

**Prepared Statement of  
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**Hearing on Federally Incurred Cost of Regulatory Changes and  
How Such Changes are Made**

**July 17, 2019**

Thank you for inviting me to testify today on unconstitutional rulemaking by unaccountable agency bureaucrats. My aim is to impress upon the committee three key points:

1. Within just one agency, the Department of Health and Human Services, more than 2,000 out of a total of 3,000 rules over the last 18 years have been signed and issued by department employees who were never nominated by the president or confirmed by the Senate. Most or all of these rules were issued pursuant to internal agency subdelegations of rulemaking power.
2. This practice of subdelegating rulemaking power is harmful for several reasons. It weakens the separation of powers by divesting the Senate of its proper role in vetting executive-branch decision-makers. It is anti-democratic, because it gives decisions to career bureaucrats rather than presidential appointees. And it harms political accountability by making it harder for the public to blame responsible officials for the rulemaking decisions they don't like.
3. This practice is also unconstitutional. Rulemaking by mere agency employees violates both the original meaning of the Appointments Clause and current Supreme Court precedent. Thousands of rules, both good and bad, have thus been placed in unnecessary legal jeopardy. These subdelegations of authority have failed to attract the attention that would attend to a statute explicitly violating the Appointments Clause, but the violations are no less harmful or serious for having been achieved by subdelegation rather than by statute.

My testimony today will be organized into four sections: the first three fleshing out these points in order, and the fourth responding to potential objections to my argument.

I hope that this testimony will encourage Congress to explore this issue further, including consideration of statutory solutions to prohibit the subdelegation of rulemaking power to career bureaucrats. Whether by across-the-board prohibitions or more targeted reforms, this is a problem that Congress can and should solve.

## Part 1: A Case Study in Subdelegating Rulemaking Authority<sup>1</sup>

Subdelegation of power is rampant within federal agencies. I am not the first to note this.<sup>2</sup> But a recent study that I coauthored with Angela C. Erickson is the first to quantify just *how* rampant. These numbers give a sense of just how much agency rulemaking occurs via illegal subdelegation of rulemaking power to career bureaucrats.

Because compiling statistics across the entire federal government would have been a years-long undertaking, our report focused on just one federal department as a case study: The Department of Health and Human Services. We collected all HHS final rules going back two full administrations and including the first year of the Trump administration.<sup>3</sup> This totaled 2,952 final rules. For each rule, we noted the name and title of the issuing official, based on the signature appearing at the end of the rule. We then determined whether each issuing official was Senate-confirmed at the time of issuing the rule, by consulting several independent sources.<sup>4</sup>

The result: 2,094 of the 2,952 rules (71%) were issued by non-Senate-confirmed persons.<sup>5</sup> Of these, 1,860 were issued by FDA employees, while 234 came from other agencies within HHS.

We then examined whether rules signed by lower-level employees were limited to the most minor rules, such as typo fixes or other small changes. But our study found that this is not the case. We homed in on a subcategory of “substantive” rules, a category that omitted rules with small changes including corrections, technical amendments, and date changes.<sup>6</sup> We found that nearly 1,300 out of 2,060 substantive rules (63%) were signed by non-Senate-confirmed employees.<sup>7</sup> Of these, 1,273 were issued by FDA employees.

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<sup>1</sup> This section is adapted from Angela C. Erickson and Thomas Berry, *But Who Rules the Rulemakers?* 18, 33 (2019) [hereinafter “Rulemakers”].

<sup>2</sup> Jennifer Nou has written the most thorough treatment to date of agency subdelegation. *See generally* Jennifer Nou, *Subdelegating Powers*, 117 Colum. L. Rev. 473, 475 (2017) (“In reality, however, much of that power is subdelegated within the agency. Agency heads, that is, take authority granted from Congress or the President and further redelegate it to their subordinates. As a result, tenure-protected career staff and lower-level political officials often make decisions initially granted to their superiors.”) (citations omitted).

<sup>3</sup> Specifically, those rules published from January 20, 2001, through January 19, 2018.

<sup>4</sup> The three sources we used were the Plum Book, a CRS list of positions requiring Senate confirmations, and the Senate’s own website, which includes a database of every presidential nomination going back to 1981. *See* Rulemakers at 18, 33.

<sup>5</sup> Rulemakers at 35.

<sup>6</sup> Rulemakers at 19, 34.

<sup>7</sup> Rulemakers at 36.

But “substantive” was not even the highest level of importance we looked at. We also narrowed our search to just rules deemed “significant” by the Office of Management and Budget.<sup>8</sup> Even for these rules, the most important ones that an agency issues, career bureaucrats continued to issue final rules with regularity. Non-Senate-confirmed employees issued 254 of the 755 significant rules in our study (34%).<sup>9</sup> Of these, 121 were issued by FDA, 109 were issued by Center for Medicare and Medicaid Services, and 24 were issued by other agencies. Notably, the FDA’s own estimates found that the 23 most economically significant rules issued by non-Senate-confirmed employees have had a combined cost of \$17.7 billion and combined benefits of only \$14.5 billion since those regulations were issued.<sup>10</sup>

How did these rules come to be issued by non-Senate-confirmed agency employees? Since the FDA is the biggest offender, we researched its history of illegal subdelegations of power in the most depth. The FDA Commissioner has subdelegated rulemaking power to a position called the “associate commissioner for policy.”<sup>11</sup> That title belongs to a career FDA employee in the Senior Executive Service, who cannot be fired for policy reasons.<sup>12</sup>

Importantly, this rulemaking power has been delegated *concurrently*. That is to say, both the Secretary of HHS and FDA Commissioner retain their authority to issue rules, and both continue to do so.<sup>13</sup> It is this concurrent form of rulemaking authority that has made such subdelegations

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<sup>8</sup> A rule is deemed significant for the purposes of Executive Order 12866 if it has “an annual effect on the economy of \$100 million or more,” adversely affects one of several economic subcategories, interferes with another agency action, alters the budgetary impact of certain core programs, or raises novel legal or policy issues. See E.O. 12866, 58 Fed. Reg. 51735, § 3(f).

<sup>9</sup> Rulemakers at 36.

<sup>10</sup> These totals are calculated from the cost-benefit analyses within the agency’s final rules. Total estimates were calculated by taking the primary annualized 7% discount rate estimate (where not available the 3% was used or an average of low and high estimates) and multiplying it by the number of years (max 10) and months between the effective date and mid-2019. These estimates were then inflation adjusted to 2019 dollars. Note two of the rules have no quantified costs and 12 have no quantified benefits. Several other rules note benefits or costs that may exist but were not quantified as part of their final estimates. In addition, there are numerous problems with how agencies conduct cost benefit analysis.

<sup>11</sup> See 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”), available at <https://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/StaffManual%20Guides/UCM273783.pdf>.

<sup>12</sup> See Senate Committee on Homeland Security and Governmental Affairs, United States Government Policy and Supporting Positions 70 (2016) (listing the associate commissioner for policy as a career position within the SES); 5 U.S.C. §§ 7541–43 (SES employees subject to removal only for cause).

<sup>13</sup> The various HHS Secretaries who served during the period of our study issued a combined 822 rules. See Rulemakers at 25.

largely unnoticed. Had the FDA Commissioner completely surrendered his rulemaking authority to a little-known career FDA employee, this subdelegation might not have flown so far under the radar. But in practice, the reality we have is not too different from that hypothetical, as the associate commissioners for policy have issued vastly more regulations than FDA commissioners during the period of our study.

Further contributing to the lack of attention is the fact that these subdelegations can be made without the President or Senate ever being aware. While the subdelegations occurred pursuant to a statute that permits the HHS secretary to delegate her authorities, it is unlikely that Congress ever contemplated that a power as important as rulemaking would be subdelegated *twice*, and that the second of these subdelegations would be to someone never nominated by the president or confirmed by the Senate (let alone to a career employee who had been working for the FDA for many years prior).<sup>14</sup> In fact, we are not aware of any statutes that directly grant rulemaking power to officials who are not appointed by the president and confirmed by the Senate.

As the numbers we have found show, rulemaking by agency bureaucrats who have never been vetted by the Senate is the norm rather than the exception, at least within the Department of Health and Human Services (and, more specifically, within the FDA). In the next section, I will explain why this is a serious problem.

## **Part 2: Why Rulemaking by Non-Senate-Confirmed Agency Employees Is a Problem**

When senators question nominated agency heads during confirmation hearings, those senators are well aware of the rulemaking power that the position holds. When Robert Califf was nominated as FDA Commissioner in 2015, senators of both parties asked questions regarding his plans for rulemaking if confirmed.<sup>15</sup> It is unlikely that any of those senators would have

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<sup>14</sup> The HHS Secretary's statutory authority to subdelegate her powers is found in Reorganization Plan No. 1 of 1953 § 6, reprinted in 5 U.S.C. Appendix. Pursuant to this authority, the Secretary has subdelegated all rulemaking power derived from the Food, Drug, and Cosmetic Act to the FDA Commissioner, with authority to further redelegate that power. *See* FDA Staff Manual Guide 1410.10(A)(1). Of course, a statute can't override a constitutional command, and thus, a statute cannot wittingly or unwittingly authorize the subdelegation of a power that must constitutionally be exercised by a Senate-confirmed officer to a career employee.

<sup>15</sup> *See* Hearing on the Nomination of Robert Califf to Serve as FDA Commissioner (Nov. 17, 2015), available at <https://www.govinfo.gov/content/pkg/CHRG-114shrg97694/pdf/CHRG-114shrg97694.pdf>, at 29 (oral question of Senator Franken) ("I want to talk about generic drug labeling and the generic drug labeling rule. . . . What is the current plan for finalizing the FDA's generic drug labeling rule?"); *id.* at 57 (written question of Senators Isakson and Murphy) ("If

anticipated that most of the FDA rules that would be issued during Califf's tenure would not be issued by Califf himself, but instead by a career FDA employee who assumed her role five years prior to that hearing and would continue in her position long after Califf had left.

When the final decision to issue a binding rule is made by someone the Senate has never vetted, the purpose of our nomination-and-confirmation system is undermined. One of the Framers of the Constitution, Gouverneur Morris, touted the strength of the Constitution's dual-role system: "as the President was to nominate, there would be responsibility, and as the Senate was to concur, there would be security."<sup>16</sup> But when a final decision can be made regardless of the Senate's choice to confirm or not confirm an agency head, such security is lost. It is the judgment of unvetted bureaucrats that determines what rules will bind the American people, not the judgment of the agency heads that this body reviews.

This is a principle that Senators on both sides of the aisle understand. In a recent lawsuit filed by three Democratic senators, their complaint argued that bypassing advice and consent "unlawfully denied the Plaintiffs their right, as sitting U.S. Senators, to vote on whether to consent to" an appointment.<sup>17</sup> The complaint further noted that the disputed officer, who had not been confirmed by the Senate, had "vast ability to shape whether and how the laws enacted by Congress are enforced and the money appropriated by Congress is spent."<sup>18</sup> Without expressing an opinion on the legal merits of that particular lawsuit, their complaint is evidence that there is a bipartisan understanding in this chamber: advice and consent is one of the Senate's core duties, and any potential abrogation of that right is a serious matter.

But it is not just the Senate's loss when unaccountable bureaucrats issue final rules, it is also the American public's loss. Just as unconfirmed agency employees lack the "security" of Senate review, they also lack the "responsibility" of presidential nomination. Our system was designed with a unitary executive: the President and Vice President are the only elected members of the executive branch, and so decisions made in that branch have democratic legitimacy only because they can ultimately be traced back to the top. When decisions are made by low-level employees, the public is deprived of the ability to trace such blame to the top. The president has never nominated—let alone likely even heard of—the FDA's associate commissioner for policy. The associate commissioner for policy is a career position within the civil service system, meaning that an FDA employee might stay in that role for years across multiple administrations. The

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confirmed, will you commit to updating FDA's regulations to address the longstanding enforcement issues as to medical gas?").

<sup>16</sup> 2 The Records of the Federal Convention of 1787, at 539 (Max Farrand ed., 1911).

<sup>17</sup> Complaint at 13, *Blumenthal, et al. v. Whitaker*, No. 18-02664 (S.D.N.Y. Nov. 19, 2018), available at <https://assets.documentcloud.org/documents/5188870/11-19-18-Blumenthal-v-Whitaker-Complaint.pdf>.

<sup>18</sup> *Id.*

public would have a hard time plausibly blaming the president for the decisions of an employee hired within the FDA who is not democratically responsible, was not hired on the basis of her policy or political judgement, and is expected to stay in that agency across multiple administrations regardless of party.

Finally, this practice is harmful because it is unconstitutional. Rulemaking is an authority that both the Constitution's text and current Supreme Court doctrine confirm to be reserved to those validly appointed as officers of the United States. The majority of the rules in our study were issued by career employees who were never validly appointed as officers. And even if some subset of these rules were issued by persons appointed as *inferior* officers, there are several compelling reasons to believe that even this is constitutionally insufficient, and that such officers must instead go through the Senate confirmation that is required of principal officers.

As a lawyer, my first instinct was to put this fact upfront as the very *first* harm. But I wish to emphasize today that even if you are uncertain about (or disagree with) our legal theory, there are compelling policy reasons to end this practice. Nonetheless, its unconstitutionality is relevant to you as well, because thousands of agency rules have been put in legal jeopardy by this practice. Some of these rules you may disagree with, but there are surely many that you support on policy grounds. Eliminating the practice of subdelegating rulemaking authority will ensure that future rules are not issued on shaky legal footing.

### **Part 3: Why It Is Unconstitutional<sup>19</sup>**

The Appointments Clause of the U.S. Constitution reads as follows:

[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.<sup>20</sup>

The Constitution never explicitly defines the terms “officer” or “inferior officer,” meaning judges and scholars have had to work out the meaning of these terms 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

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<sup>19</sup> This section is closely adapted from Rulemakers, Appendix A, pages 31–32.

<sup>20</sup> U.S. Const. art. II, § 2, cl. 2.

principal officer came into use.<sup>21</sup> 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.<sup>22</sup> 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 is to draw the two dividing lines between these three tiers. Which powers are so important that the public at the time of enactment 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.<sup>23</sup> 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.”<sup>24</sup>

The Supreme Court has explicitly held that the power to issue final rules is a significant authority that, at the least, must be exercised by an officer.<sup>25</sup> 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.”<sup>26</sup> It is inconceivable that the founding generation would have anticipated such a power being exercised by someone not even appointed an officer pursuant to the Constitution.

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<sup>21</sup> 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.”).

<sup>22</sup> 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).

<sup>23</sup> *Id.* at 126.

<sup>24</sup> *Edmond v. United States*, 520 U.S. 651, 663 (1997).

<sup>25</sup> *Buckley*, 424 U.S. at 140–41 (“[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.’”).

<sup>26</sup> 1 William Blackstone, *Commentaries* \*44.

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 the term “officer,” 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.”<sup>27</sup>

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 at that time 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 D.C. 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.”<sup>28</sup> Most tellingly, the D.C. Circuit cited with approval Justice Alito’s recent observation in a concurrence that “nothing final should appear in the Federal Register unless a Presidential appointee has at least signed off on it.”<sup>29</sup>

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 the FDA’s associate commissioner for policy), can be removed from their jobs only for cause—not for policy disagreements.<sup>30</sup> 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.<sup>31</sup>

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<sup>27</sup> Jennifer Mascott, *Who Are ‘Officers of the United States’?*, 70 *Stan. L. Rev.* 450 (2018).

<sup>28</sup> *Ass’n of Am. R.R. v. U.S. DOT*, 821 F.3d 19, 39 (D.C. Cir. 2016).

<sup>29</sup> *Id.* at 37–38 (quoting *U.S. DOT v. Ass’n of Am. R.R.*, 135 S. Ct. 1225, 1239 (2015) (Alito, J., concurring)).

<sup>30</sup> 5 U.S.C. §§ 7541–43.

<sup>31</sup> See *Edmond v. United States*, 520 U.S. 651, 664 (1997).

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.

Further, even if inferior officers may in some cases issue rules consistent with the Appointments Clause, the majority of the rules in our study would still be unconstitutional. To be properly appointed as an inferior officer without Senate confirmation, Congress must vest “by law” such an appointment in the president or the head of a department. We conducted an exhaustive search for every statute authorizing such an appointment within the Food, Drug, and Cosmetics Act, and none come remotely close to authorizing the appointment of the positions that actually issued the FDA’s 1,860 rules signed by non-Senate-confirmed officials.<sup>32</sup> In litigation, the FDA has implausibly cited several general organizational statutes as vesting a power in the HHS Secretary to create and appoint any officers she wishes, even though none of the statutes cited actually say that they are granting the power to “appoint” to the HHS Secretary. The FDA’s tenuous argument has made us even more confident that Congress has not vested this appointment power. Thus, these 1,860 rules were issued by persons not even validly appointed as inferior officers.

These 1,860 rules constitute 63% of the rules in our overall study, which means that even if inferior officers may in some cases issue rules, *and* even if every other non-Senate-confirmed signer in other HHS agencies was both validly appointed and sufficiently supervised (each unlikely on its own and both unlikely together), a clear majority of the rules we studied are nonetheless still unconstitutional. In other words, even if every non-FDA rule in our study were constitutional, the overall percentage of unconstitutional rules in our study would go down only slightly, from 71% to 63%.

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.<sup>33</sup> 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.<sup>34</sup> 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.

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<sup>32</sup> The portions of the U.S. code authorizing such appointments are 21 U.S.C. § 355; § 355-1; § 360c; § 360d; § 360e; § 360kk; § 360j; § 379d-3; § 379d-3a; § 379e; § 387q; § 393; § 399a; § 454; § 603; § 604; § 606; § 616; § 621; § 661.

<sup>33</sup> See *United States v. Morgan*, 313 U.S. 419, 421–22 (1941).

<sup>34</sup> See *Nat’l Nutritional Foods Ass’n v. FDA*, 491 F.2d 1141, 1144–46 (2d Cir. 1974).

In sum, a staggering number of rules issued within just one department since 2001 are unconstitutional. Both because this creates legal uncertainty and because it shows how much modern practice has diverged from the Framers' design, this similarly demonstrates the urgency of fixing this problem.

#### **Part 4: Potential Concerns and Objections**

I will conclude by addressing some arguments we have heard and anticipated against our thesis that subdelegating rulemaking power to non-Senate-confirmed agency employees is both undesirable and unconstitutional.

##### **A. Would our constitutional theory call into question the authority of acting officers to issue rules?**

Not for acting officers who have been confirmed by the Senate to some other position, of which there is always at least one in every department. When a vacancy arises in a position requiring Senate confirmation, the president does have the authority to appoint some non-Senate-confirmed officials to serve as the acting officer.<sup>35</sup> But most of the time, for positions of importance, an acting officer is chosen who has already been confirmed by the Senate to another position.<sup>36</sup> It is in the interest of the executive branch to do this, since acting officers who have not been confirmed by the Senate to any position risk having their most significant actions challenged in court.<sup>37</sup> The government does not want to have the rules it issues in legal limbo, and there are always a sufficient number of Senate-confirmed officers in other positions available to serve as acting officers for the most important vacant positions. This is true even during president transitions, when Senate-confirmed deputies will temporarily stay in government as holdovers from the prior administration. A Senate-confirmed Deputy Secretary of Labor, for example, may continue to serve in a subsequent administration as the Acting Secretary of Labor until a new Labor Secretary is confirmed. At the very least, such Senate-confirmed acting secretaries can sign urgent rules that must be issued, since cabinet secretaries normally retain rulemaking authority for all the agencies within a department. Thus, even if a particular agency temporarily has no Senate-confirmed officers, the rulemaking for that agency can be exercised by a Senate-confirmed acting secretary.

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<sup>35</sup> See 5 U.S.C. § 3354(a)(3).

<sup>36</sup> See *id.* at § 3345(a)(2) (authorizing the appointment of anyone currently serving in a Senate-confirmed position as an acting officer).

<sup>37</sup> See, e.g., *Guedes v. B.A.T.F.*, 920 F.3d 1 (D.C. Cir. 2019).

**B. If Congress has made the choice to allow such subdelegations in its statutes, what right does Congress have to object to such subdelegations?**

First, it must be emphasized that our objection is not to *every* type of subdelegation. There are many duties that do not affect the rights of citizens, and these powers need not be exercised by constitutional officers. Subdelegating such powers to career employees is thus not problematic. Further, rulemaking power can be subdelegated one level down if the recipient of that power is a Senate-confirmed official. Statutes that allow *some* subdelegation are thus not problematic *per se* (although Congress should certainly revise them to clarify that significant authority can only be subdelegated to Senate-confirmed officials).

Instead, as noted above, the subdelegations of power to which we object are those that push rulemaking authority all the way down to the level of career bureaucrats. In the case of the FDA (and likely other agencies as well), this happens because a statute allows multiple tiers of subdelegation, leaving discretion in each recipient of rulemaking power whether to further subdelegate. But when a statute allows subdelegation of rulemaking power to career employees via this process, that final subdelegation is unconstitutional and subject to judicial invalidation. As the Supreme Court has stated, “the separation of powers does not depend on . . . whether ‘the encroached-upon branch approves the encroachment.’”<sup>38</sup> When Congress allowed such subdelegations, it likely never contemplated that it would be used in this rampant and unconstitutional way. But it is ultimately the harm to individual liberty from unaccountable rulemaking that is the primary reason this practice must be eliminated, regardless of the views of the Congresses that originally authorized these subdelegations.

**C. Would rulemaking reform prevent those agency employees with the most technical expertise from drafting rules?**

No. We are not proposing a ban on allowing career employees to aid in researching or drafting rules. Indeed, that is a proper function when guided by democratically accountable officials who have the responsibility to exercise the ultimate policy judgement. Rather, we are insisting that the *final* decision to issue those rules, and the rules’ final content, must be made by politically accountable officers. Just as a judicial opinion may be drafted by a hired law clerk but must be signed by a Senate-confirmed judge, so must the American people know who has taken final accountability for binding rules. It is perfectly acceptable for political appointees to put great

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<sup>38</sup> *Free Enter. 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)).

trust in the work of their subordinates (although trust with some degree of verification is the proper management practice), but those appointees still must ultimately take responsibility for that trust by issuing the work of their subordinates themselves.

**D. What if the volume of rules makes it infeasible for a Senate-confirmed officer to issue every rule?**

Our study found that there is no reason to think a Senate-confirmed officer is incapable of issuing every final rule promulgated by an agency. Some agencies in our study issued rules the right way. The Center for Medicare and Medicaid Services (CMS), for example, had Senate-confirmed officers issue all of its nearly 470 substantive rules issued during the period of our study.<sup>39</sup> And CMS substantive rules were generally longer and more complex than FDA rules.<sup>40</sup> Finally, if the volume of rules issued by an agency is indeed too much for a single agency head to handle, the proper response is to create additional Senate-confirmed positions within an agency, not to subdelegate powers to positions that are not Senate confirmed.

**E. If a Senate-confirmed officer made the decision to delegate his rulemaking power to a subordinate, doesn't that decision lend political legitimacy to the decisions of the subordinate?**

No. The Supreme Court has made clear that Senate confirmation of a delegator does not allow subordinates to exercise significant authority “once removed.”<sup>41</sup> Even if final decision-making power is delegated on a case by case basis, that final decision-making power gives the recipient significant authority that can only be held by validly appointed officers.

Further, from a policy perspective, it is not enough that the Senate has vetted the delegator of power. Even if this logic were sound when a delegatee makes decisions while her delegator remains in office, subdelegations continue to be effective even after a delegator has left office.

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<sup>39</sup> See Rulemakers at 36.

<sup>40</sup> All of CMS's substantive rules combined totaled more than 32.6 million words. All of these were in rules that were constitutionally issued. This is in stark contrast to the FDA, whose substantive rules combined totaled 7.4 million words, of which 6.1 million were in unconstitutionally issued rules. See Rulemakers at 23.

<sup>41</sup> In *Lucia v. SEC*, the Supreme Court found SEC ALJs to be officers under the meaning of the Appointments Clause. *Lucia* concerned a statute that gave SEC commissioners the option to delegate some of their adjudicative power to ALJs. Thus, SEC ALJs only had this adjudicative power when it was subdelegated by the SEC commissioners. 138 S. Ct. 2044, 2049 (2018). The Court ultimately struck down this delegation as a violation of the Appointments Clause, because the subordinate ALJs had not been properly appointed. *Id.* at 2055.

For example, when Scott Gottlieb replaced Robert Califf as FDA commissioner, the associate commissioner for policy continued to issue rules pursuant to a delegation made by Califf. In such situations, even the once-removed theory of political accountability breaks down.

More fundamentally, decisions to delegate are not the same as actual decisions. If it were enough for the Senate to vet a delegator of decision-making authority, why wouldn't it also be enough to only vet the delegator to a delegator? How many chains of subdelegation would be too much? There is no principled line other than the correct one: final rulemaking decisions must be made by officers confirmed by the Senate.

Finally, the Senate should reflect on why it generally insists on Senate confirmation for deputy secretaries, associate secretaries, and assistant secretaries. Why isn't it enough for the Senate to confirm only the Cabinet Secretary for every department and leave it to that person to subdelegate all power within the department? The reason is that these other high-ranking officers also exercise significant power, and there is added security in vetting such officers. In these situations, the Senate does not simply assume that these deputies will have their judgement adequately supervised by Senate-confirmed secretaries—the Senate quite rightly has a duty to vet their judgement independently.

#### **F. What can Congress do to ensure constitutional rulemaking?**

There are several statutory options available for Congress to rein in this harmful and unconstitutional practice. The simplest and most direct may be a short bill requiring that, as a final step in the rule promulgating process, every rule published in the Federal Register must be signed by a Senate-confirmed officer who also possesses statutory authority to issue that particular rule. Such an amendment would immediately supersede any delegations of rulemaking authority to non-Senate-confirmed employees.

Short of this sweeping solution, individual organizational statutes for the various departments can and should be amended, so that subdelegations of rulemaking authority are no longer permissible except to officers confirmed by the Senate.

Further, Congress can bring attention to this matter through its oversight powers. Hearings such as this one can help encourage the executive branch to alter its practices and ensure that it issues rules in a constitutional manner. Since the executive branch never wants to have its rules invalidated in the courts, it is in the interest of that branch as well to eliminate this practice.

Finally, since subdelegation is always made at the discretion of particular officers, the Senate can question nominees on this practice and ensure that they commit that they will not subdelegate rulemaking power below the level of Senate-confirmed officers.

## **Conclusion**

Thank you for allowing me to testify today on this important matter. As the body charged by the Framers with vetting the character and judgment of executive officers, it is natural that this body should take a leading role in reining back an abusive end-run around that system. Whether through oversight, reform to delegation statutes, or a law that requires final sign-off by Senate-confirmed officers, Congress has several options at its disposal to restore the balance our Framers designed and ensure that every rule binding on the public is made by a politically accountable officer.