MERCATUS CENTER
George Mason University

3434 WASHINGTON BLVD.
4TH FLOOR
ARLINGTON, VA 22201

PHONE: 703.993.4930 / 800.815.5711
FAX: 703.993.4935
WWW.MERCATUS.ORG

From the Desk of James Broughel

January 31, 2022

Healthy Future Task Force Security Subcommittee
2112 Rayburn House Office Building
Washington, DC 20515

cc: Molly Brimmer
Andrew Keyes
Shane Hand

Dear Representatives Hudson, Banks, and Cole:

Thank you for the opportunity to respond to the Healthy Future Task Force Security Subcommittee's request for information (RFI) on Pandemic Preparedness, Public Health, and Supply Chains and Medical Independence from China.[1] My name is James Broughel, and I am a senior research fellow at the Mercatus Center at George Mason University and an adjunct professor of law at the Antonin Scalia Law School. I specialize in regulatory institutions, cost-benefit analysis, and the impact of regulations on economic growth. The Fourth Branch project at the Mercatus Center is dedicated to advancing knowledge about the effects of regulation on society. As part of the project's mission, scholars conduct careful and independent nonpartisan analysis that employs contemporary economic scholarship to assess regulations and their effects on economic opportunities and societal well-being.

This letter will focus on four areas of my research that I believe are relevant to the subcommittee's mission, as well as to the RFI:

- *Vaccination and testing*. Emergency deregulatory actions taken by the US Department of Health and Human Services (HHS) have allowed pharmacists and pharmacy support staff members to vaccinate for COVID-19. These regulatory changes should be made permanent, and further expansions of pharmacy authority should be considered, such as making it easier to obtain waivers under the Clinical Laboratory Improvement Amendments (CLIA).
- *Drug shortages*. Drug shortages have been a recurring feature in pharmaceutical markets in recent years. During the pandemic, emergency deregulation made it easier for compounding pharmacies around the country to produce medicines when those medicines went into shortage and were not available from another supplier. This process worked well and should be continued during ordinary times and even expanded upon.

1. Healthy Future Task Force Security Subcommittee, *Request for Information*, 2021, PDF file (on file with author).

- *Retrospective review of regulations*. Currently, approximately 1.1 million restrictive terms are contained in federal regulations.[2] About 65,000 of these can be found in regulations from HHS.[3] A logical response to the pandemic is to conduct a review of healthcare regulations to determine which requirements are working well and which are not working. Instead, HHS is moving in the opposite direction. The department is refusing to review its regulations, as evidenced by the fact that HHS recently proposed repealing a self-binding regulation that would require HHS to review its own rules on a 10-year recurring basis. More retrospective review and analysis is needed at federal agencies, especially at healthcare regulators such as HHS.
- *Mortality costs of regulations*. Any regulation that imposes a cost displaces activities that could otherwise provide benefits to society. When regulatory costs displace expenditures aimed at risk reduction, health and safety risks can inadvertently rise, including risks to life. Consideration of these opportunity costs should be a regular feature of regulatory analysis, but in general, such opportunity costs are overlooked by federal agencies.

Subcommittee Questions

The subcommittee RFI includes 32 questions of interest to the subcommittee. Rather than answer all of them, many of which lie outside my expertise, I will instead summarize lessons of research I have produced in the past few years. These lessons are most relevant to four specific subcommittee questions, numbers 5, 14, 15, and 20:

> 5. The COVID-19 pandemic highlighted the efficacy of removing inefficient regulatory barriers that may stall public health and recovery responses. While many federal barriers to the immediate risk were addressed, long-term impediments remain that could discourage State, local, and private sector investment in pandemic preparedness.
>
> > a. What regulatory barriers could be modified, consolidated, harmonized, or repealed to better ensure Federal and State public health agencies are better situated to quickly adapt and efficaciously respond to protect public health in a future [public health emergency]?
>
> 14. Social determinants of health are another key driver of healthcare spending. Individual behavior and social and environmental factors are estimated to account for 60% of health care costs.
>
> > a. To what extent do federal health programs already account for and address social determinants of health?
> >
> > b. How can Congress best address the factors that influence overall health outcomes in rural, Tribal, and other underserved areas to improve health outcomes in these communities?
> >
> > c. What flexibilities or authorities are needed to promote the adoption of policies and strategies in federal health programs to address these social determinants?

2. Patrick A. McLaughlin et al., RegData US 4.0 (dataset), QuantGov, Mercatus Center at George Mason University, Arlington, VA, 2021, https://www.quantgov.org/bulk-download.
3. McLaughlin et al., RegData 4.0 (dataset).

d. What innovative programs or practices, whether operated by non-governmental entities or local, State, or Tribal governments, might Congress examine for implementation on a national scale?

15. The COVID-19 pandemic has called attention to some populations' distrust of public health departments and officials, whether through historical wrongs or because of skepticism of more recent public health measures. How can Congress work to bolster Americans' confidence in public health institutions?

20. The COVID-19 pandemic highlighted the need for agile, adaptable public health agencies unencumbered by activities and actions beyond the scope of their core mission.

a. What reforms can be made to modernize and streamline Federal public health agencies?

b. What reforms, if any, are needed to Federal public health agencies to ensure an unencumbered, agile, and adaptable public health response? What actions covered by such agencies fall outside the scope of their core missions and should be moved, repealed, streamlined, or otherwise addressed?[4]

In the following sections, I refer to various regulatory reform proposals for each of the four areas I outlined earlier, but I will reference the subcommittee's questions when relevant. In particular, I believe pharmacy reform, retrospective review, and better analysis of health opportunity costs owing to regulatory costs would be beneficial to address the topics discussed in the four questions. Research in these areas is also attached at the end of this letter.

Vaccination and Testing

Pharmacists have been some of the unsung heroes of the COVID-19 pandemic. Through the Federal Retail Pharmacy Program, retail pharmacies have administered and reported more than 200 million doses of COVID-19 vaccine since a vaccine has been available.[5] This would not have been possible were it not for emergency actions taken by the FDA to authorize pharmacists,[6] as well as pharmacy support staff members,[7] to vaccinate for COVID-19. These changes should be made permanent.

Moreover, the federal government can expand pharmacists' scope of practice even further. Under the CLIA, pharmacies and other medical offices can receive a waiver from federal laboratory testing requirements, thereby authorizing them to conduct low-risk tests for ailments such as flu or strep throat. In some cases, pharmacists can even prescribe on the basis of the results of a test.[8]

The subcommittee's question 5 asks what regulatory barriers stand in the way of a better response to future pandemics. Fortunately, COVID-19 tests have been added to the list of CLIA-waived

4. Healthy Future Task Force Security Subcommittee, *Request for Information*, 2–5.
5. "The Federal Retail Pharmacy Program for COVID-19 Vaccination," Centers for Disease Control and Prevention, last updated December 27, 2021, https://www.cdc.gov/vaccines/covid-19/retail-pharmacy-program/index.html.
6. US Department of Health and Human Services, *Guidance for Licensed Pharmacists and Pharmacy Interns regarding COVID-19 Vaccines and Immunity under the PREP Act*, September 3, 2020.
7. US Department of Health and Human Services, *Guidance for PREP Act Coverage for Qualified Pharmacy Technicians and State-Authorized Pharmacy Interns for Childhood Vaccines, COVID-19 Vaccines, and COVID-19 Testing*, October 20, 2020.
8. James Broughel, Philip Haunschild, and Yuliya Yatsyshina, "Reforming the Practice of Pharmacy: Observations from Idaho" (Mercatus Research, Mercatus Center at George Mason University, Arlington, VA, April 2020).

devices.[9] Unfortunately, many states enact roadblocks that make it difficult for pharmacies to obtain CLIA waivers.[10] Congress should consider legislation that would create a simpler process for pharmacies to obtain CLIA waivers. More important, it should look for ways to either override state regulatory barriers or provide incentives to states to remove their own regulatory barriers.

Fortunately, hospitals in the United States have not been overwhelmed by COVID-19 to the extent observed in some other countries, such as Italy. That said, America may not be so lucky next time. Pharmacists can play an important role by triaging, testing, and prescribing for minor ailments, as well as directing patients to physicians or other healthcare professionals for more serious ailments.[11] But without the permanent ability to test, vaccinate, and prescribe some medications, pharmacists' public health role will be unnecessarily restricted.

Pharmacy reforms along these lines would be especially beneficial to Americans living in rural areas (relevant to the subcommittee's question 14b), given that more than three-quarters of independent community pharmacies serve areas with populations of less than 50,000.[12]

Drug Shortages

Supply chain problems now fill the daily headlines, but one area of recurring supply chain problems even before the pandemic is pharmaceutical drug shortages. Drug shortages often arise when an important manufacturer goes offline. However, the COVID-19 pandemic has also highlighted that drug shortages can arise when demand for certain medications spikes. During the pandemic, the United States has seen ventilator drugs go into shortage, as well as ordinary medicines such as acetaminophen.[13]

Compounding pharmacies produce tailor-made medicines for individuals with specific medical needs, but they can also be a vital resource to alleviate drug shortages. The FDA recognizes this fact and has created a pathway for compounders to address shortages when they arise. However, that pathway has proved inadequate for at least two reasons.[14] First, the FDA's drug shortage list does not always reflect the realities of the marketplace. Sometimes, patients have trouble obtaining medicines that have not or will not show up on the FDA's list. Second, some compounders are limited by a requirement that they obtain a prescription before filling an order. The FDA relaxed requirements on compounding pharmacies during the pandemic so that they could better address shortages.[15] This relaxation included creating a pathway for pharmacies subject to the prescription requirement to fill a shortage order without a prescription in hand. A survey of compounding pharmacies finds that, in response to the relaxation of rules, 87 of 665 respondents compounded COVID-19 shortage drugs for hospitals under the temporary guidance from the FDA and with

9. "Guidance for SARS-CoV-2 Rapid Testing Performed in Point-of-Care Settings," Centers for Disease Control and Prevention, last updated January 19, 2022, https://www.cdc.gov/coronavirus/2019-ncov/lab/point-of-care-testing.html.
10. Michael Klepser et al., "U.S. Community Pharmacies as CLIA-Waived Facilities: Prevalence, Dispersion, and Impact on Patient Access to Testing," *Research in Social and Administrative Pharmacy* 12, no. 4 (2015): 614–21.
11. James Broughel and Yuliya Yatsyshina, "Relax Pharmacy Regulations to Help with COVID-19 Testing and Treatment" (Mercatus Policy Brief, Mercatus Center at George Mason University, Arlington, VA, March 2020).
12. James Broughel and Elise Amez-Droz, "Expanding Pharmacists' Prescriptive Authority: Options for Reform" (Mercatus Policy Brief, Mercatus Center at George Mason University, Arlington, VA, December 2021).
13. Zachary Brennan, "FDA Reports More Shortages of Drugs Used to Put COVID-19 Patients on Ventilators," *Regulatory Focus*, April 13, 2020; "Pandemic-Linked Tylenol Shortages Popping Up in Some Places," *CBS News*, April 7, 2020.
14. James Broughel, "Allowing Compounding Pharmacies to Address Drug Shortages" (Mercatus Policy Brief, Mercatus Center at George Mason University, Arlington, VA, November 2021).
15. US Food and Drug Administration, *Temporary Policy for Compounding of Certain Drugs for Hospitalized Patients by Pharmacy Compounders Not Registered as Outsourcing Facilities during the COVID-19 Public Health Emergency: Guidance for Industry*, updated May 21, 2020.

approval from state boards of pharmacy.[16] Legislation has now been introduced to make aspects of these changes permanent,[17] but it is unclear whether Congress will act on the legislation. Among other things, the legislation would expand the list of drugs considered to be in shortage to include drugs on a more comprehensive shortage list,[18] and it would allow compounding pharmacies subject to the prescription requirement to obtain patient-specific information after filling an order, so long as the drug is in shortage and other options available to buyers have been exhausted.

Retrospective Review of Regulations

The COVID-19 pandemic revealed many shortcomings with the current regulatory system. All throughout the pandemic, regulations have had to be waived or suspended at all levels of government in order to facilitate a rapid and flexible public health response.[19] Moreover, in the early days of the pandemic, the first COVID-19 tests distributed around the country by the Centers for Disease Control and Prevention (CDC) produced unreliable results.[20] At the same time, commercial labs and public health officials in the states could not get initial approval to perform their own tests.[21] These examples again highlight how the CLIA process for gaining permission to conduct diagnostic testing is too complicated. These failures are not anomalies. Even now the country continues to live with the FDA's precautionary decision to keep many COVID-19 rapid tests off the market,[22] which has no doubt inhibited the response to the SARS-CoV-2 omicron variant, which emerged winter 2021.

Owing to the need to roll back so many regulations during the pandemic, states are reasonably concluding that regulations should be reviewed to ascertain which ones are working and which are not. This approach would help public health agencies become more agile and adaptable, unencumbered by excessive bureaucracy (relevant to the subcommittee's question 20). Two notable examples are Idaho and Arizona, which have both begun a process of reviewing regulations suspended during the pandemic.[23]

Retrospective review of regulations is common sense. Unless rules are periodically reviewed for their impacts, one will never know whether they are achieving their objectives and doing so at a reasonable cost. And yet, a study from the consulting firm Deloitte published in 2018 finds that 68 percent of federal regulations have never been updated.[24] A similar study, conducted by HHS, finds that approximately 85 percent of HHS regulations older than 1990 have never been edited.[25] Although regulatory agencies may assert that the lack of updating is evidence that older

16. Alliance for Pharmacy Compounding, "APC Releases 2021 Snapshot of Pharmacy Compounding: 2021 National Pharmacy Compounding Demographics Study," press release, September 16, 2021, a4pc.org/2021-09/apc-releases-2021-snapshot-of-pharmacy-compounding/.
17. Patient Access to Urgent-Use Pharmacy Compounding Act of 2021, H.R. 3662, 117th Cong. (2021).
18. "Current Drug Shortages," American Society of Health-System Pharmacists, accessed January 24, 2022, www.ashp.org/drug-shortages/current-shortages.
19. Isabelle Morales, "List: 846 Regulations Waived to Help Fight COVID-19," Americans for Tax Reform, August 4, 2020, https://www.atr.org/rules.
20. Christopher Weaver, Betsy McKay, and Brianna Abbott, "America Needed Coronavirus Tests. The Government Failed," *Wall Street Journal*, March 19, 2020.
21. Sheri Fink and Mie Baker, "'It's Just Everywhere Already': How Delays in Testing Set Back the U.S. Coronavirus Response," *New York Times*, updated March 16, 2021.
22. Lydia DePillis, "This Scientist Created a Rapid Test Just Weeks into the Pandemic. Here's Why You Still Can't Get It," *Pro Publica*, December 21, 2021.
23. Arizona Exec. Order No. 2021-02 (February 12, 2021); Idaho Exec. Order No. 2020-13 (June 22, 2020).
24. William D. Eggers and Mike Turley, *The Future of Regulation: Principles for Regulating Emerging Technologies* (New York City: Deloitte Center for Government Insights, 2018).
25. US Department of Health and Human Services, Securing Updated and Necessary Statutory Evaluations Timely, 86 Fed. Reg. 5694 (January 19, 2021).

regulations are working just fine,[26] the reality is that, without a system-wide process for reviewing regulations, many of these rules are likely to be obsolete.

The closest thing to a general retrospective review requirement for federal regulatory agencies is section 610 of the Regulatory Flexibility Act, which requires federal agencies to review regulations 10 years after the regulations go into effect for their impacts on small businesses.[27] However, compliance with this provision has always been spotty,[28] which is why, in early 2021, HHS finalized a regulation that would have added an enforcement mechanism to section 610 reviews: the Securing Updated and Necessary Statutory Evaluations Timely (SUNSET) rule. The SUNSET rule would have required HHS to conduct section 610 reviews on a revolving basis. Failure to do so would cause the regulations to expire.[29] Like Odysseus binding himself to the mast of his ship to avoid succumbing to the sirens' call, enforcement mechanisms are needed to ensure regulators commit to reviewing regulations on a timely basis.

The subcommittee's question 15 asks for ways to help bolster confidence in America's public health institutions. Given that trust may be declining in HHS subagencies such as the CDC and the FDA,[30] HHS may be able to raise public confidence in the department by committing to review its rules on a more regular basis. Identifying best and worst practices among its existing rules should also make HHS more adaptable when responding to future public health emergencies (subcommittee question 20). Bewilderingly, HHS has instead proposed repealing the SUNSET rule,[31] signaling an intent to go in the opposite direction. The agency is resisting reviewing its own regulations, arguing—ironically—that it has too many regulations and that a review would be too time consuming and burdensome for the agency.[32]

Requiring a review of regulations suspended during the pandemic, as well as encouraging more retrospective review generally, especially at agencies like HHS, could help revive the public's ailing faith in federal health regulators. Demanding that HHS maintain the SUNSET rule, or propose an alternative retrospective review regulation, would be beneficial and would add teeth to instructions Congress has already given federal agencies.[33]

Mortality Costs of Regulations

The subcommittee has asked how Congress can best address the factors that influence health outcomes, including social determinants of health (question 14). It is well known that socioeconomic factors contribute to health, and moreover, many, if not most, regulations have some regressive impacts.[34] Regulations raise prices,[35] for example, which often poses a larger burden to low-income people than to high-income people.

---

26. Indeed, HHS makes such a claim in its recent proposal to rescind a regulation requiring retrospective review. US Department of Health and Human Services, Securing Updated and Necessary Statutory Evaluations Timely; Proposal to Withdraw or Repeal, 86 Fed. Reg. 59906 (October 29, 2021).
27. 5 U.S.C. § 610.
28. Curtis W. Copeland, *Reexamining Rules: Section 610 of the Regulatory Flexibility Act* (Washington, DC: Congressional Research Service, 2005).
29. US Department of Health and Human Services, Securing Updated and Necessary Statutory Evaluations Timely, 86 Fed. Reg. 5694 (January 19, 2021).
30. Selena Simmons-Duffin, "Trust in CDC and FDA Is at a Low," NPR, September 25, 2020; Selena Simmons-Duffin, "Poll Finds Public Health Has a Trust Problem," NPR, May 13, 2021.
31. US Department of Health and Human Services, Securing Updated and Necessary Statutory Evaluations Timely; Proposal to Withdraw or Repeal, 86 Fed. Reg. 59906 (October 29, 2021).
32. James Broughel, "HHS Says 'No Thank You' to Accountability," *The Hill*, December 15, 2021.
33. James Broughel, "Evidence-Free Policymaking at the Department of Health and Human Services" (Public Interest Comment, Mercatus Center at George Mason University, Arlington, VA, December 15, 2021).
34. Diana W. Thomas, "Regressive Effects of Regulation," *Public Choice* 180, no. 1-2 (2019): 1–10.
35. Dustin Chambers, Courtney A. Collins, and Alan Krause, "How Do Federal Regulations Affect Consumer Prices? An Analysis of the Regressive Effects of Regulation," *Public Choice* 180, no. 1-2 (2019): 57–90.

It turns out that any regulation that imposes costs will likely have a health opportunity cost because the expenditures needed to comply with regulations displace some expenditures intended to reduce risks. This issue tends to be a larger issue for minorities and low-income individuals,[36] presumably because a dollar of additional health spending goes further for low-income individuals than for high-income individuals.

For example, a regulation that requires a business to spend money on a new piece of equipment redirects spending away from productive activities and toward compliance activities. In the process, workers and shareholders forgo some income, a fraction of which would be spent on risk-reducing activities. One recent study estimates that approximately 10 percent of every additional dollar earned goes toward reducing health risks.[37]

When regulations impose large enough costs, they can induce deaths in the population by reducing income and, by extension, reducing private expenditures to mitigate health risks. This phenomenon is known as the mortality cost of expenditures.[38] Two recent papers, using different methodologies, arrive at different estimates of the amount of economic cost likely to induce one death in the US population. One paper estimates the cost at around $38.6 million, another at around $108.6 million.[39]

Information like this can be combined with estimates of the cost-effectiveness of a regulation in order to ascertain whether a regulation is likely to increase or decrease mortality risk. For example, if a regulation costs $100 million per life expected to be saved, but the expected cost to induce one death in the population is $75 million, then the regulation in question is likely to increase mortality risk. It fails what economists call a "mortality risk analysis."[40]

Regulatory agencies are already required to produce cost-effectiveness analysis for rules.[41] However, this requirement is generally not obeyed. The Office of Management and Budget (OMB) at one time reported cost-effectiveness estimates for lifesaving regulations in its annual report to Congress.[42] Such information has not appeared in more recent reports, however.[43]

In order to address health disparities associated with regulatory costs, the subcommittee should promote mortality risk analysis in the federal bureaucracy. It should also encourage regulatory agencies to conduct more cost-effectiveness analysis (something already required by OMB). Cost-effectiveness analysis and mortality risk analysis should both be routine features of regulatory impact analysis. Finally, reducing the costs of regulations generally is likely to improve health

---

36. Kenneth S. Chapman and Govind Hariharan, "Do Poor People Have a Stronger Relationship between Income and Mortality Than the Rich? Implications of Panel Data for Health-Health Analysis," *Journal of Risk and Uncertainty* 12, no. 1 (1996): 51–63; Ralph L. Keeney, "Estimating Fatalities Induced by the Economic Costs of Regulations," *Journal of Risk and Uncertainty* 14, no. 1 (1997): 5–23.
37. James Broughel and W. Kip Viscusi, "The Mortality Cost of Expenditures," *Contemporary Economic Policy* 39, no. 1 (2021): 156–67.
38. Broughel and Viscusi, "The Mortality Cost of Expenditures."
39. Broughel and Viscusi, "The Mortality Cost of Expenditures"; James Broughel and Dustin Chambers, "Federal Regulation and Mortality in the 50 States," *Risk Analysis* (published ahead of print, June 23, 2021).
40. Broughel and Viscusi, "The Mortality Cost of Expenditures."
41. Office of Management and Budget, *Circular A-4*, September 17, 2003.
42. Office of Management and Budget, *2013 Report to Congress on the Benefits and Costs of Federal Regulations and Unfunded Mandates on State, Local, and Tribal Entities*, 2013.
43. "Reports," Office of Management and Budget, accessed January 24, 2022, https://www.whitehouse.gov/omb/information-regulatory-affairs/reports/#ORC.

outcomes on some margins by raising the incomes of members of the population, thereby resulting in more risk-reducing expenditures.

Conclusion
This letter addresses four different areas of my research relevant to the task force's request for information: (a) vaccination and testing, (b) drug shortages, (c) retrospective review of regulations; and (d) mortality costs of regulations. Regulations surrounding the first two areas could be permanently rolled back to facilitate an improved public health response to pandemics and especially to benefit Americans living in rural areas (subcommittee questions 5 and 14b). The third area offers ways to promote trust in public health institutions and facilitate a more agile and adaptable public health response during emergencies (questions 15 and 20). The fourth area sheds light on the social determinants of health (question 14).

Attached to this letter are some recommended readings related to the earlier-mentioned topics. These readings go into the issues in more depth than is possible in this letter. Please do not hesitate to reach out to me with questions or additional requests for follow-up information.

Sincerely,

James Broughel

Attachments (3)
James Broughel and Yuliya Yatsyshina, "Relax Pharmacy Regulations to Help with COVID-19 Testing and Treatment" (Mercatus Policy Brief)
James Broughel, "Allowing Compounding Pharmacies to Address Drug Shortages" (Mercatus Policy Brief)
James Broughel, "Evidence-Free Policymaking at the Department of Health and Human Services" (Public Interest Comment)

MERCATUS CENTER
George Mason University

POLICY BRIEF
SPECIAL EDITION

Relax Pharmacy Regulations to Help with COVID-19 Testing and Treatment

James Broughel and Yuliya Yatsyshina

March 27, 2020

One of the most urgent challenges facing policymakers managing the current COVID-19 public health crisis is how to ramp up diagnostic testing on a mass scale. Companies such as Walgreens, CVS, and Target have already started working with the federal government, as their locations are well-suited to become testing sites. As a result, pharmacies and pharmacists themselves are likely to become instrumental in testing for COVID-19 in the coming weeks and months. However, certain regulatory restrictions on pharmacists should be relaxed so that they can practice to the full extent of their training and abilities.

THE IMPORTANCE OF TESTING

The president has declared a national emergency and the federal agencies and state governments overseeing the response to the pandemic have recommended or required that citizens stay at home, practice social distancing, and, in some instances, self-isolate, self-quarantine, or shelter in place. To-date, authorities have offered little guidance as to when these recommendations will expire. Without reliable information about how many people are infected with COVID-19 as well as the rate at which the disease spreading, it is likely that policymakers currently have no clear sense of when to recommend a return to normalcy. Critical data required to inform such decisions will only emerge once large-scale testing is implemented.[1]

Tragically, the federal government botched its early response to the crisis.[2] Among other things, the first COVID-19 tests distributed around the country by the Centers for Disease Control and Prevention (CDC) produced unreliable results.[3] Furthermore, commercial labs and public health officials in the states couldn't get initial approval to perform their own tests (though in some cases,

they tested anyway).[4] These failures, largely a result of inflexible regulations,[5] have contributed to delaying the rollout of testing in the United States. Even now that many legal barriers to testing have been removed, shortages of supplies could be hampering the scaling up of testing.[6]

This is a particularly unfortunate outcome because the experience of other countries suggests that testing on a large scale has been a key ingredient of an effective response to the pandemic. Testing, when combined with practices such as isolating infected individuals and using contact tracing methods to identify who else may have been exposed to the virus, has shown promising results in places such as South Korea and Singapore.[7] Testing to confirm that those who are exhibiting no symptoms or who were previously ill are in good health could also potentially speed the transition back to normalcy.

The effectiveness of mass testing is powerfully illustrated by the experience of Vò, a small town that reported Italy's first death from COVID-19.[8] The town's 3,300 or so residents were tested and retested as part of an experiment rolled out by the University of Padua, with assistance from the government of the Veneto Region and the Red Cross.[9] Residents were tested regardless of whether they were exhibiting symptoms. Those who were confirmed as infected were quarantined. The second round of testing revealed that the number of infected residents had dropped from 3 percent of the population to nearly zero, and Vò eventually reached zero new cases within a few weeks.[10] Notably, this outcome differs dramatically from the experience of other parts of northern Italy, which has been one of the regions of the world most affected by COVID-19.

THE ROLE THAT PHARMACISTS CAN PLAY

At the time this was written, 579,000 COVID-19 tests had been administered in the United States.[11] If the disease continues to spread exponentially, testing will have to keep up with that pace of growth. Meeting that goal is going to be a significant challenge, as laboratories are already facing shortages of testing equipment.[12] Another challenge is going to be finding safe places where potentially infected individuals can be tested without infecting others and healthy individuals can be tested without getting infected themselves. A role for pharmacies is thus quickly becoming apparent.

Massachusetts, for example, set up one of America's first drive-through testing facilities in a pharmacy parking lot.[13] Other states, such as Michigan and Pennsylvania, are following suit.[14] Major drug store chains have publicly committed their support for the fight against COVID-19.[15]

Pharmacies are well positioned to become testing sites because of their geographical coverage across the country. There are more than 309,000 employed licensed pharmacists in the United States and its territories, and 90 percent of Americans live within five miles of a pharmacy.[16] Many pharmacies have adequate parking, which makes them well suited for drive-through testing. Some

pharmacies even have drive-through windows.[17] The familiarity patients have with pharmacists could prove important if sick individuals are more comfortable driving to their local pharmacy than going to a doctor's office or a hospital.

Pharmacists can be of critical assistance in triaging the coming avalanche of patients seeking diagnostics and care. Pharmacists could test patients for COVID-19 and, if the results return positive, give directions for home care if the illness is mild. If the illness is severe, pharmacists could direct patients to designated facilities for their particular area. Even if results were to come back negative, the pharmacist would save the patient from having to visit another venue of care, thereby freeing up time for other medical professionals to focus on more urgent cases. Should patients suffer from other minor ailments, pharmacists could also provide treatment (though this might require legal changes in many jurisdictions; to be discussed later in this brief).

Pharmacists' training makes them capable of providing this kind of basic medical care. It takes about eight years to obtain a doctor of pharmacy degree,[18] a regular requirement for a pharmacist license. This time includes three to four years of undergraduate prerequisite work and four years of additional professional study. The COVID-19 test is relatively simple and usually involves taking swabs from a patient's nose or throat.[19] This is a task well within the capabilities of a pharmacist to perform. Although for now the analysis of the swab is likely to take place off site at a lab, in the future this work could potentially be done on site. Indeed, rapid-turnaround COVID-19 tests are currently being developed and, in some cases, undergoing FDA approval.[20] Moreover, pharmacists themselves stand ready to assist, as identified by a recent call by the American Pharmacists Association for expanded pharmacist services to combat COVID-19.[21]

POLICY RECOMMENDATIONS

Fortunately, there are not many laws standing in the way of pharmacists and pharmacies immediately assisting in testing efforts for COVID-19. Personnel working at testing sites set up near pharmacies should be able to collect specimens from patients and send those specimens to laboratories for analysis without facing significant legal hurdles. These laboratories, however, do need government approval to operate, and indeed this has been one of the central bureaucratic hurdles that has hampered the US government's response to the crisis.[22]

These same restrictions also affect pharmacists with respect to performing laboratory testing for other ailments. For several decades, many pharmacies have been allowed to perform low-risk health tests thanks to the Clinical Laboratory Improvement Amendments of 1988 (CLIA). Even in ordinary times, pharmacies can obtain CLIA waivers and perform tests related to such ailments as influenza, strep throat, human immunodeficiency virus, and other medical conditions.[23]

Currently, however, the percentage of pharmacies holding CLIA waivers varies enormously across states. One study finds the percentage of pharmacies possessing CLIA waivers to be between 0 and 60 percent, depending on the state, with a median percentage of 19.56 percent.[24] One reason for the disparity across states is varying state and local regulations, which include restrictions related to testing procedures, licensure of the personnel conducting tests or overseeing a lab, phlebotomy requirements, and waste disposal requirements.[25]

Allowing pharmacists to perform tests in ordinary times would better prepare them for crises like the current pandemic. Moreover, as CLIA waivers have increased, pharmacists and lab technicians have been able to incorporate basic testing into their existing workload without needing to work more hours.[26] Pharmacist testing has an additional benefit of potentially reducing the time between symptom development and treatment. Thus, ensuring that CLIA-waived COVID-19 tests quickly become available should be a top priority of the US Department of Health and Human Services.

When pharmacists are testing for an ailment, they are usually qualified to treat similar conditions as well. Florida recently passed a law that allows pharmacists to test and treat for influenza and strep throat.[27] These kinds of changes are likely to alleviate some of the stress on the medical system as pharmacists take on the burden of handling some of the more routine cases. However, Florida's reform remains far from ideal, in part because it requires a licensed pharmacist to have in place a collaborative agreement with a supervising physician, which can act as a disincentive for many pharmacists.

Idaho is perhaps the model state in this regard, as Idaho allows pharmacists to prescribe autonomously if a pharmacist identifies a medical condition as a result of a CLIA-waived test,[28] as well as under a number of other routine situations,[29] all without a collaborative agreement with a physician in place. Idaho also allows for substitution of therapeutically equivalent drugs without express physician authorization (but with notification to the physician). As more states like Idaho and Florida allow for basic testing and prescribing authority for pharmacists, colleges of pharmacy are likely to respond by updating curricula, thereby enhancing preparedness for future pandemics.

Many states are relaxing other kinds of regulations as a result of the COVID-19 pandemic.[30] Massachusetts has allowed pharmacies to produce hand sanitizer and mandated that insurers cover certain telehealth services.[31] Some states are now accepting out-of-state medical licenses or embarking in reciprocity agreements with other states with regard to medical licenses.[32] Again, Idaho has a reciprocity law for pharmacists that could serve as a model in this regard.[33]

Relaxing restrictions on telepharmacy could also yield beneficial outcomes. Currently, most tests for COVID-19 have a relatively long turnaround time,[34] often requiring patients to wait at home for results. When results become available, tested individuals could have a consultation with the pharmacist on the phone or via video conferencing platforms such as Skype or Zoom. Not only is this convenient for the patient, it also encourages social distancing. Currently, there is a debate

taking place about take-at-home COVID-19 tests.[35] If these tests become common, relaxing telepharmacy rules could enable pharmacists to provide remote instructions to patients administering their own tests. Telepharmacy reforms have also been known to increase access to pharmacies among underserved populations, such as rural populations.[36]

Importantly, as pharmacists take on additional responsibilities, they will likely need to rely more on pharmacy technicians to pick up more routine tasks. However, many states have restrictions in place that mandate a maximum ratio of technicians that can work with each pharmacist. Notably, many states have no ratio requirements,[37] and some states even have provisions in place that allow technicians to work remotely,[38] suggesting that some restrictions on pharmacy technicians can be relaxed or lifted altogether.

In short, pharmacists could readily play a role in ramping up COVID-19 testing and treatment, and eventually, when available, providing the vaccine. Relaxing state phlebotomy laws could yield additional benefits, as drawing blood may be necessary in efforts to search for antibodies for COVID-19. Any restrictions on the ability of pharmacists to immunize using FDA approved vaccines should also be reconsidered.

CONCLUSION

As pharmacies and pharmacists become instrumental in COVID-19 testing, any related regulatory restrictions at the state and federal level should be reconsidered. States should make it easier for pharmacies to obtain CLIA waivers, pharmacists should have the ability to prescribe in low-risk situations, regulations should be amended to make it easier for pharmacists licensed in one state to practice in another state, and the use of telepharmacy should be encouraged. Restrictions on pharmacy technicians and the ability of pharmacists to vaccinate are also areas where liberalization could prove beneficial. Combined, these reforms are likely to improve the public's access to testing and treatment for COVID-19 as well as a variety of other medical conditions. Equally important, these reforms can enhance preparedness for future pandemics.

ABOUT THE AUTHORS

James Broughel is a senior research fellow at the Mercatus Center at George Mason University. Broughel has a PhD in economics from George Mason University. He is also an adjunct professor at the law school at George Mason University.

Yuliya Yatsyshina recently completed an MA in economics from George Mason University as well as an MA Fellowship at the Mercatus Center at George Mason University. She has had an extensive career in both the public and private sectors, and she currently works as a researcher for projects focusing on policies of economic growth, international development, and sustainability.

NOTES

1. Andy Gregory, "UK Defends Strategy as WHO Urges Governments to Test Citizens as 'Backbone' of Coronavirus Response: 'Test, Test, Test,'" *Independent*, accessed March 23, 2020.
2. Sheri Fink and Mie Baker, "'It's Just Everywhere Already': How Delays in Testing Set Back the U.S. Coronavirus Response," *New York Times*, accessed March 22, 2020.
3. Christopher Weaver, Betsy McKay, and Brianna Abbott, "America Needed Coronavirus Tests. The Government Failed," *Wall Street Journal*, March 19, 2020.
4. Adam Thierer, "How the US Botched Coronavirus Testing," *Daily Economy*, American Institute for Economic Research, March 12, 2020.
5. Alec Stapp, "Timeline: The Regulations—and Regulators—That Delayed Coronavirus Testing," *The Dispatch*, March 20, 2020.
6. Matthew Perrone, "US Virus Testing Faces New Headwind: Lab Supply Shortages," *AP News*, March 20, 2020; Robert P. Baird, "Why Widespread Coronavirus Testing Isn't Coming Anytime Soon," *New Yorker*, March 24, 2020.
7. Dennis Normile, "Coronavirus Cases Have Dropped Sharply in South Korea. What's the Secret to Its Success?," *Science*, March 17, 2020; Vernon J. Lee, Calvin J. Chiew, Wei Xin Khong, "Interrupting Transmission of COVID-19: Lessons from Containment Efforts in Singapore," *Journal of Travel Medicine* taaa039 (2020).
8. Donato Paolo Mancini and Clive Cookson, "Aggressive Testing Helps Italian Town Cut New Coronavirus Cases to Zero," *Financial Times*, March 17, 2020.
9. Lorenzo Tondo, "Scientists Say Mass Tests in Italian Town Have Halted COVID-19 There," *Guardian*, March 18, 2020.
10. Rachael Rettner, "How One Small Italian Town Cut Coronavirus Cases to Zero in Just a Few Weeks," *Live Science*, March 18, 2020.
11. Beatrice Jin, "Live Tracker: How Many Coronavirus Cases Have Been Reported in Each U.S. State?," *Politico*, updated March 26, 2020.
12. Perrone, "US Virus Testing Faces New Headwind."
13. Melissa Repko, "CVS' First Drive-Up Coronavirus Testing Site Opens in Massachusetts, Focuses on First Responders," March 19, 2020.
14. Jeff Seidel, "Michigan Pharmacist Had to Break Tough News to Wife as Coronavirus Fears Spread," *Detroit Free Press*, March 18, 2020.
15. Bruce Japsen, "Rite Aid: Pharmacist Role Will Expand Amid Coronavirus Outbreak," *Forbes*, March 16, 2020; Phil Wahba, "Walmart, Target, CVS, and Walgreens Will Loan Space for Coronavirus Test Centers," *Fortune*, March 13, 2020.
16. American Pharmacists Association et al., *Pharmacists As Front-Line Responders for COVID-19 Patient Care*, March 20, 2020.
17. Using such windows when testing for COVID-19 may or may not be a good idea. However, these windows could certainly be utilized for tests in other contexts.
18. "Pharm D. Degree Requirements," Oregon State University, accessed March 21, 2020, https://pharmacy.oregonstate.edu/pharm-d-frequently-asked-questions.
19. Weaver, McKay, and Abbott, "America Needed Coronavirus Tests."
20. Cepheid, "Cepheid Receives Emergency Use Authorization from FDA for Rapid SARS-CoV-2 Test," news release, March 21, 2020, http://cepheid.mediaroom.com/2020-03-21-Cepheid-Receives-Emergency-Use-Authorization-from-FDA-for-Rapid-SARS-CoV-2-Test; Akihiko Nishiyama, "Team Japan Develops 10-Minute Coronavirus Test," *Nikkei Asian Review*, March 20, 2020.

21. Aina Abell, "APhA Coronavirus Watch: APhA and Other Pharmacy Groups Call for Expanded Pharmacist Services amid COVID-19 Pandemic," APhA, March 20, 2020.

22. Alec Stapp, "Timeline."

23. "CLIA - Clinical Laboratory Improvement Amendments - Currently Waived Analytes," US Food and Drug Administration, last updated March 23, 2020, https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfClia/analyteswaived.cfm.

24. Michael E. Klepser et al., "U.S. Community Pharmacies as CLIA-Waived Facilities: Prevalence, Dispersion, and Impact on Patient Access to Testing," *Administrative Pharmacy* 12, no. 4 (2016): 614–21.

25. Devery Howerton, "Survey Findings from Testing Sites Holding a Certificate of Waiver Under the Clinical Laboratory Improvement Amendments of 1988 and Recommendations for Promoting Quality Testing," *MMWR Recommendations and Reports* 54, no. RR13 (2005): 1–25.

26. Edward J. Timmons and Conor S. Norris, "CLIA Waiver Pharmacy Growth: How Does Broadening Scope of Practice Affect the Pharmacist Labor Market?" (Mercatus Working Paper, Mercatus Center at George Mason University, Arlington, VA, October 2016).

27. H. B. 389, 2020 Leg., Interim (Fl. 2020); Dave Berman, "Governor Signs into Law Sirois Bill Allowing Pharmacists to Test for Flu, Starting July 1," *Florida Today*, March 12, 2020.

28. Idaho Statutes § 54-1704.

29. Such situations include when a new diagnosis is not required (e.g., when refilling a prescription or changing its quantity), when the condition is minor and generally self-limiting, or in the case of an emergency.

30. IMorales, "List: Rules and Regulations Suspended Due to COVID-19," Americans for Tax Reform, March 26, 2020, https://www.atr.org/rules?amp.

31. Jessica Bartlett, "Mass. Mandates Insurers Cover Medically Necessary Telehealth Services," *Boston Business Journal*, March 15, 2020; Darrell Etherington, "Updated FDA VOIC-19 Testing Guidelines Specifically Disallow At-Home Sample Collection," *TechCrunch*, March 23, 2020.

32. Office of Governor Larry Hogan, "Governor Hogan Orders Closure of Bars and Restaurants, Announces Unprecedented Public Health Surge To Combat COVID-19 Crisis," press release, March 16, 2020, https://governor.maryland.gov/2020/03/16/governor-hogan-orders-closure-of-bars-and-restaurants-announces-unprecedented-public-health-surge-to-combat-covid-19-crisis/.

33. H. B. 10, 65th Leg., 1st Reg. Sess. (Id. 2019).

34. Daniel Chang, "More Testing Is Available for COVID-19, but Getting Results Can Take Days or More," *Miami Herald*, March 24, 2020. See also LabCorp's website, which states, "It takes approximately 4-5 days from the date of pickup of a specimen for testing to the release of the rest result to the healthcare provider." "2019 Novel Coronavirus (COVID-19), NAA," LabCorp, accessed March 26, 2020, https://www.labcorp.com/tests/139900/2019-novel-coronavirus-covid-19-naa.

35. Amrita Khalid, "Why a Wave of At-Home Coronavirus Tests Is Dividing Global Regulators," *Quartz*, March 25, 2020.

36. Julia Tellman, "Telepharmacy Key to New Victor Drug Store," *Teton Valley News*, July 26, 2018.

37. Kristy Malacos, "Pharmacy Technician Regulation," *Pharmacy Times*, June 16, 2020.

38. Arizona Revised Statutes § 32-1923.01; California State Board of Pharmacy, *Statutory Changes to Pharmacy Law*, November 5, 2019, 20, https://pharmacy.ca.gov/laws_regs/new_laws.pdf.

MERCATUS CENTER
George Mason University

POLICY BRIEF

Allowing Compounding Pharmacies to Address Drug Shortages

James Broughel

November 2021

The COVID-19 pandemic has brought a new era of supply chain challenges. In the areas of energy, semiconductors, cargo ships, and more, once-dependable products and methods of transport are becoming less reliable. These supply chain challenges have caught policymakers off guard, which is understandable because pandemics have unpredictable consequences. However, predictable shortages also are happening in other areas and will continue to happen. In these areas, Americans should be less forgiving if their leaders do not act with deliberateness and foresight. This is especially true in the modern prescription drug market, where shortages are an unfortunate, regular feature.

Drug shortages often result from supply chain interruptions, such as an important drug manufacturer going offline to address a concern about quality. In other cases, drug shortages result from a spike in demand for drugs. For example, the outbreak of COVID-19 led to an increase in demand for drugs administered to patients on ventilators. Although some shortages are outside of the control of regulators, the magnitude and duration of drug shortages can be exacerbated by regulations.[1]

Compounding pharmacies, or compounders, have the wherewithal to step in and address drug shortages when they occur. Compounders come in different forms, but all produce individualized medicines that are tailor-made for patients with specific ailments. Some compounders are like manufacturers in the sense that they produce in bulk, mostly for medical offices and hospitals that need a constant stock of supplies on hand. Other smaller, independent compounders are like local pharmacies. Both have an important role to play in addressing shortages, because compounders can produce drugs when manufacturers of mass-market drugs cannot meet public needs.

The purpose of this policy brief is to explain the role that compounding pharmacies can play in addressing drug shortages and the way their role can be enhanced through smart public policy reforms. The brief begins with some background on the problem of drug shortages in the United States, then provides an overview of the legal framework that governs compounding pharmacies. This framework currently consists of a patchwork of federal and state laws and regulations. Emergency changes made to this system during the COVID-19 pandemic allowed compounding pharmacies to address drug shortages in a manner usually prohibited. However, the ability of compounders to assist in ordinary times is still limited. Moreover, official methods of tracking drug shortages leave much to be desired, which can hinder compounders' response during both ordinary times and emergencies. The final sections of the brief discuss ways to address these problems, including legislation that has recently been introduced in Congress to make permanent some of the changes made during the pandemic. These sections also discuss potential concerns about compounding pharmacies and their relative safety.

THE PROBLEM OF SHORTAGES

The definition of a drug shortage is itself subject to some disagreement. The Food and Drug Administration (FDA) defines a drug shortage as "a period of time when the demand or projected demand for a medically necessary drug in the United States exceeds its supply."[2] An important characteristic of a shortage, according to the FDA, is that "a registered alternative manufacturer will not meet the current and/or projected demands for the potentially medically necessary use(s) at the user level."[3] Moreover, the words "medically necessary" are particularly important in these sentences, because these are the drugs the FDA emphasizes on its official shortage list. The FDA defines medically necessary drugs as any drug product that is used to treat or prevent a serious disease or medical condition for which there is no other adequately available substitute.[4]

An alternative definition of drug shortage comes from the American Society of Health-System Pharmacists (ASHP), an authoritative private-sector source on drug shortages. This organization defines a drug shortage as "a supply issue that affects how the pharmacy prepares or dispenses a drug product or influences patient care when prescribers must use an alternative agent."[5] One area of difference between the FDA definition and the ASHP definition is the emphasis the latter places on changes in patient care as a primary determinant of a shortage.

Shortages are a problem for financial and public health reasons. Patient complaints about drug shortages are common, and shortages increase out-of-pocket costs for patients and increase travel time to obtain needed medicines.[6] Shortages also lead to personnel and other costs for hospitals and other medical facilities. Personnel costs owing to shortages have been estimated to be approximately $359 million annually for hospitals,[7] whereas increased expenditures as a result of drug prices rising and paying for more expensive substitutes have been estimated to be about $230 million each year.[8]

Costs are not limited to inconvenience or money. Shortages of insulin or EpiPens, for example,[9] can have serious adverse effects on people with diabetes and allergies, respectively. In the most severe cases, shortages lead to increases in mortality. Increases in hospitalization rates and adverse drug reactions also occur because substitutes can have unintended side effects.[10] One survey of medical professionals (primarily pharmacists) in 2014 finds that 90 percent of respondents had experienced at least one shortage that may have caused a medication safety issue or error in patient care in the prior six months.[11] Another survey of healthcare professionals reports that 35 percent of respondents' facilities had experienced a "near miss" during the past year owing to a drug shortage.[12]

The exact number of drugs in shortage depends on various factors, including how one defines a shortage. One study based on FDA shortages data counts 917 active shortages of drugs in the year from December 2015 to December 2016.[13] Another study finds that, in 2010, over 240 drugs were either in short supply or were completely unavailable and that more than 400 generic equivalents were backordered for greater than five days.[14] The ASHP reports that 166 new drug shortages occurred in 2019.[15]

As these numbers indicate, the number of shortages varies depending on how one tracks them. Furthermore, it is possible these problems are getting modestly better over time, because by some estimates, counts of drugs that experience shortages seem to be falling. However, the COVID-19 pandemic has revealed that the problem of shortages is far from being eradicated. Thus, a critical question for policymakers is how further progress can be made. Compounding pharmacies can assist during these periods of stress. However, the legal environment in which these businesses operate is complex, so whether they are able to assist when drugs are in short supply ultimately hinges not on their capabilities, but on whether they are allowed to assist under federal law.

OVERVIEW OF THE LEGAL FRAMEWORK FACING COMPOUNDING PHARMACIES

Compounding pharmacies provide custom-made medicines for patients with specific health needs. Compounders necessarily face a different legal and regulatory landscape than do producers of traditional, commercial drugs that are most common in the United States. This makes sense because the cost of going through the FDA approval process for a new drug is far too expensive and time consuming to be practical for individualized medicines that will not be available on a mass-market scale.

Compounding pharmacies come in a variety of forms. Some are like manufacturers in that they produce in bulk, largely for hospital or medical office stock. Others are like local pharmacies, except with the additional capacity to make custom-made drugs. These differences arise partially because separate legal regimes have been established for the two kinds of compounders.

The larger compounders that produce in bulk are named 503Bs (or sometimes "outsourcing facilities") after the section of the Federal Food, Drug, and Cosmetic Act that establishes their legal treatment.[16] The smaller compounders are known as 503As. A key characteristic of 503As is that these entities, outside of very well-established relationships, have to obtain a patient-specific prescription before filling an order, a requirement that does not apply to the 503Bs. Thus, 503As operate more like traditional pharmacies, dispensing medications for use by known individual patients with a prescription, whereas 503Bs operate more like manufacturers. As a result of this arrangement, the 503Bs must register with and are regulated by the FDA. They have to comply with current good manufacturing practices set by the federal government,[17] and they also face inspections by the FDA. Meanwhile, the 503As come primarily under the regulatory authority of the state boards of pharmacy that regulate pharmacies at the state level.

As a general rule, both types of compounders cannot compound drugs that are "essentially copies" of commercially available FDA-approved drugs,[18] because mass-marketed drugs under the current system must receive premarket approval from the FDA. Thus, compounders are limited to producing individualized medicines. However, given the ongoing occurrence of drug shortages, the FDA and Congress have come to recognize that compounders can play an important role in mitigating these problems and have created a pathway for compounders to produce, in special circumstances, drugs that are similar to FDA-approved drugs.

The specific pathway is outlined in FDA guidance documents.[19] Although 503s cannot compound what are essentially copies of commercially available FDA-approved drugs, when a drug is in shortage, it is not considered commercially available. Then what is considered essentially a copy of an FDA-approved drug in other times can be produced by a compounder during a shortage. This pathway to address shortages works well some of the time, but it leaves much to be desired for several reasons made clear by the COVID-19 pandemic.

First, as will be discussed in more detail later, the FDA's official drug shortage list—additions to which are what triggers 503s' ability to compound certain medications—is not comprehensive, partly because FDA drug-shortage staff rely heavily on information reported from manufacturers,[20] and this information can miss shortages that arise for reasons other than production shortfalls.

Second, 503Bs are often not able to revamp production lines rapidly because reorienting product lines takes time. Moreover, these facilities need orders of a sufficient size to justify the expense of making these changes. Thus, smaller shortages may not rise to a level of significance to justify retrofitting assembly lines. A similar issue is that, like any business, 503Bs tend to give priority to their regular customers, so addressing a shortage can take a backseat to filling regular orders.

This is where the 503As could potentially help. Smaller orders needed rapidly can be produced by 503As, which are nimbler than 503Bs—this is not a criticism of 503Bs but simply a recognition of the fact that these entities serve different markets. By their very nature, 503As exist to fill small

orders and serve individual patients, whereas 503Bs fill larger orders intended primarily for office stock. The primary impediment to 503As stepping up in these times is the prescription requirement.[21] The FDA consistently affirms this requirement and is hesitant to make it more flexible because the requirement provides a clear legal distinction between 503As and 503Bs.[22] Without the requirement for dispensing of medications only with a prescription, the line between 503As and 503Bs is somewhat blurred. Interestingly, however, the FDA relaxed this requirement during the COVID-19 pandemic.

HOW COVID-19 HAS CHANGED THE DEBATE

The FDA reports that 86 shortages were ongoing in 2020, compared with 76 in 2019.[23] The FDA exercised regulatory flexibility 110 times in 2020 to address these drug shortages, which related to 78 products.[24] Examples of drugs that went into shortage during this period are drugs related to ventilator use.[25] Acetaminophen and albuterol are two other medicines that saw spikes in demand during the COVID-19 pandemic, leading to shortages.[26]

In response to these problems, the FDA issued guidance in 2020 allowing 503As to produce copies of FDA-approved medications when a medical facility treating COVID-19 patients could not otherwise find drugs from a traditional source or from a 503B.[27] The usual prohibitions against 503As producing versions of FDA-approved drugs, as well as requirements that 503As have a prescription in hand before completing an order, were waived, though pharmacies still had to obtain patients' identifying information after the fact, within a month, and had to notify their state regulator that they compounded under these conditions.

Interestingly, during this period the FDA was keeping a list of drugs used for hospitalized patients with COVID-19. The list was associated with its guidance allowing compounding of some medications for patients hospitalized with COVID-19.[28] The medicines in the FDA guidance document were not all on the official FDA shortage list, highlighting how the FDA's official shortage list sometimes requires supplemental lists.

Another hurdle 503Bs face when responding to shortages is that the FDA usually wants 503Bs to start with FDA-approved manufactured products, even though doing so can create unique challenges. For example, US Pharmacopeia finds that some formulations do not work as well when made from a manufactured product,[29] as the FDA wants.

As a result of these complications, the 503B formula development process can be time consuming, leading to delays. Again, 503As can offer a solution. 503As can produce during the time 503Bs are developing formulas or revamping manufacturing lines. 503As produce smaller quantities, and their drugs often have short beyond-use dates, which establish when the product expires such that it must no longer be used. Even if one assumes that 503As are riskier than 503Bs, the potential

risks have to be weighed against the risks to patients who are unable to obtain medicines while 503Bs are not producing. Risks posed by any particular 503A will likely be limited owing to its small productions quantities and short beyond-use dates.

As noted earlier, 503Bs can require substantial drug orders before they will service a customer. Thus, these facilities may not respond to smaller shortages. This can especially be an issue in rural areas affected by regional shortages. These more localized shortages may not show up on the FDA drug shortage list either, owing to the FDA's national focus. A drug shortage list from ASHP, however, is better suited for detecting these kinds of regional issues. However, the ASHP list does not have the same level of policy importance as the FDA list in that adding a drug to the ASHP list does not trigger additional permissions for compounders in the same way as adding drugs to the FDA list.

DIFFERENCES BETWEEN DRUG SHORTAGE LISTS

Under the Federal Food, Drug, and Cosmetic Act, manufacturers are required to report manufacturing interruptions to the FDA.[30] The FDA relies on this information, as well as market research data on drug sales,[31] when making determinations about whether a drug shortage exists. The FDA looks at demand and supply as well as forecasts of these factors, and if estimated demand exceeds supply for the nation, then a drug is considered in shortage.

A supplement to the FDA drug shortage list is that of the ASHP, which has an online portal where its members can report drug shortages.[32] Whereas the FDA relies heavily on manufacturers to report issues that arise with production processes, the ASHP gets much of its information from medical professionals, such as pharmacists, in addition to patients and some manufacturers. This more patient-focused perspective may better reflect conditions on the ground.

The number of drugs listed as being in shortage by the ASHP is almost always higher than the number appearing on the FDA list (see table 1). This should not be surprising, given that production changes are only a subset of all the reasons drugs can become hard to obtain. Indeed, this fact became evident during the COVID-19 pandemic, when many shortages arose owing to demand spikes, not supply interruptions.

The ASHP list has several characteristics that distinguish it from the FDA list. First, drugs that are added to the ASHP list are usually first reported by practitioners, so the list is often tracking shortages in real time and is therefore forward looking. The ASHP then verifies practitioners' reports with drugmakers. A drug is included in the list if its lack of availability affects how a pharmacy prepares or dispenses a product or requires the use of alternative drugs. The ASHP keeps items on the list until they are back to full availability. The FDA list, by contrast, emphasizes drugs deemed medically necessary.[33] It focuses on the national market, using supply and

Table 1. Differences between the FDA and ASHP Drug Shortage Lists		
	FDA	ASHP
Scope	Focus is on medically necessary drugs confirmed to be in a national shortage. A shortage occurs when the demand for the drug within the United States exceeds the supply of the drug within a given period.	Focus is on drug and biologic shortages with a national impact. Products can be listed when there is partial or restricted availability, because this can still result in intermittent shortages at the provider or patient level. ASHP frequently lists more drugs than the FDA.
Source	Sources are primarily manufacturers, as well as market sales research and information from the ASHP or the public.	Sources are voluntary reports from healthcare practitioners, patients, and manufacturers. Information is confirmed with manufacturers.
Criteria for inclusion on list	Manufacturers cannot meet current national market demand for the drug (according to information provided to the FDA by manufacturers and from market sales research).	(a) Shortage is verified with manufacturers and (b) affects how pharmacy prepares or dispenses a product or (c) requires use of alternative drugs, which may affect patient care.
Criteria for shortage resolution	One or more manufacturers are producing and can meet full market demand.	All manufacturers of the drug restore all formulations and doses to full availability.

Note: The information in this table is an abbreviated version of the information in the source.
Source: "FDA and ASHP Shortage Parameters," American Society of Health-System Pharmacists, accessed October 15, 2021, https://www.ashp.org/drug-shortages/current-shortages/fda-and-ashp-shortage-parameters.

demand data either from the manufacturers or from market sales research, and it assumes that a drug is no longer in shortage when at least one manufacturer is producing that drug and can meet the national demand (see table 1).

LEGISLATIVE SOLUTIONS

Several stylized facts describe the current US drug market with respect to shortages. First, periodic drug shortages are a recurring feature of the market. Second, the process that has been laid out by Congress and the FDA to allow 503s to compound in response to shortages has not fully resolved the problem. Third, the COVID-19 pandemic has forced a policy response to this situation. That response may offer insights as to how the current legal landscape can be reformed to make further improvements.

Likely in response to this set of facts, legislators in Congress have been looking to draw lessons from changes made during the COVID-19 pandemic. A bipartisan bill introduced in the House of Representatives in 2021, H.R. 3662,[34] would codify some of the FDA's emergency permissions that it granted to 503As during the pandemic. Specifically, it would make permanent changes related to responding to urgent-use and shortage drugs when those drugs are unavailable from other sources.

If passed, the legislation would do several things. First, it would expand the exemption from drugs deemed "essentially copies of a commercially available drug product" to include drugs on the ASHP drug shortage list. This may be an improvement, because the ASHP list combined with the FDA list is probably a better barometer of drug shortages than the FDA list in isolation. Second, the legislation would carve out a predictable pathway for 503As to address drug shortages, one with a less stringent prescription requirement. That pathway would involve a hospital or other purchaser of drugs first seeking an FDA-approved drug from an ordinary source. If the drug could not be procured via that route, the licensed prescriber could then go to a 503B for a drug with the same active ingredient. If that route were to fail, it could approach a 503A.

This exact set of steps would have to be followed and appropriate records maintained. Moreover, 503As would have to procure records that identify the patient to whom the drug products were administered within a week of the medication being received or the patient being discharged. This record would be attached to the corresponding drug order.

In short, H.R. 3662 would codify the practices that the FDA itself has endorsed as a practical response to the COVID-19 emergency. This approach makes sense because it creates a predictable framework that stakeholders can anticipate, rather than having to rely on impromptu guidance from the FDA. Allowing 503As to resolve drug shortages when all other potential options run out should help both in times of emergencies, like the COVID-19 pandemic, as well as when shortages arise in noncrisis situations.

POTENTIAL CONCERNS

Critics of compounding pharmacies express concern about patient safety.[35] One concern is that, because 503As are not directly regulated by the FDA and because both they and 503Bs produce drugs that differ from mass-market FDA-approved drugs, these producers are more dangerous than other drug manufacturers.

The most notable piece of evidence in support of this claim is an outbreak of fungal meningitis that took place in 2012 and 2013 owing to contaminated drugs produced by the New England Compounding Center, located in Framingham, Massachusetts. The Pew Research Center has catalogued US illnesses and deaths associated with compounded or repackaged medications from 2001 through 2019.[36] Pew has identified 1,562 adverse events, including 116 deaths during this period, that were associated with compounding errors or potential errors.

More than one-half of the adverse events and about two-thirds of the deaths catalogued by the Pew Research Center stem from the single New England Compounding Center case. Without minimizing the seriousness of these adverse events and deaths, one can acknowledge that this event is fortunately an outlier in terms of the health harms it caused and in terms of the extent of

fraud and criminal activity on the part of the firm in question.[37] In addition to criminal sentences that were imposed in response to that event, Congress passed the Drug Quality and Security Act (DQSA) in 2013.[38] The DQSA is what created the 503A-503B distinction, detailing a process by which larger outsourcing facilities (503Bs) would be regulated by the FDA and have to conform to current good manufacturing practices, whereas smaller compounders (503As) would be regulated primarily at the state level.

Former FDA Commissioner Scott Gottlieb suggested in Congressional testimony that,[39] in response to the law, the FDA had hoped more 503As would convert to 503Bs, thereby bringing more compounders under FDA oversight. However, the considerable compliance costs associated with making that transition act as a barrier to the FDA's goal (though the FDA has also expressed a priority of preserving the traditional 503A designation). The FDA estimates that it would cost a large or a medium-sized pharmacy about $600,000 to become a 503B facility and that it would cost a large manufacturer about $1 million.[40] It seems likely that these high compliance costs are hindering the FDA's efforts to increase the number of 503Bs.[41]

Thus, a kind of limbo now exists in the regulatory system. Compounders want to be regulated in a manner that ensures the safety and reliability of their drugs. Moreover, everyone seems to accept 503As as a legitimate part of the compounding landscape that can be relied on to serve Americans' medication needs. It serves no one to force all small compounders into the current FDA-regulated framework, given that the high compliance costs would drive many of these small entities out of business. The New England Compounding Center incident should not be forgotten, and patient safety must be a top priority, but the DQSA also leaves many unanswered questions. Congress's job must be simultaneously to clarify the unresolved issues in the DQSA, preserve the role of small compounders and create flexibility for them to respond to shortages, and create a safe environment for patients. It is a tough balancing act, but a solution is now becoming evident.

CONCLUSION

The reforms suggested in this brief are meant to serve as last-resort options. There are risks associated with compounding pharmacies, but risks must be balanced with benefits. The FDA has tried for years to address the problem of drug shortages, and although some progress has been made, the COVID-19 pandemic has revealed that the country is still far from achieving the optimal solution.

When the alternative is no patient access to drugs, there is an easy choice: let compounders provide patients with the medicines they need. Currently, regulatory barriers stand in between patients and drugs in times of distress, but Congress and the FDA can solve these problems. Fortunately, good options are available, as the FDA's own emergency actions during the pandemic make clear. A window is opening for reform, and Congress now has both the tools and the information it needs to act. The question now is whether it will do so.

ABOUT THE AUTHOR

James Broughel is a senior research fellow at the Mercatus Center at George Mason University. Broughel has a PhD in economics from George Mason University. He is also an adjunct professor at the Antonin Scalia Law School at George Mason University.

NOTES

1. This policy brief focuses on shortages that may be unintentionally exacerbated by regulations affecting compounding pharmacies. In some cases, however, quantity restrictions on drugs are an intentional outcome sought by regulators. This is the case, for example, with the Drug Enforcement Agency's (DEA) quota system for controlled substances.
2. "CDER Conversation: FDA's Drug Shortages Prevention Strategies," Food and Drug Administration, February 2, 2015, https://www.fda.gov/drugs/news-events-human-drugs/cder-conversation-fdas-drug-shortages-prevention-strategies.
3. "Frequently Asked Questions about Drug Shortages," Food and Drug Administration, November 13, 2020, https://www.fda.gov/drugs/drug-shortages/frequently-asked-questions-about-drug-shortages.
4. Food and Drug Administration, "Guidance for Industry: Planning for the Effects of High Absenteeism to Ensure Availability of Medically Necessary Drug Products" (OMB Control No. 0910-0675, Food and Drug Administration, Silver Spring, MD, March 2011).
5. American Association of Health-System Pharmacists, "ASHP Guidelines on Managing Drug Product Shortages," in *Best Practices*, 2019–2020 ed., ed. Bruce Hawkins (Bethesda, MD: American Association of Health-System Pharmacists, 2019), 100–8.
6. Jonathan Minh Phuong et al., "The Impacts of Medication Shortages on Patient Outcomes: A Scoping Review," *PLOS One* 14, no. 5 (2019): e0215837.
7. Alex Kacik, "Drug Shortages Drain at Least $359m from Health Systems," *Modern Healthcare*, June 26, 2019.
8. Premier, *Drug Shortages 2014: A Premier Healthcare Alliance Update*, February 2014.
9. There was a shortage of epinephrine as of the writing of this brief in late October 2021. Moreover, some speculate that insulin shortages could be a problem in the future. See Sara Boseley, "Insulin Shortage Could Affect 40 Million People with Type 2 Diabetes," *Guardian*, November 20, 2018.
10. Phuong et al., "The Impacts of Medication Shortages."
11. Premier, *Drug Shortages 2014*.
12. "Special Issue: Drug Shortages: National Survey Reveals High Level of Frustration, Low Level of Safety," Institute for Safe Medication Practices, September 23, 2010, https://www.ismp.org/resources/special-issue-drug-shortages-national-survey-reveals-high-level-frustration-low-level.
13. Inmaculada Hernandez et al., "Changes in Drug Pricing after Drug Shortages in the United States," *Annals of Internal Medicine* 170, no. 1 (2019): 74–76.
14. Coleen Cherici et al., *Navigating Drug Shortages in American Healthcare: A Premier Healthcare Alliance Analysis* (Charlotte, NC: Premier Healthcare, 2011).
15. Sara Berg, "COVID-19 Exacerbates Drug Shortages. AMA Details Next Steps," American Medical Association, November 17, 2020, https://www.ama-assn.org/delivering-care/public-health/covid-19-exacerbates-drug-shortages-ama-details-next-steps.
16. "FD&C Act Provisions That Apply to Human Drug Compounding," Food and Drug Administration, August 13, 2021, https://www.fda.gov/drugs/human-drug-compounding/fdc-act-provisions-apply-human-drug-compounding.

17. Michael Gabay, "The Drug Quality and Security Act," *Hospital Pharmacy* 49, no. 7 (2014): 615–16.

18. Food and Drug Administration, *Compounded Drug Products That Are Essentially Copies of Approved Drug Products under Section 503B of the Federal Food, Drug, and Cosmetic Act: Guidance for Industry*, January 2018; Food and Drug Administration, *Compounded Drug Products That Are Essentially Copies of a Commercially Available Drug Product under Section 503A of the Federal Food, Drug, and Cosmetic Act: Guidance for Industry*, January 19, 2018; Food and Drug Administration, *Temporary Policy for Compounding of Certain Drugs for Hospitalized Patients by Outsourcing Facilities during the COVID-19 Public Health Emergency (Revised): Guidance for Industry*, May 21, 2020.

19. Food and Drug Administration, *Compounded Drug Products That Are Essentially Copies of Approved Drug Products*; Food and Drug Administration, *Compounded Drug Products That Are Essentially Copies of a Commercially Available Drug Product*

20. Food and Drug Administration, *Drug Shortages for Calendar Year 2020*, 2021, 12.

21. Food and Drug Administration, *Prescription Requirement under Section 503A of the Federal Food, Drug, and Cosmetic Act: Guidance for Industry*, December 2016.

22. According to the FDA, "The prescription requirement is a critical mechanism to distinguish compounding under section 503A of the FD&C Act from conventional manufacturing, or compounding by outsourcing facilities, and helps ensure that drug products that pharmacies compound under section 503A of the FD&C Act are provided to a patient only based on individual patient need." Food and Drug Administration, *Temporary Policy for Compounding of Certain Drugs for Hospitalized Patients by Pharmacy Compounders Not Registered as Outsourcing Facilities during the COVID-19 Public Health Emergency: Guidance for Industry*, April 2020, 3.

23. Lianna Matt McLernon, "FDA Went Flexible to Mitigate Shortages during COVID-19," *CIDRAP News*, July 7, 2021.

24. Food and Drug Administration, *Drug Shortages for Calendar Year 2020*.

25. Fentanyl is one such drug that is often given to patients on ventilators that has been in shortage. Despite availability issues, the DEA cut the fentanyl quota by over 30 percent in 2020. Dan Levine, "Exclusive: Opioid Supply Crunch for U.S. Coronavirus Patients Prompts Appeal to Relax Limits," *Reuters*, April 2, 2020; Zachary Brennan, "FDA Reports More Shortages of Drugs Used to Put COVID-19 Patients on Ventilators," *Regulatory Focus*, April 13, 2020; Ed Silverman, "A New COVID-19 Problem: Shortages of Medicines Needed for Placing Patients on Ventilators," *STAT News*, March 31, 2020.

26. "Pandemic-Linked Tylenol Shortages Popping Up in Some Places," CBS News, April 7, 2020; Leslie Hendeles and Sreekala Prabhakaran, "Nationwide Shortage of Albuterol Inhalers and Off-Label Use in COVID-19 Patients," *Pediatric Allergy, Immunology, and Pulmonology* 33, no. 4 (2020): 216–19.

27. Food and Drug Administration, *Temporary Policy for Compounding of Certain Drugs for Hospitalized Patients by Pharmacy Compounders*.

28. Food and Drug Administration, *List of Drugs Used for Hospitalized Patients with COVID-19*, October 13, 2020, https://www.fda.gov/media/138276/download.

29. See, for example, US Pharmacopeia, Compounded Preparation Monographs Failed Studies, April 9, 2020, https://www.usp.org/sites/default/files/usp/document/get-involved/partner/usp-compounded-preparation-monographs-failed-studies.pdf.

30. Federal Food, Drug, and Cosmetic Act § 506(c).

31. Food and Drug Administration, *Drug Shortages: Root Causes and Potential Solutions*, 2019.

32. "Current Drug Shortages," American Society of Health-System Pharmacists, accessed October 15, 2021, https://www.ashp.org/drug-shortages/current-shortages?loginreturnUrl=SSOCheckOnly.

33. "Frequently Asked Questions about Drug Shortages," Food and Drug Administration.

34. Patient Access to Urgent-Use Pharmacy Compounding Act of 2021, H.R. 3662, 117th Cong. (2021).

35. See, as an example, Allan Coukell, "Risks of Compounded Drugs," *JAMA Internal Medicine* 174, no. 4 (2014): 613–14.

36. "U.S. Illnesses and Deaths Associated with Compounded Medications or Repackaged Medications, 2001–19," Pew Charitable Trusts, March 9, 2020, https://www.pewtrusts.org/en/research-and-analysis/data-visualizations/2020/us-illnesses-and-deaths-associated-with-compounded-or-repackaged-medications-2001-19.

37. US Department of Justice, US Attorney's Office, District of Massachusetts, "Former Owner of Defunct New England Compounding Center Resentenced to 14 Years in Prison in Connection with 2012 Fungal Meningitis Outbreak," press release, July 7, 2021, https://www.justice.gov/usao-ma/pr/former-owner-defunct-new-england-compounding-center-resentenced-14-years-prison.

38. Drug Quality and Security Act; Gabay, "The Drug Quality and Security Act"; "Compounding Laws and Policies," Food and Drug Administration, September 10, 2020, https://www.fda.gov/drugs/human-drug-compounding/compounding-laws-and-policies.

39. Examining Implementation of the Compounding Quality Act, Hearing before the Subcomm. on Health of the H. Comm. on Energy and Commerce, 115th Cong. 67, 90 (2018) (statement of Scott Gottlieb, Comm'r of Food and Drugs, Food and Drug Admin.).

40. Examining Implementation of the Compounding Quality Act, 30.

41. On the number of registered outsourcing facilities, see Compounding Quality Center of Excellence (website), Food and Drug Administration, December 18, 2020, https://www.fda.gov/drugs/human-drug-compounding/compounding-quality-center-excellence; "Registered Outsourcing Facilities," Food and Drug Administration, October 25, 2021, https://www.fda.gov/drugs/human-drug-compounding/registered-outsourcing-facilities.

MERCATUS CENTER
George Mason University

PUBLIC INTEREST COMMENT

EVIDENCE-FREE POLICYMAKING AT THE DEPARTMENT OF HEALTH AND HUMAN SERVICES

JAMES BROUGHEL
Senior Research Fellow, Mercatus Center at George Mason University

Securing Updated and Necessary Statutory Evaluations Timely; Proposal to Withdraw or Repeal
Agency: US Department of Health and Human Services
Comment Period Opens: October 29, 2021
Comment Period Closes: December 28, 2021
Comment Submitted: December 15, 2021
Docket No. HHS-OS-2020-0012
RIN: 0991-AC24

The US Department of Health and Humans Services (HHS) has proposed a rule that,[1] if enacted, would rescind the Securing Updated and Necessary Statutory Evaluations Timely (SUNSET) rule finalized in January of 2021.[2] The SUNSET rule attaches sunset provisions—i.e., expiration dates—to HHS regulations such that if HHS does not conduct assessments and reviews of regulations in accordance with Section 610 of the Regulatory Flexibility Act (RFA) on a timely basis, then those regulations expire. Section 610 of the RFA requires agencies to develop and execute plans to periodically review regulations for their impact on small businesses.

In the proposed rule, HHS argues that it is unreasonable for the department to be expected to conduct the periodic reviews of HHS rules; it would be too costly and time consuming for the staff, according to the agency, diverting attention away from other department priorities.

However, the proposed rule suffers from certain deficiencies:

1. The proposed rule fails to address the problem the final SUNSET rule was intended to address, namely a failure of HHS to consistently comply with Section 610 of the RFA and to conduct retrospective reviews of its regulations.
2. The proposed rule fails to seriously consider alternative ways of complying with Section 610 of the RFA, which is troubling, given the wide array of options between the opposite approaches of attaching sunset provisions to 18,000 department regulations and returning to the pre-SUNSET-rule status quo (whereby reviews were ad hoc and relatively rare).

1. US Department of Health and Human Services, Securing Updated and Necessary Statutory Evaluations Timely; Proposal to Withdraw or Repeal, 86 Fed. Reg. 59906 (October 29, 2021).
2. US Department of Health and Human Services, Securing Updated and Necessary Statutory Evaluations Timely, 86 Fed. Reg. 5694 (January 19, 2021).

For more information, contact
Mercatus Outreach, 703-993-4930, mercatusoutreach@mercatus.gmu.edu
Mercatus Center at George Mason University
3434 Washington Blvd., 4th Floor, Arlington, VA 22201

3. HHS provides almost no evidence from the academic literature on retrospective review or sunset provisions or on the experiences of other jurisdictions with sunset provisions to justify its proposed action, instead relying on assertions from commenters.
4. The economic analysis for the proposed rule has serious deficiencies, including neglected benefits to small businesses, overstated costs, confusion about the role of baselines in economic analysis, and conflating of accounting costs and opportunity costs.

The RFA and numerous executive orders aimed at retrospective review intend for an evidence-based approach to regulation. What Americans are instead receiving from HHS is policy based on faith. HHS readily admits that many of its rules "have remained untouched for years" but confidently asserts without evidence that this is fine because rules "work as intended."[3] The great irony of HHS's assertion that too much of a burden is imposed on the department if it is required to review its own regulations is that HHS fully expects members of the public to comply with all of its regulations, on pain of penalties that include fines and even imprisonment.

I appreciate the opportunity to submit this public comment on the proposed rule. The Fourth Branch project at the Mercatus Center at George Mason University is dedicated to advancing knowledge about the effects of regulation on society. As part of its mission, scholars conduct careful and independent analysis that employs contemporary economic scholarship to assess regulations and their effects on economic opportunities and societal well-being.

HHS IGNORES THE PROBLEM THE SUNSET RULE WAS INTENDED TO ADDRESS

The first principle of Executive Order 12866 is "Each agency shall identify the problem that it intends to address (including, where applicable, the failures of private markets or public institutions that warrant new agency action) as well as assess the significance of that problem."[4] Office of Management and Budget (OMB) *Circular A-4* similarly states that "an agency must demonstrate that the proposed action is necessary."[5] And HHS's own guidelines on regulatory impact analysis state that "agencies must first describe the market failure or other social purpose that leads to the need for regulatory action."[6]

The SUNSET rule was intended to address two all-too-common government failures: the failure to systematically review regulations and, in this case, the failure also to meet statutory obligations under the RFA. When it finalized the SUNSET rule in early 2021, HHS identified just three final actions resulting from Section 610 reviews since 2011.[7] This represents about 0.7 percent of HHS rulemakings.[8] The RFA was amended in 1996 in part to give the law stronger enforcement mechanisms, including judicial review,[9] because Section 610 reviews were not being conducted systematically across the government. However, as is evident from HHS's small number

3. Securing Updated and Necessary Statutory Evaluations Timely; Proposal to Withdraw or Repeal, 86 Fed. Reg. 59916, 59920.
4. Exec. Order No. 12866, 58 Fed. Reg. 190 (October 4, 1993).
5. Office of Management and Budget, *Circular A-4*, September 17, 2003.
6. US Department of Health and Human Services, *Guidelines for Regulatory Impact Analysis*, 2016, 5.
7. Securing Updated and Necessary Statutory Evaluations Timely, 86 Fed. Reg. 5738.
8. According to HHS in the SUNSET rule, the average rulemaking amends five sections of the US *Code of Federal Regulations*. Thus, HHS's 18,000 regulations equate to about 3,600 rulemakings. The three actions amended as part of Section 610 reviews over the past decade amend about 130 sections of the US *Code of Federal Regulations*, or 26 rulemakings. Twenty-six rulemakings of 3,600 is about 0.7 percent. Securing Updated and Necessary Statutory Evaluations Timely, 86 Fed. Reg. 5737.
9. Small Business Administration, Office of Advocacy, *A Guide for Government Agencies: How to Comply with the Regulatory Flexibility Act*, August 2017, 2.

of reviews over the past decade, the enforcement mechanism remains weak, which is why alternatives are needed.[10]

The SUNSET rule offers a theory for how a sunset provision would work to spur more review and compliance with the RFA: "Sunset provisions change the default from rules staying on the books indefinitely to rules being eliminated after some predetermined amount of time unless evidence is presented for why rules should continue. When a default rule is changed, the choice architecture confronting decision makers is altered and can spur changes in behavior."[11]

The approach makes sense because the academic literature identifies the need for enforcement mechanisms to spur more periodic reviews, and sunset provisions are one such enforcement mechanism mentioned.[12] By contrast, the proposed rule contains no corresponding theory for how the department will address the problem the SUNSET rule sought to correct, namely, that HHS is not meeting its obligations under current law. Indeed, HHS does not even acknowledge this problem in the proposed rule.

HHS's failure to take seriously its obligations to periodically evaluate regulations is all the more troubling, given the overall lack of an evidentiary basis for many of its regulations. On a test of the quality and use of agencies' regulatory impact analysis, for example, HHS received an average score of 1.6 out of 10.0 on retrospective review, the worst of any agency considered.[13] On the question, "How well does the analysis identify and demonstrate the existence of a market failure or other systemic problem the regulation is supposed to solve?," HHS received a score of 2.1 out of 5.0, also a poor score, but basically about average for executive agencies.[14]

Although HHS acknowledges that 85 percent of its regulations enacted before 1990 have never been edited, it would have people believe, on the basis of the comments it has received, that these rules "work as intended."[15] However, "many rules, even those with significant effects, are often not on the public's radar once adopted."[16] In other words, the absence of evidence is not evidence of absence.[17] Just because HHS is not hearing from a regulated community that regulations are creating problems does not mean that all is well with its rulemakings.

In fact, "work as intended" may not a good thing, even if it occurs. If HHS works with special interest groups to enact regulations that protect industry incumbents at the expense of smaller rivals, then the "intended effect" of regulations is to bestow benefits on special interests at the public's expense. This could explain why some members of the regulated communities HHS is hearing from are not clamoring for HHS to implement the SUNSET rule. Once companies have complied with regulations, the private costs to them are often sunk. Meanwhile, regulations continue to act as a barrier to entry into the industry, shielding incumbent businesses from

10. According to a report from the Congressional Research Service, an "unintended effect" of the Small Business Regulatory Enforcement Fairness Act of 1996, was that it may have resulted in fewer Section 610 reviews. Curtis W. Copeland, *Reexamining Rules: Section 610 of the Regulatory Flexibility Act* (Washington, DC: Congressional Research Service, 2005), 9.
11. Securing Updated and Necessary Statutory Evaluations Timely, 86 Fed. Reg. 5739.
12. Michael Greenstone, "Toward a Culture of Persistent Regulatory Experimentation and Evaluation," in *New Perspectives on Regulation*, ed. David Moss and John Cisternino (Cambridge, MA: Tobin Project, 2009), 121.
13. Jerry Ellig, "Evaluating the Quality and Use of Regulatory Impact Analysis" (Mercatus Working Paper, Mercatus Center at George Mason University, Arlington, VA, July 2016), 32.
14. Ellig, "Evaluating the Quality and Use," 19, 109.
15. Securing Updated and Necessary Statutory Evaluations Timely; Proposal to Withdraw or Repeal, 86 Fed. Reg. 59916.
16. Yoon-Ho Alex Lee, "An Options Approach to Agency Rulemaking," *Administrative Law Review* 65, no. 4 (2013): 895–96.
17. Carl Sagan helped popularize this expression. Carl Sagan, "Introduction," in *The Dragons of Eden: Speculations on the Evolution of Human Intelligence* (New York: Random House, 1977), 1–10.

competition, thereby imposing ongoing social costs to the public. It is this political economy trap from which a sunset provision could help the department break free.

Two potential problems HHS appears to be trying to address with the proposed rule are that uncertainty is created by the SUNSET reviews and that rules might accidentally expire if the SUNSET rule goes into effect. However, new HHS regulations also create uncertainty, and it is not clear that reviewing regulations creates more uncertainty than adding new ones. Additionally, experience with existing sunset provisions discussed later in this comment yields little if any evidence that accidental expiration will seriously be a problem. Moreover, HHS considers no serious alternatives that might improve upon the SUNSET rule to prevent accidental expiration and reduce uncertainty. In fact, in its own economic analysis for the proposed rule, HHS assumes that no regulations will accidentally expire.[18] If accidental expiration is a primary motivation of the proposed rule, then this supposed consequence of the SUNSET rule should be analyzed.

RECOMMENDED ALTERNATIVES

OMB *Circular A-4* and HHS guidelines require the agency to consider alternatives when regulating. According to HHS, "agencies must justify the need for regulatory action and consider a range of policy alternatives,"[19] and "considering a wide-range of options both helps inform agency decision-making and encourages public comment."[20]

However, HHS considers only two alternatives in its economic analysis for the proposed rule. These two alternatives are (a) moving the sunset date forward for regulations older than 10 years such that these regulations are reviewed in the first two years or (b) moving the sunset date back such that existing regulations are reviewed over a 10-year period.[21]

HHS does note, "we request comment on whether, consistent with the goals of retrospective review as well as other current policy priorities and considerations discussed in this proposed rule, the Department should consider modifying, rather than withdrawing or repealing, the SUNSET final rule."[22] HHS also mentions numerous times throughout the preamble of its proposed rule that it considers a more targeted approach to reviews desirable.[23] But neither of the alternatives considered are more targeted. Instead, the sunset date in the alternatives analyzed still applies to the vast majority of HHS's 18,000 regulations. If HHS believes a more targeted approach is needed, it should consider more targeted alternatives in its analysis. In this spirit, this comment offers a few alternatives the department should consider that are more targeted than the SUNSET rule:

- HHS could review only those rules identified as having a significant economic impact on a substantial number of small entities at time of enactment.
- HHS could review only a particular section of the US *Code of Federal Regulations*, rules from a particular subagency within HHS, or rules associated with a particular statute.

18. "We maintain the assumption in the SUNSET RIA that the Department will satisfy the requirements of the SUNSET final rule and no regulations will automatically expire." Securing Updated and Necessary Statutory Evaluations Timely; Proposal to Withdraw or Repeal, 86 Fed. Reg. 59924.
19. US Department of Health and Human Services, *Guidelines for Regulatory Impact Analysis*, 6.
20. US Department of Health and Human Services, 6.
21. Securing Updated and Necessary Statutory Evaluations Timely; Proposal to Withdraw or Repeal, 86 Fed. Reg. 59929.
22. Securing Updated and Necessary Statutory Evaluations Timely; Proposal to Withdraw or Repeal, 86 Fed. Reg. 59908–09.
23. "HHS now believes more targeted alternatives suggested by commenters merit further consideration." Securing Updated and Necessary Statutory Evaluations Timely; Proposal to Withdraw or Repeal, 86 Fed. Reg. 59919.

- HHS could commit to retrospective review of new regulations going forward by including plans for retrospective review in future individual rulemakings but forgo mandating reviews of existing regulations at this time.

A benefit of these alternatives is that HHS's review policy could inform a pilot program, which, if successful, could be expanded to include more reviews. For example, Virginia recently completed a bipartisan regulatory reduction pilot program at two state agencies,[24] and HHS could do something similar.

Notably, each of the alternatives listed would eliminate most of the estimated costs and potential uncertainty regarding when regulations expire that HHS claims exist under the SUNSET rule. This is true because, by reducing the scope of the rule to a subset of department regulations, much of the workload on the department would be eliminated. The first and last alternatives mentioned would also eliminate uncertainty as to when regulations are expected to expire (because regulators know with certainty when the covered regulations were enacted).

The department also need not attach sunset provisions to regulations to review them. Rather, the department could issue a rule on rulemaking setting out a process for retrospective review that lacks a sunset mechanism. A rule on rulemaking would still create an enforcement mechanism to address HHS's general failure to conduct Section 610 reviews systematically. It could require, for example, that new rules be issued with a plan for when and how retrospective reviews will be conducted and for the use of data. The Administrative Conference of the United States (ACUS) has recommendations for rules on rulemaking, which include discussion of retrospective review.[25] ACUS research supports the suggestion that regulations be issued with plans as to how retrospective reviews will be conducted.[26] These plans, according to ACUS, should include descriptions of the objective of the rule, the way the agency plans to measure results going forward, and a time frame for conducting reviews.[27] Alternatively, a rule on rulemaking could codify Small Business Association (SBA) procedures for conducting Section 610 reviews, which HHS identifies as best practices in its proposed rule. In short, there are many alternative retrospective review approaches that HHS has failed to consider in the proposed rulemaking.

THE EVIDENCE-FREE NATURE OF THE PROPOSED RULE

HHS MAKES MANY ASSERTIONS WITHOUT EVIDENCE

Throughout the preamble to its proposed rule, HHS makes countless assertions, often without presenting any supporting evidence or, in some cases, by citing further assertions made by commenters. The word "could" appears 69 times in the preamble notice, and "may" appears more

24. James Broughel, "The Regulatory Budget in Theory and Practice: Lessons from the U.S. States" (CSAS Working Paper no. 21-47, C. Boyden Gray Center for the Study of the Administrative State, Arlington, VA, October 2021).
25. Administrative Conference of the United States, *Administrative Conference Recommendation 2020-1: Rules on Rulemaking*, December 16, 2020 (see specifically recommendation 2[f] on procedures for reassessing existing rules).
26. Administrative Conference of the United States, *Administrative Conference Recommendation 2014-5: Retrospective Review of Agency Rules*, December 4, 2014; Administrative Conference of the United States, Adoption of Recommendations, 79 Fed. Reg. 75114 (December 17, 2014).
27. Administrative Conference of the United States, *Administrative Conference Recommendation 2014-5*; Adoption of Recommendations, 79 Fed. Reg. 75114; Joseph Aldy, *Learning from Experience: An Assessment of the Retrospective Reviews of Agency Rules and the Evidence for Improving the Design and Implementation of Regulatory Policy* (Washington, DC: Administrative Conference of the United States, 2014), 66.

than 50 times. The word "assert" appears 28 times, and "commenters assert" appears 9 times. Aside from one report by the SBA (note 15 in the proposed rule) and some writings from ACUS (notes 20–26 in the proposed rule), there are almost no writings on retrospective review or sunset provisions even cited in the proposed rule.

One of ACUS's reports cited in HHS's proposed rule does mention the SUNSET rule. In rather typical ACUS fashion, it neither rejects nor endorses the SUNSET rule.[28] It also neither rejects nor endorses sunset provisions in general as mechanisms to spur retrospective review. The report does note (and HHS quotes) that "there does not seem to be a strong analytic basis presented for the periodicity (5 or 10 years) required in the HHS sunset review rule."[29]

In other words, the ACUS report criticizes the term of the sunset provision for not having an *analytic* basis, rather than criticizing the sunset provision itself. The term does have a *legal* basis, however, as it simply mirrors the timeline from Section 610 of the RFA, which requires 10-year periodic reviews. HHS is correct that the RFA does not *require* a 10-year sunset, but this sunset term does fall within the normal range of terms for sunset provisions seen in many states and countries. For example, New Hampshire and North Carolina both have 10-year sunset periods for regulations.[30] Arkansas has a 12-year sunset for regulations.[31] And some states have even shorter periods. For example, Florida has a five-year sunset.[32] Given that HHS is already required to conduct 10-year reviews under Section 610 of the RFA now, a 10-year sunset seems entirely appropriate and consistent with Congressional intent, and it could give salience to the provisions of the law with which HHS is arguably not complying.

To offer some further examples of how little regard for evidence HHS has in its proposed rule, in several places throughout the preamble, HHS claims "upon further consideration" to have changed its mind about something but offers no evidence to support its reasoning. For example, HHS states, "The Sensitivity Analysis Section of the SUNSET [regulatory impact analysis] RIA acknowledges that '[o]ne commenter noted that conducting a retrospective analysis can be as time-consuming and expensive as a prospective regulatory analysis, suggesting the Department's estimates of the time and expense of Reviews may be understated.' Upon further consideration, the Department believes that the commenter is likely correct."[33]

There is no further explanation or discussion of the evidence upon which this decision was made. Similarly, HHS dismisses, without offering any serious evidence, uncontroversial claims about political economy that virtually any political scientist would accept. Here is one passage:

> Additionally, the final rule concludes that "stakeholder input cannot be the only source of information to spur reviews" because such input would not reflect the "dispersed costs" that "consumers, small businesses, and the public" experience, given that those groups "often find it costly to organize and lobby on behalf of their own interests" and "[c]oncentrated interests" that "find it relatively easier" to do so would not take such costs into account.

28. Lori S. Bennear and Jonathan B. Wiener, *Periodic Review of Agency Regulation* (Washington, DC: Administrative Conference of the United States, 2021).
29. Bennear and Wiener, *Periodic Review*, 38.
30. N.H. REV. STAT. ANN. § 541-A:17(I) (2021); N.C. GEN. STAT. § 150B-21.3A (2021).
31. ARK. CODE ANN. § 25-15-401(d)(2)(A)(i) (2021).
32. Ron DeSantis, Letter to Governor's Agency Heads, November 11, 2019, https://www.floridahasarighttoknow.myflorida.com/content/download/147113/980326/FINAL_Directive_to_Agencies_11.19.pdf.
33. Securing Updated and Necessary Statutory Evaluations Timely; Proposal to Withdraw or Repeal, 86 Fed. Reg. 59925.

> However, HHS now doubts this conclusion because, as explained above, HHS received numerous comments to the SUNSET proposed rule from a diverse array of consumers, small businesses, and the public asserting the undue burdens and costs that rule would impose.[34]

The fact that HHS receives some comments from a variety of different trade associations and advocacy groups does not disprove the widely accepted fact that most members of the public have little incentive to take an interest in individual HHS policies, let alone participate in the rulemaking process, given that the costs and benefits to most individuals are small from any particular HHS action, whereas the costs and benefits to organized interest groups are often very large by comparison.[35] HHS's statement ignores the vast political science and public choice literatures, which emphasize the "rational ignorance" of members of the public.[36] That term describes how it is costly for members of the public to follow and participate in obscure policy actions, and the benefits to each individual of doing so are relatively small in comparison to the benefits to organized interest groups. As a result, members of the public rationally tune out. This is one of the key insights of economist Anthony Downs, arguably "one of the greatest political economists of the 20th century,"[37] whose contributions garnered deserved consideration for a Nobel Prize.[38]

Presumably all of the American public, including many individuals not yet born, would be affected if the SUNSET rule were to be adopted, given the reach of HHS regulations into American lives. Yet according to the HHS docket for the SUNSET rule on Regulations.gov, there were a mere 530 comments submitted.[39] Even if most of those comments were in opposition to the SUNSET rule's implementation, this tells us very little as to whether the regulation is warranted or serves the public interest, because the overwhelming majority of Americans did not participate in this process and probably have never heard of the SUNSET rule. Interest groups, however, whose interests may or may not align with the interests of the public more generally, have a much stronger incentive to participate. Interest groups seek economic rents via, for example, business lobbying for government favors.[40] The phenomenon of rent-seeking is a basic insight from public choice economics.[41]

Rent-seeking is a mainstream concept in economics, but HHS ignores it when considering the costs of HHS regulatory actions or the likely unrepresentative nature of the comments received by HHS on the SUNSET rule. Rent-seeking costs may also affect cost estimates made by the

---

34. Securing Updated and Necessary Statutory Evaluations Timely; Proposal to Withdraw or Repeal, 86 Fed. Reg. 59920.
35. Mancur Olson, *The Logic of Collective Action: Public Goods and the Theory of Groups* (Cambridge, MA: Harvard University Press, 1971).
36. Anthony Downs, *An Economic Theory of Democracy* (New York: Harper & Row, 1957); Geoffrey Brennan and Loren Lomasky, *Democracy and Decision: The Pure Theory of Electoral Preference* (Cambridge: Cambridge University Press, 1993).
37. Regrettably, Anthony Downs passed away in 2021. Ilya Somin, "Anthony Downs, RIP," *Volokh Conspiracy*, *Reason*, October 23, 2021.
38. Tyler Cowen, "Anthony Downs on Race and Urbanism, That Was Then This Is Now," *Marginal Revolution*, May 7, 2018; Tyler Cowen, "Who Are the Best Economists without a Nobel Prize," *Marginal Revolution*, April 13, 2010.
39. US Department of Health and Human Services, "Securing Updated and Necessary Statutory Evaluations Timely," Regulations.gov, accessed November 29, 2021, https://www.regulations.gov/docket/HHS-OS-2020-0012/comments.
40. Rent-seeking refers to wasteful competitive activities aimed at securing transfers of wealth. Rent-seeking occurs in the private sector as well as the public sector. For example, a form of private rent-seeking occurs when individuals try to improve their relative social status. When such competition is zero sum in nature (which is not always the case), these efforts waste resources.
41. Gordon Tullock, "The Welfare Costs of Tariffs, Monopolies, and Theft," *Economic Inquiry* 5, no. 3 (1967): 224–32; Anne O. Krueger, "The Political Economy of the Rent-Seeking Society," *American Economic Review* 64, no. 3 (1974): 291–303.

department. If the entities that submit comments to the department while it is undergoing retrospective reviews would have been rent-seeking in absence of having to write comments, then the private costs to these individuals and groups from writing comments could well constitute social benefits to society writ large.

HHS IGNORES EXISTING EXPERIENCE WITH SUNSET PROVISIONS

HHS's lack of concern for evidence continues with the department dismissing the numerous experiences of other jurisdictions with sunset provisions. Claims such as "the likelihood that regulations would automatically expire is high" are without merit,[42] which experience has shown in other places. To its credit, however, HHS does note that "we welcome comments regarding the experience of state and foreign governments with these laws."[43]

Of the sunset processes in any state, perhaps the one in Missouri is structured most like the HHS SUNSET rule. Missouri connects a sunset provision to a five-year periodic review requirement in a manner very similar to the SUNSET rule:[44] if a review of a regulation is not conducted and if a report based upon the review is not completed, the regulation expires. I communicated with an official from the office of Missouri's attorney general (who is also an expert on regulatory reviews for having overseen a regulatory review in the state), and he stated in an email, referencing the state's sunset provision, "I am not aware of any regulations that have expired as a result of the statute that you cited. From what I have seen, agencies review every regulation under their control."[45]

A 2021 report from the Organisation for Economic Co-operation and Development (OECD) ranks countries on the basis of how well they conduct ex post review of regulations. The United States is well below the OECD average and ranks just above Latvia.[46] Elsewhere, the OECD also notes, "Sunset requirements provide a useful 'failsafe' mechanism to ensure the entire stock of subordinate regulation remains fit for purpose over time."[47] The OECD claims that just fewer than half of member countries have some form of sunset arrangements in place.[48] The SUNSET rule itself notes that Australia, France, Germany, South Korea, and the United Kingdom have forms of sunset provisions.[49]

With respect to foreign countries with sunset provisions, HHS asserts, on the basis of the comments it has received, that "these governments are not bound by the requirements of the [Administrative Procedure Act] APA," and therefore HHS seems to presume that their experiences can be dismissed.[50] The claim is baffling for several reasons. First, many industrialized countries have processes like those required by the APA, such as a process for accepting public comments. Second, HHS's claim ignores the fact that many states have sunset provisions in place and that state regulatory agencies are bound by an administrative procedure act, just as is HHS. Every state

42. Securing Updated and Necessary Statutory Evaluations Timely; Proposal to Withdraw or Repeal, 86 Fed. Reg. 59916.
43. Securing Updated and Necessary Statutory Evaluations Timely; Proposal to Withdraw or Repeal, 86 Fed. Reg. 59919.
44. MO. REV. STAT. § 536.175.5. (2021)
45. Securing Updated and Necessary Statutory Evaluations Timely, 86 Fed. Reg. 5747.
46. Organisation for Economic Co-operation and Development, *Regulatory Policy Outlook 2021*, 2021, 84, figure 2.18.
47. Organisation for Economic Co-operation and Development, *Reviewing the Stock of Regulation: OECD Best Practice Principles for Regulatory Policy*, 2020, 11.
48. Organisation for Economic Co-operation and Development, *Reviewing the Stock of Regulation*, 25.
49. Securing Updated and Necessary Statutory Evaluations Timely, 86 Fed. Reg. 5694.
50. Securing Updated and Necessary Statutory Evaluations Timely; Proposal to Withdraw or Repeal, 86 Fed. Reg. 59919.

has an administrative procedure act,[51] and, in forthcoming research, I and my coauthors find that 17 states have some form of sunset provision for regulations.[52] A diverse set of states including Indiana, Kentucky, New Hampshire, and New Jersey have sunset provisions for regulations.

If anything, the state-level administrative procedure acts have more oversight mechanisms in place (and therefore include higher hurdles to rule reauthorization) than the federal APA because state administrative procedure acts often create an extensive role for the legislature in approving new rulemakings. Many states have legislative review committees that review new rules. Parliamentary systems tend to work similarly in that parliamentary action is often needed to reauthorize sunsetting laws.

Remarkably, HHS asserts that states "may not have the same resource constraints as HHS, for example, with respect to earmarked funds."[53] HHS's annual budget exceeds $1 trillion annually,[54] which rivals the GDP of many countries. Although much of HHS's spending is earmarked and therefore not discretionary, the claim that states are not as resource constrained as HHS strains credibility. HHS employs more than 80,000 people.[55] If anything, all states and probably many countries lack the resources HHS has to review regulations.

The evidence from the states and OECD nations casts doubt on HHS's claims that accidental expiration will be a problem under the SUNSET rule. Even if it were going to be a problem, HHS could amend the rule to give itself more time to review regulations, or review only a subset of department regulations, or, as noted earlier, it could forgo the use of a sunset provision altogether but still enact a rule on rulemaking mandating periodic retrospective reviews.

FLAWED ECONOMIC ANALYSIS

NEGLECTED BENEFITS IN THE FORM OF COST SAVINGS

HHS makes no attempt in its proposed rule to quantify the benefits forgone by rescinding the SUNSET rule (other than finding cost savings to the agency and public commenters, which it refers to as negative costs). HHS does note that there would be "disbenefits from the information" in forgone reviews.[56] Information is indeed valuable. However, the benefits of the SUNSET rule are much more substantial than just information. I have conducted an original benefits analysis of the SUNSET rule that relies on estimated benefits and costs of previous rules amended as part of retrospective review efforts (see the attachment at the end of this comment).[57] To be clear, the benefits analysis depends on ex ante estimates of the benefits and costs of regulations before they went into effect. Moreover, these reviews are not likely to be repeated in exactly the same form in

51. Rui J. P. de Figueiredo Jr. and Richard G. Vanden Bergh, "The Political Economy of State-Level Administrative Procedure Acts," *Journal of Law and Economics* 47, no. 2 (2004): 569–88.
52. Brian Baugus, Feler Bose, and James Broughel, "A 50-State Review of Regulatory Procedures" (unpublished manuscript, last modified October 19, 2021), Microsoft Word file.
53. Securing Updated and Necessary Statutory Evaluations Timely; Proposal to Withdraw or Repeal, 86 Fed. Reg. 59919.
54. US Department of Health and Human Services, "HHS Proposes Unprecedented Regulatory Reform through Retrospective Review," press release, November 04, 2020, https://www.einnews.com/pr_news/529981217/hhs-proposes-unprecedented-regulatory-reform-through-retrospective-review.
55. "What Agency Do You Want to Work For?," US Department of Health and Human Services, last updated October 26, 2020, https://www.hhs.gov/careers/working-hhs/agencies.
56. Securing Updated and Necessary Statutory Evaluations Timely; Proposal to Withdraw or Repeal, 86 Fed. Reg. 59923.
57. James Broughel, "The Benefits of HHS's SUNSET Regulation" (Mercatus Policy Brief, Mercatus Center at George Mason University, Arlington, VA, January 2021).

the future as part of reviews under the SUNSET rule; thus, my benefit estimates are subject to a high degree of uncertainty.

Nevertheless, although these efforts are not a perfect representation of what will occur under the SUNSET rule, they do shed light on the magnitude of benefits that are likely to be achievable. A reasonable approximation, made on the basis of reasonable assumptions, of the benefits of the SUNSET rule is $5 billion to $28 billion.[58] Moreover, some of these benefits stem from indirect public health benefits of the SUNSET rule, which arise from raising incomes and thereby increasing risk-reducing expenditures. This analysis highlights the public health rationale that underlies the SUNSET rule.

For comparison, HHS estimates the present value of the cost of the SUNSET rule at $530 million to $600 million, according to its updated cost analysis in the proposed rule.[59] Even if one assumes that these cost estimates are accurate, the best available estimate of benefits (HHS has not officially estimated benefits) of the SUNSET rule exceed the cost estimates by a factor of about 8 to 50. By rescinding the SUNSET rule, the math works in reverse: costs likely exceed benefits by a factor of about 8 to 50.

In a recent report, the Government Accountability Office (GAO) says five departments achieved $160 billion in net benefits under recent retrospective review efforts during the administration of Donald J. Trump.[60] Some of these net benefits may not be attributable to President Trump's Executive Order 13771—some perhaps would have occurred even absent the executive order—but the net benefits *are* attributable to retrospective review generally, highlighting the benefits of the exercise. (Strangely, HHS cites examples of past retrospective review efforts by the department as a reason *not* to instate the SUNSET rule,[61] but these have primarily been one-off efforts that have not been institutionalized into a recurring process.)[62] If HHS's experience were like that of the five departmental experiences reviewed by the GAO, and if cost savings of this magnitude could be achieved on a regular basis, then the benefits of the SUNSET rule could easily exceed the costs, perhaps by an order of magnitude or more.

None of this should be surprising, given the high cost of HHS activities to society. As noted, HHS's budget exceeds $1 trillion annually.[63] Healthcare spending more generally constituted about 17.7 percent of GDP in 2018, or $3.8 trillion (including $950 billion on nonclinical administrative functions).[64] The administration of Joseph R. Biden has identified about $20 billion of HHS

58. Broughel, "The Benefits of HHS's SUNSET Regulation."
59. Securing Updated and Necessary Statutory Evaluations Timely; Proposal to Withdraw or Repeal, 86 Fed. Reg. 59928. These are the central estimates of cost at varying discount rates.
60. Government Accountability Office, "Federal Rulemaking: Deregulatory Executive Orders Did Not Substantially Change Selected Agencies' Processes or Procedures" (report no. GAO-21-104305, Government Accountability Office, Washington, DC, September 2021).
61. "These efforts demonstrate the Department's ongoing commitment to retrospective review, which could be upended rather than strengthened by the SUNSET final rule." Securing Updated and Necessary Statutory Evaluations Timely; Proposal to Withdraw or Repeal, 86 Fed. Reg. 59920.
62. The Centers for Medicare and Medicaid Services Office of Burden Reduction and Health Informatics is one notable exception in that its reviews are recurring. The experience of this office could help inform retrospective reviews more generally across the department.
63. US Department of Health and Human Services, "HHS Proposes Unprecedented Regulatory Reform."
64. Anne B. Martin et al., "National Health Care Spending in 2019: Steady Growth for the Fourth Consecutive Year," *Health Affairs* 40, no. 1 (2020): 14–24; Nikhil R. Sahni, Brandon Carrus, and David M. Cutler, "Administrative Simplification and the Potential for Saving a Quarter-Trillion Dollars in Health Care," *JAMA* 326, no. 17 (2021): 1677–78.

spending that constitutes improper Medicare payments in 2021.[65] Meanwhile, HHS's updated cost analysis of the SUNSET rule finds that, if it were implemented, the rule would cost between $70 million and $76 million annually (over a 10-year period).[66] These statistics suggest that if HHS, as part of its reviews, identifies savings equal to even a miniscule amount of annual department spending or annual national spending on healthcare, the regulation will pay for itself.

This expectation is not unrealistic, given the reach of HHS regulations. For example, a recent study coauthored by economist David Cutler of Harvard University notes that "simplifying administration could save the US health care system an estimated $265 billion annually."[67] Moreover, that money "could be saved without compromising quality or access."[68] In other words, the costs HHS is anticipating from the review of its rules are a drop in the bucket compared to the potential savings of streamlining administrative bloat in the economy generally, much of which likely owes directly or indirectly to federal regulations.

A recent OECD report finds that the United States spends more as a percentage of GDP on healthcare than any other OECD nation, even when looking only at government and compulsory health insurance.[69] This finding is true, even though other nations' public healthcare systems cover their entire population, whereas the US public healthcare system does not.

The Regulation Rodeo database from the American Action Forum catalogues 628 final regulations from HHS between 2005 and 2021, with total costs of $183.2 billion and 357 million paperwork hours.[70] Some of these costs may be sunk, meaning they cannot be recovered. But paperwork burdens in particular are likely to be a source of low-hanging fruit, where HHS could save the economy billions of dollars (support for which is the recent decline in improper Medicare payments).[71] Cass Sunstein, a former administrator in the Office of Information and Regulatory Affairs (OIRA) during the Obama administration, has recommended that paperwork burdens be targeted as part of what he calls "sludge audits."[72] President Biden is also asking agencies to consider reducing paperwork burdens as a means of making government more customer focused. Finalizing the SUNSET rule or an alternative retrospective-review-oriented regulation would be consistent with this goal.[73]

NEGLECTED OPPORTUNITY COST

HHS claims that the proposed rule repealing the SUNSET rule would generate cost savings of approximately $70 million to $76 million annually. However, from a purely technical standpoint,

65. Centers for Medicare and Medicaid Services, "Biden-Harris Administration Announces Medicare Fee-for-Service Estimated Improper Payments Decline by over $20 Billion since 2014," press release, November 15, 2021, https://www.cms.gov/newsroom/press-releases/biden-harris-administration-announces-medicare-fee-service-estimated-improper-payments-decline-over?s=09.
66. Securing Updated and Necessary Statutory Evaluations Timely; Proposal to Withdraw or Repeal, 86 Fed. Reg. 59923.
67. Sahni, Carrus, and Cutler, "Administrative Simplification."
68. Sahni, Carrus, and Cutler.
69. Organisation for Economic Co-operation and Development, "Health Spending" (dataset), accessed November 29, 2021, https://data.oecd.org/healthres/health-spending.htm.
70. "Explore the Data," Regulation Rodeo, accessed December 6, 2021, https://regrodeo.com/.
71. Centers for Medicare and Medicaid Services, "Biden-Harris Administration Announces."
72. Cass R. Sunstein, "Sludge Audits," *Behavioral Public Policy* (published ahead of print, January 6, 2020).
73. "Executive Order on Transforming Federal Customer Experience and Service Delivery to Rebuild Trust in Government," Presidential Actions, White House, December 13, 2021, https://www.whitehouse.gov/briefing-room/presidential-actions/2021/12/13/executive-order-on-transforming-federal-customer-experience-and-service-delivery-to-rebuild-trust-in-government/.

this is not true. Although HHS would possibly have to hire additional staff to implement the SUNSET rule, it is quite likely (and indeed stated by the department) that existing personnel and resources would have to be reallocated away from other programs and activities toward conducting reviews and assessments if the SUNSET rule were to be implemented. To quote the department, "Preventing the automatic expiration of regulations, however, would require prioritizing retrospective review above many other Department programs and missions,"[74] and, "given the large scale of resources that would be required to conduct the required reviews, compliance with these new review requirements would lead to the diversion of resources from existing and new priority programs to the detriment of the other programs."[75]

These claims undermine HHS's cost estimates. Because most reviews would apparently be done by existing personnel, the expenditures HHS makes on staff will be made whether the SUNSET rule goes into effect or not. Thus, these costs to the agency and to taxpayers are in the baseline. The real opportunity cost of HHS's proposed rule is not what is spent on the staff, but rather what activities the staff would have done in absence of this regulation being enacted.[76] Furthermore, HHS has no idea the of value of these foregone activities, both because HHS has failed to estimate them in its economic analysis and because HHS refuses to systematically conduct retrospective reviews of its regulations.

HHS's cost estimates are clearly in violation of various best practices. According to OMB *Circular A-4*, "'Opportunity cost' is the appropriate concept for valuing both benefits and costs."[77] Similarly, HHS guidelines state that "opportunity costs are easy to confuse with accounting costs" and "economists measure costs by the value of forgone opportunities. In other words, costs are incurred when resources are used for one purpose and hence cannot be used for another purpose. . . . This interpretation differs from the concept of accounting costs (i.e., actual expenses plus depreciation of capital equipment)."[78]

A recent book by former FDA economist Richard Williams, who was the FDA's director of social science at the Center for Food Safety and Applied Nutrition, provides further context on this topic. In a discussion of opportunity cost, Williams notes that

> When a new regulation goes into effect, managers have to figure out how it applies to their firm and oversee implementation. That means instead of developing a new product or training workers, they need to work on the regulation instead. But the "price tag" for the managers, their salary, doesn't change. To economists, even though they are paid the same amount of money, the cost is not being able to do what would have been done in absence of the

74. Securing Updated and Necessary Statutory Evaluations Timely; Proposal to Withdraw or Repeal, 86 Fed. Reg. 59909.
75. Securing Updated and Necessary Statutory Evaluations Timely; Proposal to Withdraw or Repeal, 86 Fed. Reg. 59909
76. It could be argued that markets are so efficient that the wage of HHS staff exactly represents the opportunity cost of their time. Such an argument is unlikely to be true in this case because (a) the government is unlikely to produce competitive market outcomes because the price mechanism is generally absent in the public resource allocation process and (b) if markets really were this efficient, there would be little need for further government interventions because resources would already be allocated efficiently. Employee wages, especially government employee wages, often bear little connection to the social opportunity cost of individuals' time.
77. Office of Management and Budget, *Circular A-4*, 18.
78. US Department of Health and Human Services, *Guidelines for Regulatory Impact Analysis*, 23.

> regulation. . . . I told the scientists that the same thing holds true for when they're working on a regulation and their manager comes along and tells them to do something else.[79]

The discussion highlights that the problem facing HHS analysts when calculating the cost of the proposed rule is not how to tally up how much HHS employees and the monitoring public are paid, as has been done. Instead, the problem is figuring out the social value of these people's forgone activities. The value of those activities could be positive, negative, or zero, depending on whether HHS activities and public commenters' activities are, in general, net beneficial.

HHS has presented accounting costs in its RIA, not opportunity costs, in direct violation of its own guidelines. Even if the $70 million or so in annual costs to HHS is a perfect estimate, these are not the opportunity costs of the proposed regulation. To be fair, this criticism probably applies to most HHS cost estimates (including the SUNSET rule's cost analysis). However, the systematically poor analysis conducted by HHS generally does not excuse the poor analysis conducted in this particular instance.

IGNORANCE OF BASELINE

HHS cites "questions of attribution" in its proposed rule[80]—i.e., questions about whether benefits and costs of rules *emanating* from the SUNSET rule, yielded by the reviews that would be conducted, should be counted as benefits and costs of the sunset rule *itself* (or its repeal). On this matter, "the Department no longer believes it was appropriate to unambiguously attribute to the SUNSET rulemaking subsequent regulatory actions of this nature in the context of a regulatory impact analysis."[81]

If HHS is correct, then costs related to having to write comments to HHS on future regulations reviewed and amended under the SUNSET rule should not be counted as costs of the SUNSET rule (and, by extension, savings of the proposed rule). These savings represent about 70 to 80 percent of the estimated cost savings of the proposed regulation.[82] Arguably the costs to the agency of reviewing rules in the future should not be counted either, because these would also be attributable to future actions (thereby eliminating 100 percent of the estimated cost savings HHS claims in its proposed rule).

Putting that aside, however, HHS's own guidelines suggest that the costs and benefits of future regulatory actions should count. OMB *Circular A-4* states, "You need to measure the benefits and costs of a rule against a baseline. This baseline should be the best assessment of the way the world would look absent the proposed action."[83] HHS's guidelines on regulatory impact analysis state, "The core of the RIA is an assessment of the benefits and costs of regulatory and other policy options in comparison to a 'without regulation' (or 'no action') baseline."[84] HHS guidelines go on: "The analysis should, at minimum, compare conditions with and without the policy once the policy is fully implemented."[85]

---

79. Richard A. Williams, *Fixing Food: An FDA Insider Unravels the Myths and the Solutions* (Nashville, TN: Post Hill Press, 2021), 223–24.
80. Securing Updated and Necessary Statutory Evaluations Timely; Proposal to Withdraw or Repeal, 86 Fed. Reg. 59929, 59930.
81. Securing Updated and Necessary Statutory Evaluations Timely; Proposal to Withdraw or Repeal, 86 Fed. Reg. 59930.
82. Securing Updated and Necessary Statutory Evaluations Timely; Proposal to Withdraw or Repeal, 86 Fed. Reg. 59928.
83. Office of Management and Budget, *Circular A-4*.
84. US Department of Health and Human Services, *Guidelines for Regulatory Impact Analysis*, 1.
85. US Department of Health and Human Services, 6.

Without the SUNSET rule, a number of reviews and subsequent amendments to regulations enacted in response to those reviews will not happen. Any regulatory amendments, rescissions, accidental expirations, or other activities not occurring because the SUNSET rule is rescinded need to be counted as consequences of the proposed rule. These events occur in the baseline scenario but not in the scenario in which the proposed rule takes effect.

Consider this example from HHS's guidelines: "If a change in food handling procedures is expected under the baseline, the associated costs would not be counted as costs of the regulation. Similarly, the benefits of that change would have materialized in the baseline and cannot be attributed to the regulation."[86] Therefore, if a policy were to prevent the food handling regulation from being updated—because, for example, a retrospective regulation requiring that the rule be reevaluated were repealed—then the net benefits forgone from updating the food handling regulation would obviously have to be counted as costs of this new policy.

One of the challenges that has been identified with legislative impact accounting (i.e., impact analysis for congressional legislation) is that it is difficult to produce cost and benefit estimates for all of the regulations likely to emanate from a particular piece of legislation.[87] This is precisely the issue that arises with analyzing the costs and benefits of the SUNSET rule: many subsequent regulations are likely to be modified owing to this change in department policy. This fact no doubt makes regulatory analysis more challenging. But the response to this challenge should not be to invent a new definition of the baseline concept. Rather, HHS should acknowledge the analytical challenge involved and do the best it can. I again direct the agency's attention to the good faith attempt this author has made to estimate benefits of the SUNSET rule in an attachment to this comment.

Even if HHS's approach to the baseline is defensible, OMB notes that multiple baselines can be considered in an analysis.[88] Indeed, I have pointed to the practice of utilizing multiple baselines as a best practice.[89] The department should heed this good advice and assess the baseline in the standard way, where the net benefits from all forgone regulatory actions conducted under the SUNSET regulation are counted as costs of the proposed rulemaking. Then HHS can, if it wants, use an alternative baseline where these are considered part of separate actions (though the economic rationale for doing so is unclear).

OVERSTATED COSTS

HHS's cost estimates are likely to be inaccurate for several reasons. First, HHS states, "We assume that, under the baseline scenario of the SUNSET final rule, the Department will follow the recommendations in the SBA guidance."[90] I sincerely hope the department would follow through on this promise to adhere to SBA guidance when conducting Section 610 reviews, but past experience and even the proposed rule itself suggest that this is unlikely to be the case.

86. US Department of Health and Human Services, 7.
87. Jason J. Fichtner, Patrick A. Mclaughlin, and Adam N. Michel, "Legislative Impact Accounting: Incorporating Prospective and Retrospective Review into a Regulatory Budget," *Public Budgeting and Finance* 38, no. 2 (2018): 40–60.
88. Office of Management and Budget, *Circular A-4*.
89. Jerry Ellig and James Broughel, "Baselines: A Fundamental Element of Regulatory Impact Analysis" (Mercatus on Policy, Mercatus Center at George Mason University, Arlington, VA, June 2012).
90. Securing Updated and Necessary Statutory Evaluations Timely; Proposal to Withdraw or Repeal, 86 Fed. Reg. 59925.

HHS has a history of not complying with guidelines and of having low-quality analysis generally. A review of HHS RIAs over the 2008 to 2013 period gave the agency an average score of 8.9 out of 20.0 on the quality of analysis.[91] This score places HHS near the bottom of the ranking of agencies considered. Similarly, HHS received an average score of 1.3 out of 5.0 on the extent to which it uses analysis in decision-making, again placing it near the bottom of agency rankings.[92] These scores reflect not just a lack of competency and attention to evidence when regulating, but also a lack of adherence to principles in Executive Order 12866, OMB *Circular A-4*, and HHS guidelines on RIAs.

Even within the current proposed rule, HHS violates elements of its own guidelines as well as OMB guidelines because (as noted earlier) it fails to rigorously consider the problem the regulation is addressing, it does not consider a wide array of alternatives to the proposed action, and it misunderstands basic regulatory analysis concepts such as baselines and opportunity cost. In short, given HHS's track record, there is little reason to believe that analysts at HHS will comply with SBA guidelines that are not binding on the agency and for which there are no serious penalties if HHS does not comply. (However, as noted earlier, HHS should consider adopting a rule on rulemaking that codifies SBA's Section 610 review procedures as official department policy.)

More generally, there is a strange mental disconnect in the department's cost analysis. The department considers costs to the public of monitoring HHS activities while it is conducting retrospective reviews and updating regulations in the future. For example, it considers the costs of writing comments, yet the purpose of the RFA was clearly to alleviate burdens of regulations on small businesses. Thus, presumably the regulations these commenters will be writing about will be eliminating costs on these same (and other) commenters. Yet these cost savings are completely ignored by the department. As noted earlier, HHS also neglects the costs of rent-seeking, which leads to questions about the opportunity cost of the commenters' time. The one-sided nature of the department's cost analysis is highly concerning.

HHS's economic analysis is also problematic because it neglects the differential timing of benefits and costs. HHS cites uncertainty as a major reason for not enacting the SUNSET rule,[93] but if there is any uncertainty from the rule, it is mostly upfront. Even if one assumes that HHS's assertions about accidental expirations are true, uncertainty will be resolved as the schedules for expiration are discovered.[94] Within a few years, it is reasonable to conclude that most uncertainty will fade and any accidental expirations will stop.

After an initial pass through the regulatory code occurs, the job of conducting reviews becomes much easier as well. Because regulations are likely to be updated in response to the SUNSET rule in perpetuity, if one assumes that these regulatory actions are net beneficial, then the benefits of the SUNSET rule seem to be ongoing whereas the costs may be mostly immediate.

---

91. Ellig, "Evaluating the Quality and Use," 29, figure 11.
92. Ellig, "Evaluating the Quality and Use," 30, figure 12.
93. For example, HHS asserts that "in the event regulations automatically expire, they will be faced with enormous administrative costs such as computer system upgrades, staff training, amended services contracts, and public education on new requirements." Securing Updated and Necessary Statutory Evaluations Timely; Proposal to Withdraw or Repeal, 86 Fed. Reg. 59915.
94. Note that in the SUNSET rule, HHS states plans to publish a schedule of when rules were enacted, which may reduce most of this uncertainty.

Thus, HHS demonstrates a kind of present bias by giving so much emphasis to short-term costs while downplaying long-term benefits.

There is one additional point about uncertainty worth noting. HHS takes a one-sided view of uncertainty in its proposal. The department notes that uncertainty is created by the SUNSET rule (because, for example, existing rules might expire or be updated in response to reviews conducted under the rule). However, HHS ignores any consideration of uncertainty in the baseline. HHS activities create uncertainty. To the extent fewer new regulations are issued by the department, as resources are reallocated toward conducting reviews and away from other HHS actions, then there is a corresponding reduction in uncertainty, which is a benefit of the proposed rule. This benefit should be acknowledged, as it could easily offset whatever uncertainty might arise from rescinding or updating regulations in response to reviews. Again, the one-sided nature of HHS's analysis is troubling.

CONCLUSION

With the notable exception of the current administration, retrospective review has been a critical component of every president's regulatory program going back to Jimmy Carter.[95] These one-off review programs, however, also highlight the need for a systematic process that institutionalizes reviews into the existing process. As former OIRA administrator Cass Sunstein has noted, "After rules are in place, [agencies] should test [their ex ante] speculations, and they should use what they learn when revisiting a regulation or issuing a new one" because this is "one of the most important steps imaginable."[96]

There are many reasons to believe that regulations, once enacted, will not have the same effects that were anticipated before enactment. The billionaire investor David Rubenstein summed up this issue nicely in a recent interview:

> Most business people—if you go back and look at their original business plan, you'll find that it bears no relationship to what they actually became. If you go back and look at what Bill Gates, Steve Jobs, Mark Zuckerberg, Jeff Bezos were going to do at the beginning—what they ultimately turned out to do was completely different. For example, Jeff Bezos—and I knew him at the beginning—he was just going to sell books over the internet, and that was it, nothing else. And then later he evolved to doing everything over the internet.[97]

Most regulations are probably having effects completely unanticipated from those predicted ex ante, just as occurs in business. Without some form of retrospective review, these impacts will never be understood.

Imagine if a business decided it would estimate revenues from the sale of a new product once, before the product went on the market, and then never evaluate the sales from the product

95. Exec. Order No. 12044, 43 Fed. Reg. 12661 (March 24, 1978); Exec. Order No. 12291, 46 Fed. Reg. 13193 (February 17, 1981); Memorandum on Reducing the Burden of Government Regulation (January 28, 1992); Exec. Order No. 12866, 58 Fed. Reg. 51735 (October 4, 1993); Draft Report to Congress on the Costs and Benefits of Federal Regulations, 66 Fed. Reg. 22041, 22054 (May 2, 2001); Exec. Order No. 13563, 76 Fed. Reg. 3821, 3822 (January 21, 2011); Exec. Order No. 13771, 82 Fed. Reg. 9339, 9339 (February 3, 2017).
96. Cass R. Sunstein, "The Regulatory Lookback," *Boston University Law Review* 94, no. 3 (2014): 591.
97. David Rubenstein and Tyler Cowen, "David Rubenstein on Private Equity, Public Art, and Philanthropy (Ep. 136)," November 17, 2021, in *Conversations with Tyler*, produced by the Mercatus Center at George Mason University, podcast, MP3 audio, https://conversationswithtyler.com/episodes/david-rubenstein/.

ever again. Instead, the managers say, "it would be nice to measure those returns in theory, but accounting departments cost money. It is far too time consuming to assess revenues year after year. We have many, much more important new product lines to launch. And besides, the product is going great. No one is complaining, so it must work as intended."

Rational investors would immediately pull all their money out of this company. Yet this is exactly the logic HHS follows in its proposed rule and exactly what occurs in the federal government when regulatory agencies produce ex ante analysis and do not follow up with ex post retrospective analysis.

HHS claims, "the Department is committed to exploring ways to improve its processes for conducting retrospective reviews under the Regulatory Flexibility Act (RFA) and identify and retire obsolete rules."[98] However, HHS's claim is not credible. HHS could make its claims convincing by adopting a final rule that requires the agencies to conduct retrospective reviews in some form. If it does not like the approach taken by the previous administration, it should offer its own alternative.

The entire point of retrospective review is to make policy evidence based. Ironically, the proposed repeal of the SUNSET rule, with its near-complete dearth of supporting evidence, is one of the strongest recent examples I can think of for enacting the SUNSET rule. Without an enforcement mechanism, the danger that HHS will implement its agenda based on politics, blind faith, and special-interest favoritism appears strong.

ATTACHMENT

James Broughel, "The Benefits of HHS's Sunset Regulation" (Mercatus Policy Brief, Mercatus Center at George Mason University, Arlington, VA, January 2021).

98. Securing Updated and Necessary Statutory Evaluations Timely; Proposal to Withdraw or Repeal, 86 Fed. Reg. 59910.

MERCATUS CENTER
George Mason University

POLICY BRIEF

The Benefits of HHS's SUNSET Regulation

James Broughel

January 2021

On January 8, 2021, the US Department of Health and Human Services (HHS) announced that it would be finalizing a regulation titled "Securing Updated and Necessary Statutory Evaluations Timely," which forms the acronym SUNSET.[1] Despite its unassuming name, the regulation is actually one of the more ambitious rule changes to emerge in the four years of the Trump administration.

Regulatory agencies in the federal government are required to conduct periodic reviews of their regulations under Section 610 of the 1980 Regulatory Flexibility Act (RFA).[2] Section 610 requires agencies, consistent with their other statutory objectives, to periodically look back at existing regulations to minimize economic impacts on small businesses. In so doing, agencies are to determine whether rules are still needed, whether they are overly complex, and whether they should be updated to reflect evolving circumstances. The RFA was intended to alleviate regulatory burdens and create regulatory flexibility for small businesses, which are known to be disproportionately burdened by the costs of regulations.

Historically, RFA compliance has been weak. HHS, during the process of promulgating the SUNSET rule, identified just three regulations in the past decade that were finalized in response to Section 610 reviews. HHS estimates that 85 percent of regulations adopted before 1990 had never been edited. As one study recently noted, the periodic review requirement of the RFA has not been complied with consistently "in part because there is no penalty if an agency ignores the RFA."[3]

HHS's new SUNSET rule is an attempt to increase compliance with the RFA and to spur more retrospective reviews. It does so by creating a new forcing mechanism according to which, if HHS fails to review a rule in accordance with the RFA, the regulation automatically expires after a predetermined amount of time (in most cases after 10 years). Such an expiration date is known as a

sunset provision. The SUNSET rule imposes a sunset provision on the vast majority (with some exceptions) of the approximately 18,000 sections of the US *Code of Federal Regulations* (CFR) under HHS's purview.

The RFA review process HHS sets forth in the SUNSET rule works as follows: First, regulations need to be assessed in order to determine if they have a significant economic impact on a substantial number of small entities (SEISNOSE—a term of art from the RFA). If they do, a more in-depth review follows, based on review criteria set forth in the RFA. The first sunset date kicks in five years after the SUNSET rule is finalized, meaning that about 95 percent of HHS regulations will have to be assessed (and potentially reviewed if found to have a SEISNOSE) by the end of 2026 or else the various regulations expire, since most HHS regulations were adopted before 2016 and, thus, will be 10 years old by the time of the first sunset date. Once assessed (and reviewed, if necessary) a regulation's expiration date is pushed back another 10 years. If a regulation requires updating, HHS has two years to update it, though this deadline may be extended.

HHS's preamble to the SUNSET rule includes some estimates of the rule's costs. These estimated costs fall into two categories: (a) costs to the department from allocating personnel to assessing and reviewing department regulations and (b) costs to the public from monitoring and commenting on regulations during the review process. HHS estimates that annualized costs over 10 years would fall in the range of about $8 million to $25 million. However, like most regulatory impact analyses (RIAs) issued by federal agencies, the RIA for the SUNSET rule does not include a monetized estimate of the rule's benefits.

The purpose of this policy brief is to provide such an estimate of benefits to compare with the department's estimated costs of the SUNSET rule. This policy brief is organized as follows. The next section provides a benefit estimate for the rule based on some recent HHS experiences with retrospective review. All told, the benefits of the rule are potentially very large, such that it could pass a benefit-cost test, perhaps paying for itself many times over. After that, the brief compares estimated benefits to the costs found in the RIA accompanying the rule, which tend to be about two orders of magnitude lower than the estimated benefits. Later, the brief discusses potential shortcomings of this benefit estimate, which, because it is based on past government RIAs, is subject to considerable uncertainty. The brief concludes that the success of the rule will ultimately depend on which regulations are amended in response to conducting future retrospective reviews. The identities of these regulations are to some extent unknowable. However, the SUNSET rule's new forcing mechanism gives reason to believe that in the future, retrospective reviews will become a much more prevalent and important part of HHS policy than they have been historically.

BENEFITS ANALYSIS

Background

The benefits stemming from the SUNSET rule are the net social benefits of whatever regulatory updates, amendments, or rescissions end up occurring as a result of the assessments and reviews that will take place following the rule's implementation. It is impossible to know with certainty the universe of regulations that will be updated in light of strengthened enforcement of periodic review requirements and better department compliance with the RFA. However, past Section 610 reviews offer some perspective, as does former President Barack Obama's Executive Order 13563, which ordered a review of existing regulations. Both past experiences can potentially inform an estimate of the benefits of the SUNSET rule.

In order to produce an estimate of benefits, the analysis in this brief makes several assumptions. The first assumption is that the initial assessments (which are conducted to determine whether HHS regulations will have a SEISNOSE) result in no new rulemaking activity on their own. This assumption seems reasonable, given that once a regulation is deemed not to have a SEISNOSE, HHS will have fulfilled its retrospective review requirement, and the expiration date will move back 10 years on the relevant regulation. In its final notice of the SUNSET rule, HHS is clear that it contemplates amendment or rescission of regulations that have been reviewed, which is a step that comes after rules are assessed.

The next assumption is that no regulations will accidentally expire owing to HHS not conducting a timely assessment or review. This assumption also seems reasonable, given the experiences of many states with sunset provisions in their laws. For example, in its final notice of the SUNSET rule, HHS points to states such as Idaho, Missouri, New Jersey, and North Carolina, which have sunset provisions for regulations and where accidental expiration of rules seems to be an exceptionally rare phenomenon.

HHS has also built safeguards into the SUNSET rule to prevent inadvertent expiration of regulations. For example, the public will be able to submit comments requesting that HHS commence an assessment or review, and HHS plans to release a list of when all of the regulations under HHS authority were created or last modified, which will allow the monitoring public to determine the expiration date for all or nearly all HHS regulations.

Benefits Assessment

The benefit estimates in this section focus on the reviews expected to be conducted and the corresponding amendments and rescissions that follow from these reviews. As noted, HHS identifies three regulations in the past decade that emanated from its Section 610 reviews. These regulations are presented in table 1, along with the corresponding impacts these regulations were expected to produce, according to the economic analyses accompanying these regulations at the time of their promulgation.

Table 1. HHS Completed Final Rulemaking Actions as a Result of Section 610 Reviews since 2011

NAME OF RULEMAKING	RIN	YEAR	PRESENT VALUE OF ESTIMATED COST SAVINGS (MILLIONS OF 2020$, 7 PERCENT DISCOUNT RATE)	PRESENT VALUE OF ESTIMATED COST SAVINGS (MILLIONS OF 2020$, 3 PERCENT DISCOUNT RATE)
Medicare and Medicaid Programs; Regulatory Provisions to Promote Program Efficiency, Transparency, and Burden Reduction; Fire Safety Requirements for Certain Dialysis Facilities; Hospital and Critical Access Hospital (CAH) Changes to Promote Innovation, Flexibility, and Improvement in Patient Care	0938-AT23	2019 (Final Rule)	$5,976	$7,277
Medicare and Medicaid Program: Conditions of Participation for Home Health Agencies	0938-AG81	2017 (Final Rule)	−$1,317	−$1,471
Medicare and Medicaid Programs; Reform of Requirements for Long-Term Care Facilities	0938-AR61	2016 (Final Rule)	−$3,431	−$3,821
Total			$1,228	$1,985

Note: Annualized figures from the RIAs for these regulations were converted into present values and updated to 2020 dollars.
Sources: US Department of Health and Human Services, Medicare and Medicaid Programs; Regulatory Provisions to Promote Program Efficiency, Transparency, and Burden Reduction; Fire Safety Requirements for Certain Dialysis Facilities; Hospital and Critical Access Hospital (CAH) Changes to Promote Innovation, Flexibility, and Improvement in Patient Care, 84 Fed. Reg. 51732 (September 30, 2019); US Department of Health and Human Services, Medicare and Medicaid Programs; Conditions of Participation for Home Health Agencies, 82 Fed. Reg. 4504 (January 13, 2017); US Department of Health and Human Services, Medicare and Medicaid Programs; Reform of Requirements for Long-Term Care Facilities, 81 Fed. Reg. 68688 (October 4, 2016).

None of the rules in table 1 have monetized estimates of nonmarket benefits in their RIAs, but they do have estimates of cost savings, which, although sometimes appearing on the cost side of the ledger, are indistinguishable from benefits (since net benefits are calculated by subtracting costs from benefits). Relying on cost savings is defensible in a benefits analysis for several reasons. First, it is reasonable to conclude that reducing regulatory burdens on small businesses may end up being one of the primary benefits of the SUNSET rule. Cost savings has been one of the primary benefits associated with regulatory reform efforts under Executive Order 13771.[4] Finally, cost savings have been used to evaluate net social benefits in other federal government reports, most notably from the Council of Economic Advisers.[5]

As is evident from table 1, at the time of promulgation two of the regulations were expected to impose net costs (suggesting that it is possible for regulators to impose additional costs on the public as a result of retrospective reviews), but the other regulation was estimated to produce enough savings to more than make up for the net costs imposed by the other two.[6]

On balance, the present value of the net benefits of the three regulations is estimated to be $1.2 billion (in 2020 dollars, at a 7 percent discount rate), according to the economic analyses accompanying these regulations. However, these regulation amended more CFR sections than typical regulation under HHS's authority. In HHS's RIA for the final SUNSET rule, HHS notes that one regulation amends five CFR sections on average. However, approximately 130 CFR sections were amended by the three regulations in table 1. Thus, the total benefits and costs reported in table 1 can be thought of as having emanated from 26 average regulations for the purposes of this benefits analysis.[7]

In the RIA for the SUNSET rule, HHS also projects that 53 average regulations are likely to be rescinded and 159 are likely to be amended as a result of the rule. HHS does not provide information about whether savings are more likely to come disproportionately from amended regulations or from rescinded regulations. If one assumes that savings are likely to come from both equally, then these 212 combined updates could be expected to yield $10.0 billion to $16.2 billion in net savings,[8] provided that HHS's recently completed actions stemming from Section 610 reviews are representative of the benefits likely to follow from the SUNSET rule.[9]

However, any regulations updated in response to the new retrospective review procedure would not be promulgated immediately. Some would likely be finalized in the decade following implementation of the SUNSET rule, and the finalization of some could even extend into the following decade. Assuming that, on average, regulations deliver benefits 10 years in the future, then the present value of these benefits is $5.1 billion (in 2020 dollars) at a 7 percent discount rate and $12.1 billion at a 3 percent discount rate.[10]

Given the uncertainty surrounding this benefit estimate, one could look at other retrospective review efforts in addition to HHS's Section 610 reviews. Another source of information about the

benefits of retrospective review efforts are the regulations promulgated in response to Executive Order 13563. A study of these efforts by the Administrative Conference of the United States identifies three major regulations from HHS that were the result of retrospective review and were included in the 2013 and 2014 Office of Management and Budget reports to Congress on the benefits and costs of federal regulations.[11] Table 2 presents those regulations along with estimates of their impacts, as quantified in their RIAs at the time of promulgation. The preamble of one of the rules (0938-AQ89) notes that the rule's provisions meet the objectives of Section 610 of the RFA. However, the rule is not labeled as resulting from a Section 610 review in HHS semiannual agendas, which explains why it is left out of table 1.

As a group, at the time of their promulgation, the three rules were expected to achieve net benefits of $4,640 million at a 7 percent discount rate and $5,227 at a 3 percent discount rate (in 2020 dollars). Those rulemakings amend between 120 and 180 CFR sections. Taking the midpoint of this range suggests these rules amended 30 average rulemakings. Assuming that 212 rulemaking updates occur in coming years, these could be expected to yield $32.8 billion to $36.9 billion in benefits. If these benefits arrive in 10 years, then the present value of these benefits is $16.7 billion at a 7 percent discount rate and $27.5 billion at a 3 percent discount rate.

If one assumes that the entire sample of rules in tables 1 and 2 should be considered together, then the combined estimated net benefits of the regulations are $5,868 million to $7,212 million, amending approximately 280 sections of the CFR. Taking into account that an average rulemaking amends five sections, and assuming that benefits arrive 10 years in the future, this approach yields a present value of estimated benefits of $11.3 billion at a 7 percent discount rate and $20.3 billion at a 3 percent discount rate.[12]

Sensitivity

The secretary of Health and Human Services has the option to extend expiration dates, so there is a chance that benefits will be pushed further into the future, which would lower the present value of these benefits. If the review of a regulations concludes that regulations should be amended or rescinded, then HHS has two years from the date that the findings of the review are published in the *Federal Register* to amend or rescind the regulation. If the secretary determines that completion of the amendment or rescission is not feasible by the established date, he or she can certify this in a statement published in the *Federal Register* and then extend the completion date by one year at a time for no more than three times. For sensitivity purposes, one might assume therefore that the benefits estimates, which range from $5.1 billion to $27.5 billion, might arrive three years later as a result of the delay provisions available to the secretary. In that case, benefits would range from a low of $4.2 billion to a high of $25.2 billion.

Table 2. HHS Rules Resulting from Retrospective Review That Appear in the 2013 and 2014 OMB Reports to Congress on the Benefits and Costs of Federal Regulations

RULE	RIN	YEAR	PRESENT VALUE OF ESTIMATED COST SAVINGS (MILLIONS OF 2020$, 7 PERCENT DISCOUNT RATE)	PRESENT VALUE OF ESTIMATED COST SAVINGS (MILLIONS OF 2020$, 3 PERCENT DISCOUNT RATE)
Modifications to the HIPAA Privacy, Security, Enforcement and Breach Notification Rules	0945-AA03	2013 (Final Rule)	−$354	−$350
Medicare and Medicaid Programs; Reform of Hospital and Critical Access Hospital Conditions of Participation	0938-AQ89	2012 (Final Rule)	$4,387	$4,900
Medicare and Medicaid Program; Regulatory Provisions to Promote Program Efficiency, Transparency, and Burden Reduction	0938-AQ96	2012 (Final Rule)	$607	$677
Total			$4,640	$5,227

Note: Annualized figures from the RIAs were converted into present values and inflation adjusted to 2020 dollars.
Sources: Joseph E. Aldy, *Learning from Experience: An Assessment of the Retrospective Reviews of Agency Rules and the Evidence for Improving the Design and Implementation of Regulatory Policy* (unpublished manuscript, November 17, 2014), PDF file; US Department of Health and Human Services, Modifications to the HIPAA Privacy, Security, Enforcement, and Breach Notification Rules Under the Health Information Technology for Economic and Clinical Health Act and the Genetic Information Nondiscrimination Act; Other Modifications to the HIPAA Rules, 78 Fed. Reg. 5566 (January 25, 2013); US Department of Health and Human Services, Medicare and Medicaid Programs; Reform of Hospital and Critical Access Hospital Conditions of Participation, 77 Fed. Reg. 29034 (May 16, 2012); US Department of Health and Human Services, Medicare and Medicaid Program; Regulatory Provisions to Promote Program Efficiency, Transparency, and Burden Reduction, 77 Fed. Reg. 29002 (May 16, 2012).

Context

To put these estimates (which may seem large at first glance) in context, one recent study estimates that the cumulative cost of federal regulations in 2012 was $4 trillion.[13] The $4 trillion federal regulatory cost estimate is derived using an endogenous growth model and data on regulatory restrictions across US industries. Regulatory counts, and specifically counts of regulatory requirements or restrictive terminology, are now often used to evaluate regulatory burdens. For example, Canada recently adopted measures of regulatory burdens across agencies using regulatory counts.[14] These kinds of metrics are employed in states as part of regulatory reform efforts and now appear widely in peer-reviewed academic studies.[15]

In 2012, HHS regulations comprised about 5 percent of federal regulatory restrictions.[16] If HHS restrictions impose on average the same burden as restrictions from the federal government as a whole, then HHS regulations imposed costs of $200 billion in 2012, which, in 2020 dollars, is $228 billion.[17] Meanwhile, $10 billion in benefits annualized over 10 years at a 7 percent discount rate constitutes about $1.4 billion per year in savings, which is less than 1 percent of the annual estimated costs of HHS regulations, suggesting that the benefits estimates earlier are plausible and may even be modest compared to the estimated costs of HHS regulations. It is also worth noting that many of the regulations appearing in tables 1 and 2 amend the Medicare program. Because of that program's size, it is not surprising that regulations amending it could have impacts in the billions of dollars.

Indirect Benefits

The benefits of the SUNSET rule are not purely financial, as coincident risk reductions are likely to extend from the benefits estimated earlier. One recent study estimates that for every $109 million (in 2019 dollars) in costs resulting from a regulation, one can expect one death to occur.[18] Regulatory costs induce mortality because income reductions reduce expenditures on health and safety, thereby increasing risks to life. Put differently, every $109 million in 2019 dollars (or $111 million in 2020 dollars) HHS saves through its retrospective review efforts will yield one expected life saved. These lives saved (or extended) in turn produce additional cost savings not considered in the previous calculations and are thus a cobenefit of the SUNSET rule.

The fact that HHS regulations cost an estimated $228 billion annually suggests that approximately 2,050 additional expected deaths occur annually as a result of the cost of HHS regulations. Although this increase in mortality does not account for how the HHS's regulations may reduce mortality, it is unlikely that the costs and the benefits of HHS policy all fall on the same individuals, so these effects deserve attention in their own right.

The cost savings in the discussion of benefits earlier can be used to estimate the coincident health benefits—as well as their corresponding cost savings—that serve as additional cobenefits of the

SUNSET rule. These cobenefits help to reduce any overall negative health consequences imposed by the costs of HHS's regulations. For example, the $5.1 billion to $12.1 billion in projected cost savings based on HHS's past Section 610 reviews yields an indirect benefit of 46 to 109 initial expected lives saved (this range is "initial" because it is a present value). Assuming saved individuals contribute roughly the average amount of goods or services an American produces in their remaining lifespan, extending each life saved yields an additional return (in terms of cost savings) of $1.1 million on average,[19] which cumulatively yields another $50.6 million to $119.9 million in additional cost savings.

The cobenefits will be offset to a modest extent by the costs of the SUNSET rule and could also be offset if there are unquantified risk increases that stem from the rule. However, even at the high end of HHS's projected total cost estimates, which are around $200 million in present value terms, costs may not induce more than two initial deaths, meaning that the net risk reduction anticipated from the rule may not differ significantly from the gross risk reduction.

Although these cobenefits are relatively minor compared with the direct benefits anticipated from the SUNSET rule, the cobenefits alone may be large enough to exceed the estimated costs of the rule. Furthermore, because HHS intends to assess and (if necessary) review most important health and safety regulations, it is possible that regulations that reduce risks on balance will not be allowed to be rescinded to offset these estimated indirect cobenefits. The estimated indirect cobenefits of the SUNSET rule appear in table 3.

Table 3. Estimated Indirect Mortality Cobenefits of the SUNSET Rule, in Present Value Terms

BASIS OF ESTIMATE	EXPECTED BENEFITS (BILLIONS OF 2020$)	INITIAL EXPECTED LIVES SAVED	ADDITIONAL COST SAVINGS FROM LIFE EXTENSION (MILLIONS OF 2020$)
610 reviews	$5.1 to $12.1	46 to 109	$50.6 to $119.9
13,563 reviews	$16.7 to $27.5	150 to 248	$165.0 to $272.8

NET BENEFITS

Table 4 aggregates the direct benefits and cobenefits estimated in this analysis with the costs estimated in the SUNSET rule RIA. Total benefits are estimated to range from $5.2 billion to $27.8 billion. On an annualized basis, the benefits are expected to range from $740 million to $3.3 billion annually over a 10-year time horizon, depending on the discount rate used. Meanwhile, total costs range from $60 million to $199 million. The costs are expected to range from $7.9 million to $25.2 million on an annualized basis. Thus, benefits are expected to exceed costs by about two orders of magnitude. The present value of the net benefits expected from the SUNSET rule range from $5.0 billion to $27.7 billion (in 2020 dollars) depending on the discount rate used and the source of the benefit estimate.

Table 4. Present Value of Projected Benefits, Costs, and Net Social Benefits of the SUNSET Rule, at 3 and 7 Percent Discount Rates (Millions of 2020 Dollars)		
	7 PERCENT DISCOUNT RATE	3 PERCENT DISCOUNT RATE
BENEFITS		
Direct cost savings	$5,100 to $16,700	$12,100 to 27,500
Additional cost savings from reduced mortality	$51 to $165	$120 to $273
Total benefits	$5,151 to $16,865	$12,220 to $27,773
COSTS		
Total costs	$60 to $177	$68 to $199
NET SOCIAL BENEFITS		
Total net social benefits	$5,000 to $16,800	$12,000 to $27,700

Note: Figures may not sum exactly owing to rounding.
Source: Author's calculations; US Department of Health and Human Services, Securing Updated and Necessary Statutory Evaluations Timely (January 19, 2021) (to be codified at 21 C.F.R. pt 6; 42 C.F.R. pts 1, 404, and 1000; 45 C.F.R. pts 200, 300, 403, 1010, and 1390).

DISCUSSION AND UNCERTAINTY

The estimates of benefits presented earlier are surrounded by a great deal of uncertainty because it is impossible to know which regulations will be affected by the SUNSET rule. It is, therefore, worth revisiting some of the assumptions underlying the benefits estimates. First, this analysis assumes that past retrospective reviews such as those resulting from past Section 610 reviews or as a result of Executive Order 13563 are likely to be representative of future review efforts under the SUNSET rule. This could turn out not to be true. And while these past reviews also offer some reason to be optimistic that substantial savings are already being achieved even without a new forcing provision, the analysis here also suggests the net benefits of reviews could be increased substantially if the number of reviews were increased. This would likely occur with stronger enforcement mechanisms, such as a sunset provision.

Also, the prospective forecasts of the effects of rules emanating from these past review efforts could turn out not to be correct. For example, sometimes important cost or cost savings estimates are left out of HHS regulatory analyses. Hence, an implicit assumption in the calculations earlier is that the RIAs for those rules were produced competently and absent political interference, which may not be the case. However, uncertainty in prospective analyses is also one of the primary reasons for conducting more retrospective reviews, an aim of the SUNSET rule. Moreover, the net benefits stated earlier are so large that billions of net savings could be wiped out and the net benefits would still be positive. For example, 50 percent of the combined benefits from the regulations identified as cost saving in tables 1 and 2 could be wiped out and cumulatively the projected net benefits of the SUNSET rule would still be over $1 billion.

A plausible way that the SUNSET rule could produce negative net benefits is HHS using the enhanced review process to impose additional regulations with negative net benefits. Sometimes

regulators use retrospective review efforts as a justification to move forward with policies that were already a priority for other reasons.[20] To the extent that the rule facilitates such efforts, it could impose net costs. That said, to some extent this issue has already been considered, since some of the rules appearing in tables 1 and 2 were expected at the time of their promulgation to impose net costs. Moreover, to the extent HHS uses retrospective review efforts as a justification to move forward with policies that were already a priority, such regulations may have been likely to be promulgated even absent the SUNSET rule. HHS is likely to impose costly regulations with or without an enhanced retrospective review process, and it seems more likely that HHS will choose to reduce burdens on balance if it has stronger incentives to conduct retrospective review.

Another source of uncertainty relates to HHS's cost estimates, which, although modest relative to estimated benefits, may actually be overstated in the RIA for the SUNSET rule. The largest cost identified by HHS is the estimated cost of monitoring, which essentially involves the writing of comments and tracking of HHS regulatory activities by interested members of the public. However, HHS has not taken into account the cost of rent-seeking. To the extent that lobbying for anticompetitive regulations is displaced by having to monitor HHS's new regulatory reviews and write additional comments, this may well constitute a social benefit to society as a whole (even if it constitutes a private cost to the monitors). The analysis in this brief has not attempted to quantify the costs of this rent-seeking but notes that benefits may be underestimated here (or, similarly, costs may be overestimated in the RIA) if rent-seeking activity is reduced by the SUNSET rule.

A final source of uncertainty is the small size of the sample of rules used to project the future benefits of regulations emanating from retrospective review. This small sample size results from there not being a large number of rules updated in response to reviews and from few rules having any economic analysis associated with them, regardless of whether they are the result of retrospective review or any other reason. The sample size certainly leads to questions about the precision of the benefits estimates here. However, a goal of the SUNSET rule is to stimulate retrospective analysis (although perhaps not a complete cost-benefit analysis in most cases). Thus, conceivably a larger sample of regulations will be available for future studies of the benefits and costs of retrospective review owing to the SUNSET rule.

CONCLUSION

Overall, there is considerable uncertainty with respect to this analysis. In general, the numbers stated earlier should be taken with caution, since HHS is not going to be updating the same regulations in response to future reviews as it did in response to past reviews, and there is considerable uncertainty about whether these past efforts were as successful as their forward-looking analyses projected at the time of their implementation.

That said, the potential for billions of dollars in net benefits is realistic, especially given the reach and burden of HHS rules across the economy. Benefits could conceivably extend into the tens of billions of dollars, dwarfing costs that are in the tens to low hundreds of millions. Given the vast discrepancy between estimated benefits and estimated costs, it is not surprising that HHS has concluded that it is appropriate to move forward with the SUNSET rule. The rule may also lead to substantial health benefits for the public as an indirect consequence of the cost savings that future review efforts are likely to uncover.

Ultimately, the success of the SUNSET rule will depend on the civil servants tasked with executing it. However, a forcing mechanism such as a sunset provision seems likely to ensure that more good-faith efforts at retrospective review actually occur.

ABOUT THE AUTHOR

James Broughel is a senior research fellow at the Mercatus Center at George Mason University. Broughel has a PhD in economics from George Mason University. He is also an adjunct professor at the Antonin Scalia Law School at George Mason University.

NOTES

1. US Department of Health and Human Services, "HHS Finalizes Unprecedented Regulatory Reform through Retrospective Review," press release, January 8, 2021, https://www.hhs.gov/about/news/2021/01/08/hhs-finalizes-unprecedented-regulatory-reform.html.
2. Regulatory Flexibility Act, 5 U.S.C. § 610 (2020).
3. Keith B. Belton and John D. Graham, *Trump's Deregulatory Record: An Assessment at the Two-Year Mark* (Washington, DC: American Council for Capital Formation, 2019).
4. See, for example, annual accounting statements from the Office of Management and Budget, providing status report updates from Executive Order 13771 efforts.
5. See, for example, Council of Economic Advisers, *Economic Report of the President*, March 2019; Council of Economic Advisers, *Deregulating Health Insurance Markets: Value to Market Participants*, February 2019.
6. This result may be driven to some extent by the time horizon used in these analyses. Sound analytical practices require that a time horizon be selected that captures the most important costs and benefits of a rulemaking. If the analyses for these rules leave out important costs or costs savings because, for example, those impacts occur outside the time horizon considered by the analyst, this could influence the cost and cost savings presented in table 1. This analysis has not attempted to make any adjustments for poor time horizon selection, because adjustments of this sort could cast doubt on the vast majority of cost estimates produced by HHS, not just those presented here. Addressing the competency of HHS cost analyses in general is beyond the scope of this benefits analysis.
7. The number 26 is 130 divided by 5.
8. Net savings is calculated as follows: 212 rulemakings × 1,228 million in savings / 26 rulemakings = $10,012 million, and 212 rulemakings × 1,985 million in savings / 26 rulemakings = $16,185 million.
9. This calculation assumes that the sample in table 1, which is admittedly small, is representative of amended and rescinded rules emanating from future sunset reviews.

10. This analysis uses a 3 percent discount rate for sensitivity purposes because the use of this rate is a standard practice that the Office of Management and Budget enforces in RIAs. However, it is generally inappropriate to discount cash flows with the Office of Management and Budget–recommended 3 percent rate because that rate is a consumption rate of interest that reflects society's time preference. For the purposes of this analysis, the 3 percent rate can be thought of as reflecting a relatively low opportunity cost of capital.

11. Joseph E. Aldy, *Learning from Experience: An Assessment of the Retrospective Reviews of Agency Rules and the Evidence for Improving the Design and Implementation of Regulatory Policy* (unpublished manuscript, November 17, 2014), PDF file, 112–20.

12. It is often the case that benefits asserted in RIAs are overstated. Even if some of the estimated cost savings from the rules' RIAs are overestimated, the net benefits of the six rules listed in tables 1 and 2 are large enough that all of the net benefits of the rules in table 1 could be eliminated and the rules together would still produce net savings in the billions.

13. Bentley Coffey, Patrick A. McLaughlin, and Pietro Peretto, "The Cumulative Cost of Regulations," *Review of Economic Dynamics* 38 (2020): 1–21.

14. "Government-Wide Administrative Burden Baseline Counts," Government of Canada, last modified November 19, 2020, https://www.canada.ca/en/government/system/laws/developing-improving-federal-regulations/requirements-developing-managing-reviewing-regulations/administrative-burden-baseline/government-wide-administrative-burden-baseline-counts.html.

15. For just a few examples, see Justin D. Smith, "Regulatory Reform at the State Level: A Guide to Cutting Red Tape for Governors and Executive Branch Officials," *Business, Entrepreneurship & Tax Law Review* 3, no. 2 (2019): 276; Omar Al-Ubaydli and Patrick A. McLaughlin, RegData: A Numerical Database on Industry-Specific Regulations for All United States Industries and Federal Regulations, 1997–2012, *Regulation & Governance* 11, no. 1 (2017): 109–23.

16. In 2012, the CFR contained 1,033,847 regulatory restrictions, of which 50,801 were from HHS. Data are from Quantgov.org. Patrick A. McLaughlin, RegData 3.2 Annual (dataset), QuantGov, Mercatus Center at George Mason University, Arlington, VA, 2020, https://www.quantgov.org/regdata-us-documentation.

17. The assumption that HHS restrictions impose, on average, the same costs as other federal departments may underestimate HHS costs, given the reach of healthcare regulations in the nation's economy. HHS cost estimates here may also be underestimated, given that the $4 trillion annual cost estimate of federal regulations is exceeded by cost estimates in some other studies. See, for example, John W. Dawson and John J. Seater, "Federal Regulation and Aggregate Economic Growth," *Journal of Economic Growth* 18, no. 2 (2013): 137–77.

18. James Broughel and W. Kip Viscusi, "The Mortality Cost of Expenditures," *Contemporary Economic Policy* 39, no. 1 (2021): 156.

19. James Broughel and Michael Kotrous, "The Benefits of Coronavirus Suppression: A Cost-Benefit Analysis of the Response to the First Wave of COVID-19" (Mercatus Working Paper, Mercatus Center at George Mason University, Arlington, VA, June 2020), 52–55.

20. Randall Lutter, "Regulatory Policy: What Role for Retrospective Analysis and Review?," *Journal of Benefit-Cost Analysis* 4, no. 1 (2013): 17–38.