g., 21 U.S.C. § 360kk (“The Secretary [of HHS] shall establish a Technical Electronic Product Radiation Safety Standards Committee The Committee shall be appointed by the Secretary.”); 21 U.S.C. § 379d-3a (“The Secretary may ... appoint outstanding and qualified candidates to scientific, technical, or professional positions that support the development, review, and regulation of medical products.”).

⁴⁰ *Morrison v. Olson*, 487 U.S. 654, 697 (1988) (Scalia, J., dissenting). Though included in the introduction of his most famous dissent, few American scholars would dispute the separation of powers principles he began with in any age.

⁴¹ See, e.g., Jon D. Michaels, “An Enduring, Evolving Separation of Powers,” *Columbia Law Review* 115 (2015): 515.

⁴² U.S. Const. art. I, § 1.

⁴³ U.S. Const. art. II, § 1, cl. 1.

⁴⁴ Adam J. White, “Toward the Framers’ Understanding of ‘Advice and Consent’: A Historical and Textual Inquiry,” *Harvard Journal of Law & Public Policy* 29 (2005): 110–11.

⁴⁵ *The Records of the Federal Convention of 1787*, vol. 2, ed. Max Farrand (New Haven: Yale University Press, 1911), 539.

⁴⁶ U.S. Const. art. II, § 2, cl. 2.

⁴⁷ “Nominations,” U.S. Senate Committee on Armed Services, accessed May 3, 2017, <https://www.armed-services.senate.gov/nominations>.

⁴⁸ See, e.g., *Morrison v. Olson*, 487 U.S. 654, 670–71 (1988) (“The initial question is, accordingly, whether appellant is an ‘inferior’ or a ‘principal’ officer.”).

⁴⁹ See, e.g., *Buckley v. Valeo*, 424 U.S. 1, 126 n.162 (1976) (“‘Officers of the United States’ does not include all employees of the United States Employees are lesser functionaries subordinate to officers of the United States”) (citations omitted).

⁵⁰ *Id.* at 126.

⁵¹ *Edmond v. United States*, 520 U.S. 651, 663 (1997).

⁵² See *Buckley v. Valeo*, *supra* note 25.

⁵³ 1 William Blackstone, Commentaries *44.

- ⁵⁴ Jennifer Mascott, “Who Are ‘Officers of the United States’?,” *Stanford Law Review* 70, no. 2 (2018): 450.
- ⁵⁵ *Ass’n of Am. R.R. v. U.S. DOT*, 821 F.3d 19, 39 (D.C. Cir. 2016).
- ⁵⁶ 5 U.S.C. §§ 7541–43.
- ⁵⁷ See *Edmond v. United States*, 520 U.S. 651, 664 (1997).
- ⁵⁸ See *United States v. Morgan*, 313 U.S. 419, 421–22 (1941).
- ⁵⁹ See *Nat’l Nutritional Foods Ass’n v. FDA*, 491 F.2d 1141, 1144–46 (2d Cir. 1974).
- ⁶⁰ U.S. Congress, *United States Government Policy and Supporting Positions* (Washington, DC: U.S. Senate’s Committee on Governmental Affairs, 2000), 119–21; U.S. Congress, *United States Government Policy and Supporting Positions* (Washington, DC: U.S. House of Representatives’ Committee on Government Reform, 2004), 72–3; U.S. Congress, *United States Government Policy and Supporting Positions* (Washington, DC: U.S. Senate’s Committee on Homeland Security and Governmental Affairs, 2008), 72–4; U.S. Congress, *United States Government Policy and Supporting Positions* (Washington, DC: U.S. House of Representatives’ Committee on Oversight and Government Reform, 2012), 66–8; U.S. Congress, *United States Government Policy and Supporting Positions* (Washington, DC: U.S. Senate’s Committee on Homeland Security and Governmental Affairs, 2016), 69–71.
- ⁶¹ Christopher M. Davis and Michael Greene, *Presidential Appointee Positions Requiring Senate Confirmation and Committees Handling Nominations* (Washington, DC: Congressional Research Service, May 3, 2017), 31, <https://fas.org/sgp/crs/misc/RL30959.pdf>.
- ⁶² “Search for ‘food and drug’ in category ‘Nominations,’” Congress.gov (Search last executed April 13, 2018), <https://www.congress.gov/search?q=%7B%22source%22%3A%22nominations%22%2C%22search%22%3A%22%5C%22food%20and%20drug%5C%22%22%7D&searchResultViewType=expanded>.
- ⁶³ The authors did not know the identity of the principal peer reviewers until final substantive edits to the report were completed. Peer reviewers were offered modest honoraria from Pacific Legal Foundation for their review and commentary; they did not know the identity of the authors at the time of their review. Professor Michael Rappaport is a constitutional and Appointments Clause scholar at the University of San Diego Law School. Richard Williams is a former professor of economics, former vice president for policy and former director of the Regulatory Studies Program at the Mercatus Center, and he worked at the FDA for 27 years.

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ABOUT PLF

Pacific Legal Foundation is a national nonprofit legal organization that defends Americans' liberties when threatened by government overreach and abuse. Each year, PLF represents hundreds of Americans, free of charge, who seek to improve their lives but are thwarted by government. We give them their day in court to vindicate their rights and set a lasting precedent to protect everyone else.

Started in 1973 in California, PLF now brings cases nationwide, scoring precedent setting victories for our clients, with an unmatched track record at the United States Supreme Court.

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