

PUBLIC HEARING ON THE SECURING UPDATED AND NECESSARY
STATUTORY EVALUATIONS TIMELY
NOTICE OF PROPOSED RULEMAKING

Monday, November 23, 2020

10:02 a.m.

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P R O C E E D I N G S

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Introduction

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MR. HECHT: As you may know, the purpose of today's public hearing is to discuss a notice of proposed rulemaking that HHS recently issued called Securing Updated and Necessary Statutory Evaluations Timely. On Friday, the Department circulated the agenda for today's meeting to those who registered. If you do not have a copy of the agenda, you can find it on the HSS website.

The easiest way to do that is probably to google for HHS comment on open rules. That's HHS comment on open rules. If you click on the first link, there'll be a link to the agenda for this meeting. It's called Securing Updated and Necessary Statutory Evaluations Timely Notice of Proposed Rulemaking Agenda on November 23, 2020.

In a minute I will turn it over to Brian Harrison, the Chief of Staff here at HHS, who will provide an overview of the proposal. We will then

1 hear from those who requested to present. I will call
2 on each participant when it is their time to speak.
3 And the agenda specifies how much time is allotted to
4 each speaker. Time allocations were based on how much
5 time each speaker requested to speak. For the
6 convenience of others, we ask that you do not speak
7 beyond your allocated time. I will let each speaker
8 know when they have 1 minute left, as well as when
9 their time is up. And of course, if you like to speak
10 for less than your allotted time, that is also your
11 prerogative.

12 And lastly, the Department has also set aside
13 time at the end of this public hearing for comments by
14 those who did not request -- that time will be
15 allocated solely to those who have not already spoken.
16 Thank you again for your participation in this public
17 hearing today. I would request again that you please
18 mute your phone when you are not speaking.

19 And with that, I will turn it over to Brian
20 Harrison, Chief of Staff here at HHS.

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22 Overview of the Notice of Proposed Rulemaking

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MR. HARRISON: Great. Thank you. Thank you very much, Jonah. And just want to start off by saying how much I greatly appreciate everybody taking time to join us today for this hearing. We are very glad to have robust public participation in this rulemaking process.

All right. As you may know, the purpose of this public hearing is to discuss the notice of proposed rulemaking that HHS recently issued called Securing Updated and Necessary Statutory Evaluations Timely. The Department proposed this rulemaking to enhance its implementation of Section 3(a) of the Regulatory Flexibility Act and various executive orders, as well as to improve accountability in the performance of HHS regulations.

The RFA requires federal agencies to publish in the Federal Register a plan for the periodic review of the rules issued by the agency, which have, or will have a significant economic impact on a substantial number of small entities in order to determine whether such rules should be continued without change or

1 should be amended or rescinded, consistent with the
2 stated objectives of applicable statutes to minimize
3 any significant impact of the rules upon a substantial
4 number of small entities.

5 In conducting this retrospective review,
6 agencies must consider a variety of factors, including
7 the continued need for the rule, legal issues, public
8 input, overlap and duplication with other federal or
9 state and local governmental rules and technological,
10 economic or other changes.

11 The department has tried to carry out the
12 evidence-based approach or the evidence based
13 approach, I should say, to regulation prescribed by
14 Congress and the executive orders, but HHS' efforts
15 have met varying levels of success. Therefore, in
16 order to ensure evidence-based regulation that does
17 not become outdated as conditions change, HHS issued
18 this notice of proposed rulemaking.

19 It proposes that, subject to certain
20 exceptions, HHS regulations would expire after 10
21 years, unless the department performs an assessment to
22 determine if the rules have a significant economic

1 impact upon a substantial number of small entities.
2 If they do, HHS would have to perform the review
3 called for in the RFA. For regulations already in
4 effect for more than 10 years after this proposed rule
5 is finalized, HHS would have to perform the assessment
6 and, if required, the review within 2 years.

7 The RFA and executive orders have only
8 resulted in limited retrospective review by the
9 Department. The Department believes this proposed
10 rule would effectuate the desire for periodic
11 retrospective review as expressed in the RFA and
12 executive orders, as well as ensure the department's
13 regulations are having appropriate impacts and have
14 not become outdated. Also, the principal of
15 retrospective review does enjoy longstanding
16 bipartisan support.

17 Retrospective review of regulations can yield
18 tremendous benefits. Former OIRA administrator, Cass
19 Sunstein, has explained that when agencies issue
20 rules, they have to speculate about benefits and
21 costs. Therefore, after rules are in place, agencies
22 should test those speculations and they should use

1 what they learn when revisiting a regulation or
2 issuing a new one.

3 Professor Sunstein described this as one of
4 the most important steps imaginable for regulatory
5 reform, not least because it can reduce cumulative
6 burdens and promote the goal of simplification. He
7 has noted that agency's failure, until very recently,
8 to gather, let alone act on retrospective reviews is
9 an astonishing fact.

10 Michael Greenstone, who served as chief
11 economist on the Council of Economic Advisors between
12 2009 and 2010 similarly concluded that the single
13 greatest problem with the current system is that most
14 regulations are subject to a cost benefit analysis
15 only in advance of their implementation. This is the
16 point when the least is known and any analysis must
17 rest on many unverifiable and potentially
18 controversial assumptions.

19 According to Professor Greenstone, the lack
20 of a regulatory look-back created a system largely
21 based on faith rather than evidence, where the agency
22 all too frequently takes shots in the dark. And we

1 all too infrequently fail to find out if we had hit
2 anything. Or even worse, we only find out when things
3 have gone horribly wrong.

4 If retrospective analysis could be firmly
5 institutionalized, Professor Sunstein observed, then
6 it would count as the most important structural change
7 in regulatory policy since the original requirement of
8 prospective analysis during the Reagan administration.

9 Other administrative law experts have also
10 urged agencies to more robustly institutionalize
11 retrospective review of regulations. Because the
12 department has, in many instances, not performed
13 retrospective reviews, the department believes it
14 needs a stronger incentive to achieve the benefits of
15 retrospective review. This proposed rule proposes a
16 mechanism to more firmly institutionalize the
17 retrospective reviews that experts have been calling
18 for.

19 As explained in the NPRM, the Department has
20 calculated it can perform the required reviews at a
21 manageable cost. Certain regulations would be exempt
22 from this proposed rule. For example, the annual

1 Medicare payment rules would be exempt since they are
2 reviewed annually. Other exemptions include
3 regulations issued jointly by HHS with other federal
4 agencies and regulations that involve a military or
5 foreign affairs function of the United States.

6 The NPRM contains a list of subjects on which
7 HHS is particularly interested in comments. But HHS
8 welcomes comments on all aspects of the NPRM, both
9 during this public hearing and through written
10 submissions on regulations.gov. The public comment
11 period for most of this rule remains open until
12 December 4th. The public comment period for the
13 portion of this rule amending 42 CFR Parts 400 through
14 429 and Parts 475 through 499 remains open until
15 January 4, 2021.

16 So, with that, just want to say thank you
17 once again for taking the time out of your day to join
18 us. And very much greatly appreciate your interest in
19 this NPRM. And with that, Jonah, I have to give it
20 back to you.

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Public Comments

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MR. HECHT: Okay. Thank you very much, Brian. And now we will hear from the public. So, first up is Wayne Taylor (sic), senior attorney at the National Health Law Program. And just to remind you, once again, I will let everybody know when they have 1 minute left, as well as when their time is up. But first up on the agenda is Wayne -- sorry, Wayne Turner. You have 10 minutes. Thank you.

MR. TURNER: Correct. Thank you very much. Good morning. My name is Wayne Turner. I'm a senior attorney with the National Health Law Program. The National Health Law Program has worked to improve healthcare access and quality through education, advocacy, and litigation on behalf of low-income and underserved individuals for over 50 years.

My remarks today supplement the written comments that I will be submitting on behalf of my organization. And I request that both the oral comments here and the written comments be included as part of the administrative record.

Today, November 23, 2020, is a dark day.

1 There have been -- there are more than 12.4 million
2 people in this country infected with COVID-19, and
3 over 250,000 deaths, yet the federal agency chiefly
4 responsible for public health and healthcare safety
5 net programs in the United States is undergoing this
6 ill-conceived rulemaking to retroactively impose an
7 expiration date on duly promulgated regulations.

8 If implemented, this proposal would tie up
9 limited agency resources and pose an undue burden on
10 department personnel that would then detract from
11 important work. Moreover, we create legal uncertainty
12 in vital components of the Health and Human Services
13 regulatory framework, and it would wreak havoc in HHS
14 programs and policies.

15 Programs like Medicaid and the Children's
16 Health Insurance Program are quite complex. And
17 they're implemented through a strong regulatory
18 framework. States, providers, managed care entities,
19 individuals and families who receive their health care
20 through these programs rely on duly promulgated
21 regulation. So, the prospect of the rule kind of
22 slipping through this assessment and review process

1 and suddenly one day being labeled expired creates
2 serious, serious implications for the Medicaid
3 program. One of the areas where I chiefly work is on
4 eligibility and regulations surrounding the
5 determination of financial eligibility, using a
6 modified adjusted gross income methodologies.

7 So, the MAGI rules were implemented pursuant
8 to the Affordable Care Act. They apply to insurance
9 affordability programs, including Medicaid, the
10 Children's Health Insurance Program, basic health
11 plans, and then of course eligibility for subsidies
12 through the ACA marketplaces. So, these are fairly
13 complex rules. And it's taken quite a bit of effort
14 on behalf of advocates, but also HHS to fully -- to
15 work with states so that states can program the
16 eligibility systems, working with marketplaces so that
17 the marketplaces and the Medicaid programs are
18 interacting and operating off of a common set of rules
19 and understandings.

20 In addition, advocates, you know, rely on the
21 MAGI regulations to properly determine the appropriate
22 insurance affordability programs for an individual be

1 it Medicaid or some other program.

2 And so, the prospect that if this or any of
3 the other regulations may slip through the cracks of
4 this assessment and review process and simply expire
5 would create havoc for -- in the Medicaid program.
6 So, the states would have no federal regulations to
7 rely on in determining how to determine financial
8 eligibility. Even today, you know, 6 years after the
9 MAGI methodologies became mandatory for states, there
10 are still issues and problems with states fully
11 implementing these methodologies.

12 And so, without federal regulations to point
13 to, the eligibility, the ability for individuals to
14 enroll in programs like Medicaid would be put at risk.
15 The rule creates these kind of like a regulatory
16 purgatory. So, if a rule slips through the cracks
17 again and is automatically rescinded, you know, that's
18 the end of it.

19 But if a rule is labeled as to be required
20 further assistance, further review and to be, you
21 know, updated, that creates this legal uncertainty
22 that HHS itself acknowledged in this proposed

1 rulemaking. And so, for a regulation that's been
2 labeled as needing revision, as being outdated, what
3 degree of deference is the court to provide for that
4 regulation. Any attempts to enforce such a regulation
5 would be arbitrary and capricious.

6 And so, again, it creates this legal
7 uncertainty that for people who rely on Medicaid,
8 people who rely on the Children's Health Insurance
9 Program, to make sure that their families, that their
10 children have access to healthcare for which they --
11 in the programs for which they are eligible, that is
12 all put at risk.

13 I want to also point too that if advocates
14 wanted, if HHS wanted to include a SUNSET provision on
15 the rules that it promulgates, it perfectly, it could
16 have proposed one on each and every one of these
17 regulation, some 18,000 rules, regulations that would
18 be subject to this proposal.

19 If stakeholders and interested parties
20 thought that the SUNSET provision was -- would be a
21 wise thing to include in the regulation, then
22 stakeholders have had every opportunity to argue for

1 such a provision during the comment period. I also
2 want to kind of focus on a point raised, the need for
3 this, that supposed need for this rule, that because
4 regulations may become outdated, that there needs to
5 be a process for reviewing and updating those.

6 Well, there is a process, and it's called the
7 Administrative Procedure Act, and that was established
8 by Congress, and establishes very specific
9 requirements for updating, revising or rescinding duly
10 promulgated regulations. And that requires a notice
11 and comment period. And this is the process that HHS
12 should be following for each of these some 18,000
13 regulations that will be subject to this kind of
14 blanket expiration provision.

15 The other piece of the Administrative
16 Procedure Act is that it also establishes a process
17 whereby interested parties and stakeholders can
18 petition federal agency. And so, that petition
19 process is an important component whereby stakeholders
20 can identify regulations that the agency should
21 revisit, should update, should consider revising.

22 So, Congress has already spoken to this issue

1 and has established in federal law processes where --
2 to update federal rules and regulation. None of that
3 is envisioned by this kind a blanket expiration date
4 being posed.

5 I also want to object to this real sloppy
6 rulemaking process. The truncated comment period of
7 30 days for such a far-reaching and potentially
8 dangerous rule is simply not adequate. I also want to
9 note that for this hearing, you know, I never received
10 a confirmation e-mail or follow up from the agency.
11 But I'm fortunate that I'm able to talk, address this
12 proposed rulemaking right now.

13 And I just want to sum up by saying that in
14 the past 3-1/2 years we've seen from this
15 administration relentless attacks on the Affordable
16 Care Act and the Medicaid program. There've been
17 countless acts of sabotage. And the result of that is
18 1 million people lost their health insurance in 2019,
19 including 300,000 children. So, that's the record of
20 accomplishment from this administration and this
21 agency.

22 And of course these numbers and these

1 coverage losses were before the pandemic. So, we
2 viewed this proposed rulemaking as nothing more than
3 further attempts to sabotage HHS programs and policies
4 upon which so many lives depend.

5 So, we urge HHS to withdraw this proposed
6 rule and end these (inaudible) policies that are
7 really designed to destroy the public's safety net
8 programs. And with that, I conclude my remarks.

9 MR. HECHT: Thank you very much, Mr. Turner.
10 We would just again request that if you're not
11 speaking to put your phone on mute. If there's noise
12 in the background, that's not fair to the person who
13 is speaking.

14 So, next up is Laura MacCleery, a policy
15 director at the Center for Science in the Public
16 Interest. Ms. MacCleery, you have 10 minutes.

17 MS. MACCLEERY: Thank you so much. You can
18 hear me, I hope. Can you confirm?

19 MR. HECHT: Oh, yes, we can hear you, yes.

20 SPEAKER: Yes. Yes, we can.

21 MS. MACCLEERY: I just want to make sure.
22 So, thank you very much. I really appreciate the

1 opportunity to comment on the HHS proposed rule,
2 Securing Updated and Necessary Statutory Evaluations
3 in a Timely Manner. I first want to note that I think
4 there is some history of failed attempts at cross-
5 cutting hyper-regulatory processes. There have been
6 numerous bills introduced in the Congress to
7 essentially reconfigure the regulatory process.

8 And I understand the temptation to create a
9 kind of false architecture of purported rigor in this
10 area. I see that it has intellectual attraction. But
11 I think it is essentially counter-democratic and it's
12 impulsive. The edifice that is constructed by
13 regulations over time and in the long ongoing process
14 of dialogue and checks and balances between the
15 legislative and executive branch create a kind of
16 stability and set of expectations for regulated
17 entities that are actually quite reassuring and give
18 rise to better living conditions generally in
19 societies.

20 And the notion that it would be appropriate
21 or desirable for HHS on the full to conduct some kind
22 of a wholesale default sunseting of rules that are

1 really part of a foundation built over nearly a
2 century, it is, I think, just simply wrongheaded. It
3 doesn't actually result in the kind of regulatory
4 benefits to regulated entities that one might imagine
5 because many of the costs of compliance with
6 regulation has actually been factored into the cost of
7 doing business, and are essentially evanescent over
8 time, meaning that they recede into the backdrop and
9 they become part of the way that business is done and
10 the way that consumers are benefited.

11 So, I want to say that, that sort of impulse
12 actually has a lot of cost. For a concrete example,
13 the menu labeling delays that occurred the day before
14 the rule was intended to go into compliance effects
15 within the early months of the Trump administration,
16 we asked regulatory economists to do an economic model
17 of whether those -- whether that delay in expectation
18 -- compliance expectations would actually result in
19 cost savings to the restaurant industry. And his
20 model, which we submitted as part of our docketed
21 comments, found that it would actually incur costs of
22 extra millions of dollars for the regulated entities.

1 Deregulation is often intended to assist industry.
2 And in actuality, it is the steady expectation over
3 time that are most beneficial.

4 Specifically turning to this proposal, I'll
5 note without belaboring some of the points that were
6 just made, Congress can obviously SUNSET rules and
7 know how to create SUNSET provisions in authorizing
8 statutes whenever it desires to. Oftentimes it does
9 the opposite, it asks the agency to take on a new
10 responsibility ad infinitum and failed to provide a
11 concrete SUNSET provision because the expectations of
12 the legislature is that once a rule is in place it
13 will go on to then become part of, again, the
14 regulatory edifice that Food and Drug Administration
15 or HHS will continue to build on, and for businesses
16 as well.

17 Some examples of that would be, you know, the
18 recently enacted Food Safety Modernization Act.
19 Congress required the Food and Drug Administration to
20 write rule of keeping pathogens out of produce,
21 requiring inspection of foreign food. And we would
22 firmly contend that disposing of those rules after an

1 arbitrary period of time is in direct opposition to
2 Congressional intent and is thus extra-statutory and
3 illegal.

4 The blanket nature of the proposal also means
5 that there are embedded violations of the
6 Administrative Procedures Act. Under the State Farm
7 jurisprudence and its progeny, agencies must attend
8 the rescission or withdrawal or amendment of a rule
9 with the same amount of attention that they had given
10 to procedure to create that rule. And with that in
11 mind, it is illegal, therefore, to SUNSET a rule
12 automatically without adequate attention to notice and
13 comment on the docket that's relevant to that
14 particular rule.

15 In addition, HHS has pre-existing processes
16 to SUNSET rules that are not in use. Any member or
17 entity of the public can file citizen petitions to ask
18 agencies to withdraw, or rescind, or amend rules. And
19 the agency also, HHS in particular also conducted a
20 rule-making review exercise in the early days of the
21 Trump administration where it created a docket of
22 rules that should be rescinded, amended, or withdrawn,

1 and a number of groups participated in that.

2 And the agencies of course can do that as
3 part of their ongoing regulatory review process.
4 Agencies can also sua sponte propose that rules be
5 withdrawn, rescinded or amended as they become
6 obsolete or require that. So, there's no need for a
7 cost-cutting and wholesale provision. The rule-making
8 notice itself acknowledges that SUNSET provisions were
9 previously considered but were rejected on the
10 grounds, and this is quoting the proposal, "Agencies
11 cannot entirely eliminate regulations unless the law
12 which authorizes the regulations allows it." So, that
13 was under the Carter administration that conclusion
14 was made.

15 There is not an adequate explanation in the
16 proposal text to justify why that particular
17 interpretation of the law is no longer enforced or
18 should be discarded at this time. Also note that I
19 think that the timing of this proposal is problematic.
20 We expect and had every reason to believe that a
21 transition will take place.

22 The stated intention of completing this rule

1 in a way that would be finalized prior to a change of
2 administration, I think is totally inappropriate. It
3 could affect a significant number of the regulations
4 on the book. And it should be a moment really for the
5 HHS teams to be thinking primarily about the needs of
6 the nation under the pandemic, and also about the
7 needs for a smooth transition given the cost to life
8 and the economy that our current circumstances are
9 inflicting.

10 So, I'm not sure why HHS leadership would
11 pick this moment to suggest what it admits is such a
12 sweeping proposal to remake the regulatory landscape.
13 But I would suggest that rushing this to judgment
14 would be entirely inappropriate and an act of the most
15 ranked political nature. That concludes my remarks.

16 MR. HECHT: Okay. Thank you very much. Next
17 is Thomas Gremillion, Director of Food Policy at the
18 Consumer Federation of America. Mr. Gremillion, you
19 have 10 minutes.

20 MR. GREMILLION: Thank you. Again, I'm
21 Thomas Gremillion, I'm the Director of Food Policy and
22 Consumer Federation of America. I just want to say I

1 think the previous two speakers have really
2 articulated many of the concerns that we have and
3 feelings we have about this rule and -- this proposed
4 rule and the propriety of putting it out at this stage
5 and, you know, late stage of the Trump administration
6 before the president-elect Biden takes office. I will
7 go through some of my concerns that arose as I read
8 through the rule however. And I appreciate the
9 opportunity for doing do.

10 First a little about the Consumer Federation
11 of America. We are an association of nonprofit
12 consumer organizations that was established in 1968 to
13 advance consumer interests through research, advocacy
14 and education. And over the years we've advocated for
15 many regulations that has been promulgated by HHS. I
16 work in the food space as the Director of Food Policy,
17 and couple of examples from the food space of
18 regulations that we feel like consumers have come to
19 rely on through the Nutritional Facts Panel and the
20 protections afforded by the rules implementing the
21 Food Safety Modernization Act.

22 This is an anti-regulation proposal. And so,

1 I'd like to point out that consumer protections are
2 popular. Survey after survey shows that Americans
3 favor more, not less, government action to address
4 problems ranging from Internet privacy, the labor
5 rights, food safety, you name it.

6 According to a recent poll conducted by Data
7 for Progress, majority of voters, including 62 percent
8 of Republicans, think that regulations serve an
9 important role in protecting the environment and for
10 keeping workers safe and ensuring a fair economy.

11 So, as the proposed rule points out,
12 retrospective review is a popular idea among
13 academics. And it has -- I will grant that it has
14 intuitive appeal a way to kind of ground truth
15 perspective analyses of regulation, impacts and
16 optimize the regulatory process. But, you know, any
17 paraphrase of this rule can only see it as akin to
18 using a missile to kill a mouse.

19 And the proposed rule talks about how several
20 states have adopted sunseting policies. But those
21 policies were passed by legislators who were directly
22 accountable to their constituent voters. And aside

1 from that, as the rule points out, you know, reputable
2 impartial scholars, not ones that are associated with
3 think tanks that are funded by oligarchs, those
4 scholars have documented how several states then
5 repeal their SUNSET laws after concluding that "
6 SUNSET provisions quickly prove to be an expensive,
7 cumbersome and disappointing method for enhancing
8 legislative control."

9 The rule cites several foreign examples of
10 what it claims are similar rules. And I'd just like
11 to point out that foreign regulatory systems are much
12 different from that of the United States, and it's
13 very difficult to evaluate the claims made in the
14 proposed rule on the basis of few reports by the
15 office for Economic Co-operation and Development. And
16 among many other reasons, HHS should extend the
17 comment periods to members and public and familiarize
18 themselves with these foreign regulatory systems that
19 the proposed rule purports to be emulating.

20 According to HHS, this proposed rule seeks --
21 this proposed rule "seeks to advance democratic values
22 and apply the lessons learned from states, foreign

1 jurisdictions and the academic community." And, you
2 know, the law has pointed out much more eloquently
3 than I can, waiting until now in the final days of the
4 Trump administration to reveal this rule to the public
5 and rushing to finalize the rule before president-
6 elect Biden takes office in January is antithetical to
7 democratic values. And rushing to finalize this rule
8 would also run roughshod over the democratic values
9 that are embedded in the Administrative Procedure Act.

10 And speaking of the Administrative Procedure
11 Act, I am concerned and, frankly, confused by the
12 proposed rule's abandonment of the APA's definitions
13 of the term "rule". The proposed rule, it talks about
14 evaluating the code of federal regulations section by
15 section. Regulation will be defined as just a section
16 of the code of federal regulations. But then it also
17 maintains that "the department should in many cases
18 perform a single assessment and where required a
19 single review that considers all regulations issued as
20 part of the same rulemaking."

21 So, this seems clearly a situation that's
22 right for, you know, savvy, savory lawyers, you know,

1 associated with money interest to kind of pick off
2 regulatory provisions that they don't like and water
3 down consumer and public health protections through a
4 piecemeal process. That's very concerning.

5 HHS claims that the proposed rule does not
6 conflict with the APA. I disagree. The HHS logic --
7 the HHS logic is false that says, "It complies with
8 the APA to amend regulations to add dates by which
9 regulations expire unless the assessment and/or review
10 is timely performed."

11 And that's because, "An agency can through
12 notice-and-comment rulemaking amend its regulations to
13 provide that they expire at a future date." But the
14 proposed rule goes on to more or less concede that
15 reviewing and reentry in the Code of Federal
16 Regulations will be impossible. And so, many of these
17 "regulations" which are really just the provisions of
18 the CFR, many of these regulations would expire.

19 And in order to make sure we don't lose any
20 really important rules, the backstop proposed by the
21 rule is that members of the public use a website to
22 make comments asking for the department to review a

1 particular regulation.

2 This seems very problematic and very, you
3 know, favorable to interests who, you know, can
4 dedicate resources to pouring over the Code of Federal
5 Regulations and making sure that the regulations they
6 like are kept in the queue and very detrimental to
7 dispersed groups of consumers and other dispersed
8 interests who might not be able to fund a watchdog
9 group to propose which regulations need to be reviewed
10 by the agency.

11 Proposed rule indicates that this undertaking
12 is going to result in myriad final agency action under
13 the APA. And I can only imagine that all those agency
14 actions would produce many lawsuits challenging
15 whether those agency actions are arbitrary and
16 capricious under the APA. And so, even if HSS could
17 manage to sort through all of its regulations and make
18 informed accurate decisions about which regulatory
19 requirements are justified and which aren't, it would
20 then have to fend off a lot of legal claims second-
21 guessing those decisions.

22 I question whether HHS has estimated the

1 burden of defending those lawsuits, whether it's
2 included, you know, the legal burden of the aftermath
3 of this rule and its cost benefit analysis and whether
4 it's consulted with the Department of Justice about
5 whether their lawyers would respond --

6 MR. HECHT: You have 1 minute left.

7 MR. GREMILLION: Yeah. To the increased
8 workload. I conclude by just saying, you know,
9 pointing out there is a document called a the
10 Regulatory Streamline Analysis published by Deloitte
11 Consulting in March of 2019, and posted on
12 regulations.gov. Two or three bullet points in the
13 executive summary page of that document are redacted,
14 they will be redacted. And all the 25 of the 170
15 pages in that document are blacked out. I'd like to
16 ask why. And why didn't HHS have a public meeting to
17 discuss the Deloitte findings and solicit feedback on
18 its regulatory reform ideas back in 2019.

19 With that, I will conclude and yield my time.
20 Thank you very much.

21 MR. HECHT: Okay. Thank you very much, sir.
22 Next we have Zach Corrigan, a senior staff attorney at

1 the Food & Water Watch and Food & Water Action. Mr.
2 Corrigan, you have 10 minutes.

3 MR. CORRIGAN: Great. Thank you. And can
4 you hear me?

5 MR. HECHT: Yes. Thank you.

6 MR. CORRIGAN: Great. Thank you. My name is
7 Zach Corrigan. I'm a senior staff attorney with Food
8 & Water Watch and Food & Water Watch -- Food & Water
9 Action. And our organization is a national public
10 interest advocacy organization that fights for a
11 healthy future world where everyone can eat the food
12 they trust, drink clean drinking water and have a
13 livable climate.

14 First, as a preliminary matter, it is just
15 simply bad administrative agency practice to rush this
16 midnight rule as we are now currently in transition
17 between the presidential administrations. Second, as
18 an example of this, it will be simply impossible for
19 the agency to adequately consider and address all the
20 comments in the final rule before January 20th, as the
21 agency is now attempting to do with this rulemaking.

22 In fact, we did not even have an adequate

1 opportunity to evaluate this rule and to make comments
2 and offer full comprehensive comments before this
3 hearing. I would thus request this comment be, period
4 be extended and further hearings be held before the
5 agency finalizes this rule.

6 Third, as written, the rules are arbitrary
7 and capricious. There is no reason that some
8 longstanding and successful rules would be required to
9 be evaluated every 10 years. To adequately address
10 such rules, the agency would have to evaluate their
11 fact for sunseting these rule. At the very least,
12 the rulemaking would have to carve out exceptions so
13 that these rules would not be subject to review, not
14 solely because some rules are regularly evaluated, but
15 because the cost of performing a 10-year -- of rule
16 every 10 year would far surpass any benefits for these
17 long-standing and well-known benefits of successful
18 rules.

19 The agency's proposal does not do that, but
20 instead offers theoretical platitudes by academics
21 such as CAS MC (phonetic) and other that simply will
22 not withstand judicial scrutiny. Fourth, this is

1 simply a deregulatory proposal and they're giving
2 agencies the excuse to revisit rules that do not need
3 revision. Agencies should not be forced to review
4 their rules every 10 years when they have other
5 millions of void, outdated or nonfunctioning rules.
6 They can simply follow the APA and (inaudible) rules.
7 But, of course, to do this the agency would have to
8 support its findings that rules were no longer needed.

9 And this proposed rule is an attempt by HHS
10 to get around this by issuing blanker SUNSET rules.
11 The agencies can also use their enforcement discretion
12 for rules that are no longer warranted. But to do
13 this, they would have to do so on a case-by-case basis
14 for each rule. They cannot do it for a group or set
15 of rules with much. So, the agency is now attempting
16 to get around this with its rulemaking.

17 Fifth, and most importantly, we are very
18 concerned that this will force public health agencies
19 to send critical resources that they would otherwise
20 spend on putting forth new rules or enforcing their
21 existing rules and spend these resources on evaluating
22 well-functioning rules. We are very -- we are

1 particularly concerned about the effects on public
2 health from food and waterborne illnesses. Food-borne
3 illness sickens approximately one in six people in the
4 United States each year. That's 48 million people.
5 It leads to 128,000 hospitalizations and 3,000 deaths.

6 CDC data shows an increase in the number of
7 reported multi-state food-borne illness outbreaks from
8 28 in 2014 to more than double that, 58, in 2018.

9 The agency, FDA, is critical for food safety efforts,
10 inspecting food facilities to both ensure food safety
11 and compliance with regulations. Recently the Food
12 Safety Modernization Act enabled FDA to focus more on
13 preventing food safety problems by amending the Food,
14 Drug and Cosmetic Act to increase the frequency of
15 inspections of domestic food.

16 This is a monumental law. But yet, a 2017
17 OIG report found that FDA did not inspect a greater
18 number of facilities than it had in the years prior to
19 the implementation of the Food Safety Modernization
20 Act.

21 FDA -- and further, FDA own -- still remains
22 a fraction of the imported foods and drugs that are

1 needed to protect public health. This is a great
2 example, FDA should be advocating for more resources
3 to inspect more facilities, more often, more imports,
4 and to protect food safety better. It should not be
5 wasting its time reviewing old rules.

6 Sixth, and finally, to the extent the rules
7 need to be evaluated every 10 years, the agency should
8 be evaluating the impact, not only on small
9 businesses, but also on public health and environment.
10 I think the fact that this is aimed at only the
11 required evaluation on businesses shows where the
12 agency's true intentions lie.

13 In sum, this is an arbitrary and capricious
14 proposed rule. At the very least, we request further
15 public hearings and extended comment period. It's
16 probably best that this rule just die on the vine.
17 Thank you.

18 MR. HECHT: Thank you very much, Mr.
19 Corrigan.

20 Next up is Donna Garren, Executive Vice
21 President, Science & Policy at the American Frozen
22 Food Institute. Ms. Garren, you have 5 minutes.

1 MS. GARREN: Thank you. Hello. My name is
2 Donna Garren, Executive Vice President of Science &
3 Policy for the American Frozen Food Institute or AFFI.
4 Today I am also representing the Food & Beverage Issue
5 Alliance or FBIA. Thank you for the opportunity to
6 share insights about HHS' SUNSET proposed role today.

7 AFFI represents America's frozen food and
8 beverage makers. We're the voice to frozen food
9 industry as FBIA represent over 62 allied food and
10 trade -- beverage trade associations. AFFI and FBIA
11 supports modernizing all regulations covering the sale
12 and production of foods, and making sure that they are
13 science-based and practical to implement.

14 Today I will share our concerns about
15 process, content and unintended consequences of this
16 proposed rule. Process. While we might agree that
17 every regulation under HHS should be reviewed and
18 justified or allowed to expire if no longer necessary
19 or relevant, the approach proposed is a sledgehammer
20 when a scalpel or even the scissors would be a better
21 tool.

22 To that end, there are already measures in

1 place for systematic review of the existing
2 regulations, namely the Regulatory Flexibility Act or
3 RFA, requires agencies to periodically analyze if
4 there were rules that are -- have a significant
5 economic impact and determine whether these rules
6 should be amended or rescinded.

7 In addition, several executive orders have
8 also directed agencies to submit plans for a periodic
9 review of regulations. While the RFA and executive
10 orders technically require agencies to conduct these
11 periodic reviews, there are no immediate consequences
12 for failing to do so.

13 In addition, it is unprecedented for a
14 government proposal of this magnitude to be published
15 with only 30 days for public commentary, especially
16 given we are in the middle of a pandemic and
17 approaching Thanksgiving holiday break. The short
18 timeframe calls into question the fundamental fairness
19 principles underlying the Administrative Procedures
20 Act, assuring a reasonable opportunity to review and
21 comment on new government actions.

22 At a minimum, there should be additional time

1 in which to comment, commensurate with the breath,
2 scope and impact of this proposed rule. Such an
3 extension should be at least an additional 150 days or
4 a total of 180 days.

5 Second, content. The proposed rule would
6 require FDA to analyze and justify as warranted its
7 entire scope of assessment regulations that have been
8 propagated over the past 80-plus years. In addition
9 to the other product categories the agency regulates
10 for the food industry, this would include virtually
11 all regulations pertaining to food safety, nutrition,
12 food labeling, food ingredient, review and approval,
13 and food standard of identify and quality.

14 Second, content -- unintended consequences.
15 If the proposed rule is finalized, the retrospective
16 reviews required of the agency would become FDA's top
17 regulatory priority. And the agency's attention to
18 this would prevent it from considering actions more
19 pressing and important to the industry it regulates
20 and to American consumers. The agency's focus on
21 conducting reviews to ensure the continued
22 effectiveness of existing regulations could prevent it

1 from conducting meaningful reviews to eliminate change
2 or modernize existing regulations or even other public
3 policies or guidance. This rule also could thwart the
4 issuance of new regulations, such as the approval of a
5 new color additive, for example.

6 Finally, AFFI and FBIA would like HHS to give
7 serious consideration to extending the public comment
8 period for, again, additional 150 days.

9 Again, thank you for allowing me to provide
10 comments during this public meeting. AFFI and FBIA
11 stand ready to provide additional input on the
12 proposal, and on specific regulations to assist with a
13 comprehensive regulatory review that takes place under
14 the right conditions. Thank you.

15 MR. HECHT: Okay. Thank you very much, Ms.
16 Garren.

17 Next we have Emily Eckert, Manager, Health
18 Policy at the American College of Obstetricians and
19 Gynecologists. Ms. Eckert, you have 10 minutes.

20 MS. ECKERT: Good morning. Can you hear me
21 okay?

22 MR. HECHT: Yes. We can hear you great.

1 Thank you.

2 MS. ECKERT: Excellent. Thank you. My name
3 is Emily Eckert; I'm a Policy Manager with the
4 American College of Obstetricians and Gynecologists,
5 or ACOG. ACOG is the premier professional membership
6 organization for obstetricians and gynecologists,
7 representing more than 60,000 physicians and partners
8 dedicated to improving women's health.

9 The comments that I will make this morning
10 are a supplement to written comments that I plan to
11 submit on behalf of ACOG prior to the December 4th
12 comment deadline. And I request that both my
13 comments, today as well as my written comments, be
14 included in the administrative record.

15 ACOG views the SUNSET NPRM as an unnecessary
16 and administratively burdensome proposals that, if
17 finalized as proposed, would undermine critical public
18 insurance programs, including Medicare, Medicaid, and
19 the Affordable Care Act individual market. The
20 proposed rule provides that HRF regulations will
21 automatically expire at the latter of 2 two years
22 after the SUNSET proposal takes effect, 10 years after

1 the regulation was originally promulgated or 10 years
2 after HHF assesses and if necessary review the
3 regulation.

4 In other words, if finalized as proposed, the
5 SUNSET NPRM would require SUNSET NPRM would require
6 that over the next 2 years, the department reconsider
7 literally thousands of health insurance regulations.
8 We view this as completely unnecessary as HHS has
9 existing processes in place to review regulations and
10 would also be administratively burdensome and could
11 detract from other necessary rulemaking and governing
12 including initiatives related to the ongoing COVID-19
13 pandemic as well as our nation's maternal health
14 crisis. ACOG opposes regulatory actions that
15 undermine vital healthcare and other social safety net
16 programs and as such we recommend that this NPRM be
17 withdrawn immediately. Thank you.

18 MR. HECHT: Thank you very much. Next up is
19 Sasha Buchert, apologize if I'm not pronouncing that
20 correctly, the senior attorney at Lambda Legal. You
21 have 10 minutes.

22 MR. BUCHERT: Thank you so much. Yeah, it's

1 close enough. Yeah, I appreciate you hearing our
2 comments and I would like to request that our -- these
3 comments be submitted as part of the administrative
4 record along with our written comments. I'm speaking
5 today representing Lambda Legal on behalf of LGBTQ
6 people and people living with HIV. Founded in 1973,
7 Lambda Legal is the oldest and largest national legal
8 organization whose mission is to achieve full
9 recognition of the civil right of LGBTQ people and
10 everyone living with HIV to impact litigation,
11 education, and public policy work.

12 Before jumping into our main concerns with
13 this, I want to just flag what other folks has said
14 already that it's deeply concerning that HHS has
15 chosen to prioritize this right now in a moment when
16 we're experiencing over a 100,000 cases of COVID a day
17 and more states are reporting record high caseloads
18 and hospitalizations and with the death rate jumping
19 up past 1000 again every day. It just seems that it
20 is inappropriate for the department to be focusing on
21 this in this moment. I would also add my comment to
22 what has already been said regarding the 30 day

1 comment period that Mr. Harrison has quoted in news
2 article saying that this rule is "The boldest and most
3 significant regulatory reform ever undertaken by HHS."
4 And it's just irresponsible to not have a longer
5 comment period for a rule that is "The boldest and
6 most significant regulatory reform ever undertaken by
7 HHS."

8 Getting into the nuts and bolts of the rule
9 itself, I just want to -- we're deeply concerned that
10 the rule would divert significant personnel in the
11 next administration, you know, the rule itself quotes
12 20,000 to 45,000 hours to assess and if necessary
13 review the backlog, you know, the 2500 rules and many
14 more sections. But I believe that that's an
15 undercount considering the data collection and the
16 deep analysis that's going to have to be invested into
17 that work if this rule came to fruition. So, I think
18 it would suck up almost all staff time and the rule
19 obviously doesn't provide for any increases in funding
20 to hire more staff. So, it would clearly hamstring
21 HHS' functions. And it's deeply concerning to our
22 community because as HHS is recognized through its

1 Office of Disease Prevention and Health Promotion.
2 Research shows that LGBTQ people face healthcare
3 disparities leading to societal stigma and
4 discrimination and denial of their civil and human
5 rights.

6 And unfortunately the department in the last
7 4 years hasn't moved to address these disparities and
8 instead frankly has chosen to ignore them completely
9 and in many cases, you know, issue a rulemaking that
10 attacks our community over and over and over. So,
11 we're just deeply concerned that this eleventh-hour
12 rule would hamstring the agency from being able to
13 meaningfully address the disparities impacting our
14 community as well as failing to address the
15 disparities of all vulnerable Americans and it would
16 hamper the department's ability to address the COVID-
17 19 pandemic.

18 Couple of other points along this line would
19 be that, you know, the rule was likely emptied, in our
20 view, HHS' efforts to meaningfully update regulations
21 since so much staff time would be diverted and it
22 would be extremely costly as the rule points out, up

1 to 26 million dollars. And furthermore there is not
2 any clear showing here that, you know, that any
3 regulations would be amended or resented, so the
4 benefit of the rule is unclear. As others have
5 pointed out, the basis for the rule was the regulatory
6 flexibility act, but that doesn't obviously require
7 that the SUNSET provision be implemented. You know,
8 there's a lot of discussion about academic, you know,
9 Sunstein and others, talking about the importance of
10 regulatory review, but that there was not a
11 recommendation that the answer to that is to provide
12 SUNSET provision 5 U.S.C., 610A (inaudible), you know,
13 the agency should publish a plan for the periodic
14 review of the rules issued by the agency that have a
15 significant economic impact on small entities.

16 So it doesn't -- the RFA doesn't provide the
17 regulations to automatically expire if the issuing
18 agency doesn't review them. So, we're deeply
19 concerned that the agency went beyond that.
20 Furthermore HHS already does periodically review and
21 update its regulations in many contexts. In our view,
22 the solution is to create better review systems, not

1 to create a system that creates burdensome
2 requirements and eliminates key protections. The
3 existing rules, you know, are extremely important for
4 both beneficiaries and businesses, you know, and this
5 rulemaking would increase regulatory complexity and
6 disrupt expectations because, you know, businesses
7 wouldn't know what to expect when rules automatically
8 sunset and it would harm beneficiaries who have relied
9 upon these regulations for many years. It would
10 create, you know, a tremendous uncertainty for
11 regulated industries. And it would also place an
12 enormous burden on the public to -- there is this
13 proposal to create a website, but I think that that's
14 an incremental burden to place on the public to have
15 the responsibility of flagging for HHS rule better or
16 sets a SUNSET. To make the programs work safe and
17 providers a managed care plans need stability and
18 predictability, not this kinds of SUNSET turmoil.

19 With regard to the APA points, I would
20 completely agree with others that have made this point
21 already, but it's pretty clear to me, you know, the
22 rule flags the standard APA considerations like

1 failing to articulate a satisfactory explanation and
2 failing to consider an important factor and a rational
3 connection through the -- found and the choices made.
4 But this is the general rule, this is not a particular
5 rule and the department has shown already that, you
6 know, when it wants to as a rule, you know, flag that
7 the department can input a SUNSET provision into a
8 particular rule, but, you know, allowing this
9 wholesale process clearly violates the APA by not
10 providing the public an opportunity to consider that
11 as part of their notice of comment process. It would
12 just sunset it without that input. So, in our view,
13 it clearly violates the APA. And it also violates the
14 APA because it failed to consider and grapple with the
15 reliance interests on the rules that have been issued.
16 And we don't agree, as others have already mentioned,
17 that the departments authorizing statutes allow it to
18 create this rescission process.

19 And last couple of points I would just make
20 are that, you know, one part of the rule that was a
21 little bit of an aside that it was concerning that
22 NPRM quoted an administrative law article that

1 asserted that, you know, career staff are only
2 interested in keeping their agencies going or
3 continuing to exist, you know, and that is
4 reprehensible in my view because these are men and
5 women that come to everyday to improve the health and
6 welfare of all Americans and it shouldn't have been in
7 the rule. So, I hope that gets taken out of the final
8 rule if there is a final rule here. And then I would
9 just closely just again ask the department to withdraw
10 the rule completely. It's not appropriate, it would -
11 - it violates the APA and would harm all vulnerable
12 Americans. Thank you.

13 MR. HECHT: Thank you very much. Next up is
14 Jessica Schubel, senior policy analyst at the Center
15 on Budget and Policy Priorities. Ms. Schubel, you
16 have 10 minutes.

17 MS. SCHUBEL: Great. Thank you. Good
18 morning. My name is Jessica Schubel and I'm a senior
19 policy analyst at the Center on Budget and policy
20 Priorities. The center is a non-partisan research and
21 policy organization that conducts research and
22 analysis to inform public debates and policymakers

1 about a range of budget, tax, and programmatic issues
2 affecting individuals and families with low or
3 moderate income. Thank you for providing this
4 opportunity to comment on the Securing, Updated and
5 Necessary Statutory Evaluations Timely or SUNSET
6 proposed rule. While the Center on Budget and Policy
7 Priorities will be submitting written comment, I ask
8 that both the center's written comments as well as my
9 oral comments provided here this morning be included
10 in the administrative record.

11 The proposed SUNSET rule would undermine
12 Medicaid, Medicare, and the marketplaces as well as
13 other core functions of government such as the
14 federal, food and drug administration operations. As
15 such I strongly urge HHS to withdraw this rule for
16 reasons as follows.

17 As a former senior policy advisor at the
18 Center for Medicaid and CHIP Services or CMCS, I can
19 attest that this rule is totally unnecessary for
20 proper program administration of Medicaid, the
21 children's health insurance program or the basic
22 health program. That's because HHS already

1 periodically reviews and updates its regulations and
2 I've personal experience to attest to this. For
3 example, I've personally worked on annual updates that
4 CMCS has made to the basic health program funding
5 methodology to update the factors used to calculate
6 program funding for states participating in the basic
7 health program. Working with CMS' office of the
8 actuary CMCS staff, myself included, used updated
9 information and insurance data to amend the previous
10 year's funding methodology.

11 Another example that I would like to
12 highlight is the work that CMCS did in 2015 and 2016
13 to revise the 2002 regulations governing Medicaid
14 managed care. It was apparent to CMCS through our
15 close collaborations with states and stakeholders that
16 the 2002 managed care regulation did not address
17 changes that had occurred over the last decade to
18 manage care. For example, over the last several
19 years, states have moved towards enrolling seniors and
20 people with disabilities who need long term services
21 and supports into managed care. But the 2002
22 regulation did not contemplate such a practice and

1 there was no guidance for states on how to implement
2 managed long term services and support programs, nor
3 was it clear what beneficiary protection were in
4 place. I believe that this is a perfect example of
5 how the current rulemaking process affords HHS the
6 ability to revise and modernize, in fact, its
7 regulations to reflect updated practices without an
8 arbitrary expiration date hanging over the
9 department's head.

10 If finalized, it would be administratively
11 burdensome to implement, requiring significant
12 resources and funding. For starters that proposed
13 SUNSET rule would redefine regulations subject to
14 review and each section of the Code of Federal
15 Regulations or CFR which would require HHS staff to
16 assess and review each individual CFR section subject
17 to the rule, which is nearly all of them. HHS
18 estimates that in the first 2 years of implementation,
19 it would have to assess over 2400 rules. It's likely
20 that most of these rules would need to be reviewed as
21 well. This would be a costly endeavor with HHS
22 estimating that the new review procedures would cost

1 up to 19 million dollars to implement in the first 2
2 years and 26 million over the 10 years.

3 During my time at CMS, I was the principal
4 drafter of two regulations and a funding methodology
5 and I can say from personal experience that the
6 rulemaking process is a lengthy one. From the
7 drafting and editing process to reviewing,
8 synthesizing, and summarizing comments to the HHS
9 clearance process where every agency in the department
10 as well as the office of management and budget and the
11 Whitehouse have an opportunity to review. It's a very
12 labor intensive process. Given my experience, I
13 believe that HHS' estimate of its costly endeavor is
14 conservative. Even if the comment review and summary
15 task is contracted out to third party, it will cost a
16 significant amount of money for HHS to do this really
17 potentially 18,000 rules that maybe subject to the
18 SUNSET rule's new process.

19 Ironically I also believe that the SUNSET
20 rule would likely impede HHS' efforts to meaningfully
21 update regulations where needed since staff time would
22 have to be dedicated to the unnecessary reviews

1 mandated by the SUNSET rule. Because of the
2 additional and significant administrative burden the
3 SUNSET rule would place on HHS staff, the rule would
4 likely divert key resources from responding to the
5 COVID-19 crisis, other priorities, and day-to-day
6 program administration. Redirecting staff time from
7 their normal duties could potentially wreck havoc on
8 HHS programs and harm the people who rely on them. If
9 HHS was unable to dedicate the necessary resources to
10 review all rules, some might expire causing major
11 harm. Important regulations implementation the
12 Affordable Care Act as well as updates to other
13 provisions of Medicaid law are approaching their 10
14 year anniversary by the Medicaid cost sharing rule.
15 The Medicaid cost sharing rule, for example, would
16 need to be reviewed within the next two years,
17 otherwise it would be expired.

18 But the underlying law governing Medicaid
19 cost sharing still exist even if this rule expires
20 leaving states with no guidance on how to implement
21 Medicaid law. For example, Medicaid allows a lot of
22 states to impose nominal cost sharing charges in their

1 program. But the cost sharing regulation specify the
2 cost sharing amounts and other implementation
3 requirements. Without the cost sharing rules, states
4 would no longer have clear guidance for establishing
5 these amounts. This would wreck havoc with state's
6 ability to administer their Medicaid program and more
7 importantly to potentially harm beneficiary.

8 Finally, I want to echo a concern raised at
9 this hearing regarding the short comment period. This
10 will have far reaching consequences on HSS' programs
11 and the people who rely on them. And a 30 day comment
12 period is a suggestion especially when the comment
13 period occurs over a major national holiday, not to
14 mention over the COVID-19 pandemic that is raging
15 across the country at the moment.

16 In closing, I urge HHS to withdraw this rule.
17 If finalized, this rule would add new burdens for HHS
18 and likely detract from critically important
19 priorities that the department must address such as
20 responding to COVID-19. Again, thank you for the
21 opportunity to comment.

22 MR. HECHT: Thank you very much, Ms. Schubel.

1 I would again remind folks, if you're not speaking, to
2 please mute your phones for the benefit of those who
3 are speaking at the moment. The agenda listed a break
4 after Ms. Schubel's comments, but that was on the
5 assumption that it would now be 11:30 and we're
6 running ahead of schedule.

7 So, we're going to proceed with the next
8 speakers and then take our break at 11:30. So, with
9 that, Melanie Buzzelli, you're up. She is a National
10 Director of Advocacy at the American Lung Association.
11 Ms. Buzzelli, you have 5 minutes. Melanie Buzzelli,
12 are you on the line?

13 UNIDENTIFIED SPEAKER: Probably waiting till
14 11:40.

15 MR. HECHT: Yeah, exactly. Okay. We did
16 request that folks dial-in in advance of their time to
17 speak on the assumption that folks might not take
18 their allotted time. Kim Musheno, Vice President of
19 Public Policy at the Autism Society of America. Are
20 you on the line?

21 Okay. Well, if the next several speakers are
22 not up, then I think we can take a break now and we

1 can reconvene at 11:30. So, we will reconvene at
2 11:30. Thank you very much.

3 BREAK

4 MR. HECHT: Okay. It is 11:30. So, we're
5 going to resume with the Public Hearing on HHS NRPM
6 proposed rule making called Securing Updated and
7 Necessary Statutory Evaluations Timely. Once again,
8 we would request that folks mute their phone when they
9 are not speaking. We have Melanie Buzzelli from the
10 National Director -- the National Director of Advocacy
11 at the American Lung Association. Are you on the
12 line?

13 MS. BUZZELLI: Yes, I am. Can you hear me?

14 MR. HECHT: Yes, we can. You have 5 minutes.
15 As we mentioned at the outset, the time has been
16 allocated based on what was requested by participants
17 and we will notify each participant when they have 1
18 minute remaining as well as when their time has
19 expired. So, Ms. Buzzelli, you have 5 minutes.

20 MS. BUZZELLI: Thank you, and good morning.
21 My name is Melanie Buzzelli, that's M-e-l-a-n-i-e
22 Buzzelli, B as in bravo-u-z-z-e-l-l-i, and I am a

1 National Director of Advocacy at the American Lung
2 Association. Thank you for the opportunity to speak
3 to you today regarding the Department of Health and
4 Human Services notice of proposed rulemaking entitled
5 Securing Updated and Necessary Statutory Evaluations
6 Timely. The American Lung Association is the oldest
7 voluntary public health association in the United
8 States representing the millions of Americans living
9 with some diseases, including chronic obstructive
10 pulmonary disease or COPD, lung cancer, asthma, cystic
11 fibrosis, and pulmonary fibrosis.

12 The lung association is the leading
13 organization working to save lives by improving lung
14 health and preventing lung disease through research,
15 education, and advocacy. Much of what we work on in
16 our advocacy is touched by federal regulations. In a
17 sense regulations are to laws as air is to lungs as
18 they give laws life. Every aspect of public health,
19 including those aspects critical to lung health, are
20 impacted by federal regulations. With its proposal to
21 proceed existing federal regulations will be put at
22 risk and the ability for agencies to thoughtfully

1 promulgate new rules to protect our health would be
2 hampered. For this reason and those that I will
3 subsequently articulate, the American Lung Association
4 strongly opposes this proposal and urges HHS to
5 withdraw it.

6 We also note that this proposal is being
7 rushed through during the COVID-19 pandemic. We
8 reiterate our request for a consolidation of the
9 deadlines with a 60 day extension of the comment
10 period to February 4th. Requiring agency officials to
11 assess and likely review nearly all of HHS'
12 regulations will quickly become an all consuming task
13 and one for which there will have been no additional
14 appropriations. Even if this were the sole job of
15 those working underneath HHS' umbrella, there would
16 still be not enough time to carry out this gargantuan
17 task with due diligence. Consequently, in the most
18 ideal of circumstances, certain regulations important
19 to lung health would be at risk of expiring simply due
20 to a lack of resources, a concept that is anathema to
21 good governance and to the health safeguards required
22 by law that such regulations implement.

1 Yet this is not the sole job of HHS. The
2 agencies impacted by this proposal; the Food and Drug
3 Administration, the Centers for Disease Control and
4 Prevention, the Centers for Medicare and Medicaid
5 services, and more are responsible for orchestrating
6 an immense number of programs and activities that
7 impact the lives of every single individual in the
8 United States, responsibilities that will be gravely
9 strained by this proposal. During the COVID-19
10 pandemic, these resources are already stretched and
11 rightfully focused on the current public health
12 emergency. With the proposal to advance, agencies
13 would struggle to efficiently administer their
14 existing functions, let alone make progress with new
15 regulations. And a consequence of the struggle would
16 be actual pain for individuals in this country,
17 whether through a loss of coverage, a delay of
18 innovative therapies, exposure to harmful products, or
19 worsening of a calamitous pandemic that has already
20 taken the lives of more than a quarter million in the
21 United States. This proposed rule would have profound
22 implications on FDA's ability to protect public health

1 from tobacco products.

2 The Family Smoking Prevention and Tobacco
3 Control Act became law in 2009. And a number of
4 critical rules have since been promulgated, including
5 the deeming rule that gives FDA authority over e-
6 cigarettes. Currently 1 in 5 kids use e-cigarettes
7 and it is clear, more rules are needed to protect the
8 public health not just from e-cigarettes, but other
9 tobacco products, including menthol cigarettes. FDA
10 has been tasked by Congress with protecting the public
11 health. Using the latest science, FDA must be able to
12 build upon its existing regulatory framework to issue
13 new rules that help it better meet its mandate. So,
14 there are several millions of individuals across the
15 United States who rely on Medicaid and the Children's
16 Health Insurance Program or CHIP for healthcare.

17 Almost one-fifth of people with COPD are
18 enrolled in Medicaid or qualify as dual eligible,
19 close to a half of all children with asthma receive
20 their healthcare coverage through Medicaid or CHIP and
21 Medicaid enrollees smoke at rate over twice as high as
22 privately insured individuals. These individuals, the

1 people we represent, are at risk of being harmed by
2 this proposal.

3 Implementation of the Medicaid and CHIP
4 programs is heavily reliant on regulations, all who
5 interact with the program, States, providers, patients
6 managed care plans, rely on existing regulations to
7 interpret existing statute and perform their jobs.
8 These programs depend on predictability and certainty.
9 This proposal would not only call into question CMS'
10 ability to administer the program, but it would
11 jeopardize the very certainty necessary for proper
12 implementation. Where a regulation regarding
13 eligibility of benefits to slip through the cracks,
14 chaos would ensue and innocent beneficiaries would
15 bear the brunt.

16 So, why proceed with such a proposal. With
17 the nation still in the grips of a devastating
18 pandemic that has taken so many, there is no possible
19 justification for enacting a proposal that would
20 hamstring our public health agencies and place our
21 nation at greater risk of harm. Consequently, on
22 behalf of American Lung Association, I wish to again

1 urge HHS to withdraw this proposal. Thank you again
2 for the opportunity to speak with you all today.

3 MR. HECHT: Okay. Thank you very much, Ms.
4 Buzzelli. Next up is Kim Musheno, apologies if I'm
5 pronouncing that wrong, Vice President of Public
6 Policy at the Autism Society of America. You have 10
7 minutes. Okay. It sounds like Ms. Musheno is not
8 here.

9 So, we are going to just to go now to
10 Jennifer McEntire, Senior Vice President of Food
11 Safety & Technology at United Fresh Produce
12 Association. Ms. McEntire, you have 5 minutes.

13 MS. McENTIRE: Yes. Thank you very much.
14 Hello. And thank you for the opportunity to comment.
15 The United Fresh Produce Association is the national
16 association representing over 1,500 members of the
17 fresh fruit and vegetable supply chain, including
18 growers, shippers, fresh cut processors, wholesalers,
19 distributors, retailers, food service operators,
20 industry suppliers, and allied associations. For over
21 115 years, we've empowered industry leaders to seep
22 sound government policy. Throughout the COVID-19

1 crisis, members of the fresh produce industry have
2 continued to keep Americans nourished. It's important
3 for the stakeholders to not review and consider this
4 proposed rule in a thoughtful manner if given nearly
5 30 days to do so. This rule has the potential to
6 create many unintended consequences that will be
7 detrimental to the produce industry. And we
8 respectfully request that the comment periods for this
9 proposed rule be extended from 30 days to 180 days.

10 It's well-recognized that fresh produce is a
11 critical part of the healthy diet and we struggle to
12 get consumers to eat enough fruits and vegetables.
13 The United States overweight and obesity crisis is not
14 new. However, COVID-19 has further revealed the
15 consequences of diet related chronic diseases, many of
16 which have put Americans at higher risk of
17 complications when contracting the virus. Addressing
18 high overweight and obesity rates requires a
19 multifaceted approach from both individuals and
20 private and public sectors. At the same time, several
21 produce items have been implicated in food borne
22 illness outbreaks.

1 We're well aware of the ongoing vigilance it
2 takes to grow and handle safe produce and encourage
3 consumer confidence and the assumptions. For this
4 reason, we've advocated four legislations and
5 supported the Food and Drug Administration, the FDA,
6 in the development and implementation of several rules
7 related to food safety and nutrition. We're quite
8 concerned that the process laid out in this proposed
9 rule could unintentionally undue some of the
10 regulations that we rely upon to ensure it's helpful
11 choices and maintain the standard for food safety, not
12 only for domestic growers and processors, but for the
13 roughly half of fresh fruits and vegetables that we
14 import.

15 We support a process whereby outdated rules
16 for the owners' compliance issues with little public
17 health gain should be reevaluated. We hope to work
18 with the department to identify an approach that
19 accomplishes this objective without taking resources
20 away from mission critical work to protect the
21 Americans and the industry. If this rule is
22 finalized, the retrospective reviews required of the

1 agency would become FDA's top regulatory priority.
2 And the agency's attention to this would prevent it
3 from considering actions more pressing and important
4 to the industry that regulate.

5 The agency's focus on conducting reviews to
6 ensure the continued effectiveness of existing
7 regulations to prevent it from conducting meaningful
8 reviews to eliminate change or modernize existing
9 regulations. The rule could also support creation of
10 new regulations such as the food traceability rule,
11 which sought a must finalized by November, 2022 as per
12 consent decree. As proposed, the FDA would be
13 required to conduct these detailed reviews and
14 assessments of regulations within a 2 year period to
15 commence their automatic expiration. This isn't
16 practical. We worked very closely with staff at the
17 FDA and they're already stretched then owing in part
18 to the pandemic. We're fearful that some of the
19 regulations, the industry has invested so much time in
20 will be eliminated, including many that are still
21 quite new and in which we are even at the point of
22 full implementation, despite being at the 10-year mark

1 for the passage of the Food Safety Modernization Act.

2 Prior to the COVID-19 public health
3 emergency, FDA was engaged in an education campaign to
4 assist industry and the public, including healthcare
5 providers on how to understand and effectively utilize
6 the updated nutrition facts panel. The ability for
7 FDA to continue to do this, relaying consumer
8 confidence in the updated label, especially at a time
9 when Americans are consuming more food at home, is a
10 significant endeavor (phonetic). Additionally, things
11 like many late points (phonetic) play a key role in
12 addressing dietary quality wherever Americans access
13 food.

14 An example on the food safety side is the
15 produce safety rule finalized in 2015, a rule that had
16 issues when it comes to the management of agricultural
17 water, but to which FDA has committed to getting it
18 right. And we would much rather FDA spend time fixing
19 the single issue, than conducting a thorough review of
20 this or other rules using the process laid out by HHS.
21 The industry can't afford to have these types of rules
22 eliminated. When we have potential trade issues, as

1 we did with Canada just last month regarding their
2 acceptance of U.S. grown Romaine lettuce, a 78 million
3 dollar market for California, we used this rule and
4 the other food safety rules to support our case that
5 they're concerned was unfounded. The worldwide
6 confidence in the U.S. government helps protect our
7 regulated industries. Seventy eight million dollars
8 may not sound like a lot to HHS, but to our nation's
9 farmers, this is their livelihood.

10 I hope that these comments help illustrate
11 the potential to disrupt the regulatory system that
12 keeps our food system in check, protecting consumers
13 and providing a level playing field for our domestic
14 food industry. Any efforts that would distract from
15 this important work, both in implementation and
16 further progress to address dietary quality and food
17 safety is detrimental to the overall ability of the
18 government to address these crises, both acute and
19 long-term. We strongly urge HHS to reconsider the
20 necessity of this proposed rule and its structure as
21 well as allow the effective industry more time to
22 develop comments. Thank you very much for the

1 opportunity to comment. This concludes my remarks.

2 MR. HECHT: Thank you very much, Ms.

3 McEntire. Ms. Musheno from the Autism Society of
4 America, are you on the line now? Okay. Well, then
5 we will proceed down the agenda.

6 Next up, we have Betsy Booren, Senior Vice
7 President, Regulatory and Technical Affairs at the
8 Consumer Brands Association. Ms. Booren, you have 10
9 minutes.

10 MS. BOOREN: Great. Thank you. The Consumer
11 Brands Association champions the industry whose
12 products Americans depend on every day. From
13 household and personal care to food and beverage
14 products, the consumer packaged goods or CPG industry
15 plays a vital role in powering the U.S. economy
16 contributing 2 trillion to the U.S. GDP and supporting
17 more than 20 million American jobs. We have concerns
18 of the proposed rule and our comments will build on
19 the following points.

20 The CPG industry including in part
21 manufacturers of the food and beverage, personal care
22 and household products industry are not provided with

1 sufficient time to review and comment on this proposal
2 given the scope of potential impact it may have on our
3 businesses. The CPG industry has served as an
4 integral part of American's ability to stay home and
5 stay safe through the COVID-19 pandemic, populating
6 key segments of the nation's critical infrastructure
7 as recognized by the Department of Homeland Security.

8 This important group of stakeholders will not
9 be able to review and consider this proposed rule in a
10 thoughtful manner if given a mere 30 days to do so.
11 As such we respectfully request the comment period for
12 this proposed rule be extended from 30 to 180 days.
13 This request was officially put on the docket last
14 week.

15 In addition, the practical implications of
16 the proposed rule raise many questions and concerns.
17 Particularly concerning is the fact that it would
18 require FDA to analyze and justify all of the
19 sustenance regulations promulgated over the past 80-
20 plus years, including for the CPG industry,
21 regulations pertaining to product safety, good
22 manufacturing practices in imports and exports. The

1 implications to products like infant formula, low acid
2 and acidified food, dietary supplements, personal care
3 products, over-the-counter drugs and all of their
4 respective ingredients is overwhelming.

5 The CPG industry relies on durable federal
6 standards established through these regulations,
7 standards that have been established and shown to
8 stand the test of time. The uncertainty created
9 regarding whether or not these federal standards will
10 undergo sunseting is disconcerting. Additionally
11 important, consumers trust CPG products because they
12 are regulated by federal agencies such as FDA. These
13 type of action as proposed could cause that trust to
14 erode.

15 Also, as proposed all federal agencies
16 including FDA would be required to conduct detailed
17 reviews and assessments of regulations under the
18 Regulatory Flexibility Act within a 2-year period to
19 prevent their automatic expiration. We are concerned
20 that the time limits proposed for the review of
21 existing regulations will require reallocation of
22 regulatory agency employee resources away from the

1 activities that protect public health. And in the
2 case of FDA, the subject matters experts are those
3 that are responsible for modernizing existing
4 regulations and guidance. This work would need to be
5 put on hold.

6 And in the short term, this is even more
7 concerning as it may pull away -- staff away from
8 critical public health activities as related to the
9 COVID-19 pandemic.

10 SPEAKER: Sorry.

11 MS. BOOREN: Consumer brands is a -- please
12 mute yourself, we're getting a lot of feedback.
13 Consumer Brands is a passionate champion of a modern,
14 agile regulatory system that maintain affordability,
15 promote choice and build consumer trust. We have a
16 strong point of view that smart regulations are the
17 following. They result in uniform regulatory
18 framework. They empower consumers to make informed
19 choices. They enhance trust in consumer packaged
20 goods. They consider what the consumer want and their
21 expectations. They are informed by risk-based
22 science. They achieve outcomes efficiently and stand

1 the test of time.

2 Consumer Brands supports the reviews of
3 regulations to ensure that they are smart regulations,
4 but the proposed rule provides no clarity on how it
5 would impact longstanding regulations that are
6 implicitly tied to product safety disclosure and other
7 product standard. The idea that these regulations
8 would be SUNSET because the regulations timer went too
9 long is not acceptable. Consumer Brands recommends
10 that any sunset rule includes a clear process for
11 review that considers product safety disclosure and
12 other product standard.

13 Stakeholders should be given the opportunity
14 to comment throughout the development of the
15 regulatory framework. This transparency will ensure
16 that effective and durable regulations are developed.
17 Stakeholders and federal agencies share the common
18 goal of providing consumers with safe, trustworthy,
19 reliable products. Clear, simple, consistent
20 information supported by risk-based science will
21 enhance consumers' trust in both the products
22 themselves, and the agencies that regulate them.

1 Thank you.

2 MR. HECHT: Okay. Thank you very much, Ms.
3 Booren. Once again, I'm going to remind everybody to
4 please mute your phone when you're not speaking. It's
5 not fair to the person speaking. It's not fair to the
6 people who're trying to listen to the speaker. If
7 there's, you know, a lot of feedback in the
8 background, that makes it hard to focus. So we said
9 this many times, but please mute your phone if you're
10 not the one speaking. With that, I will turn it over
11 to Swati Rawani, a staff attorney at the Campaign for
12 Tobacco-Free Kids. Ms. Rawani, you have 5 minutes.

13 MS. RAWANI: Great. Thank you very much. My
14 name is Swati Rawani, and I am an attorney at the
15 Campaign for Tobacco-Free Kids. I appreciate the
16 opportunity to share my organization's views about the
17 proposed rule. My comments address two of our primary
18 concerns with the proposed rule as they pertain to the
19 regulation of tobacco products.

20 First, instead of allowing FDA's Center for
21 Tobacco Products to focus on this lifesaving mission
22 of protecting Americans from deadly tobacco products,

1 this rule will divert FDA's and the Center's attention
2 and resources. Second, the proposed rule, if
3 finalized, would violate the Administrative Procedure
4 Act because it adds an automatic SUNSET provision to
5 18,000 regulations and thus would amend thousands of
6 rules without having each rule go through the legally
7 required individualized notice and comment rulemaking.
8 It would have that effect without regards to whether
9 or not the rule is out of date or still needed.

10 Cigarette smoking is a leading cause of
11 preventable disease and death in the United States,
12 killing more than 480,000 Americans every year. Over
13 16 million Americans suffer from tobacco-related
14 disease. According to CDC data issued last week, 34.1
15 million U.S. adults still smoke cigarettes. In
16 addition, e-cigarette use among youth has reached
17 epidemic proportion with about one in five American
18 kids now using these highly addictive products. It is
19 essential to public health that FDA be allowed to
20 focus on its critical task of protecting the American
21 people from addictive and deadly tobacco products.

22 Since 2009 when the Family Smoking Prevention

1 and Tobacco Control Act was enacted, it is clear that
2 the Agency has not sufficiently used its authority to
3 protect Americans from the myriad health harms of
4 tobacco. For example, FDA has had the authority to
5 establish tobacco product standards to make tobacco
6 products less harmful, less addictive, and less
7 appealing, especially to kids. Yet, FDA has yet to
8 issue a single product standard. Also, consider the
9 youth e-cigarette epidemic. In April 2011, FDA first
10 announced its intention to regulate e-cigarette as
11 tobacco products. But FDA did not extend its
12 authority to e-cigarette until May 2016.

13 During this 5-year delay, e-cigarettes gained
14 a foothold in the American market with a particular
15 appeal to kids. Youth use of e-cigarette accelerated
16 dramatically in 2017 after FDA suspended its public
17 health review of these products. Thus, the story of
18 tobacco regulation is not unnecessary regulatory
19 burdens on the tobacco industry and small businesses,
20 but rather FDA's failure to use its regulatory
21 authority to protect public health, and particularly
22 to protect our kids.

1 Yet, this proposed rule would require FDA to
2 engage in unnecessary assessments and reviews that
3 impose unjustifiable cost on the regulatory process,
4 which is subject to legal action, as the rule
5 envisions, would further divert FDA from its public
6 health mission. The core SUNSET provisions in the
7 proposed rule would violate the APA because the
8 provisions are arbitrary and capricious, and violate
9 the APA itself. The APA requires a notice of proposed
10 rulemaking for each rule that is amended so that the
11 effect of each rule can be properly considered and be
12 subject to public comment.

13 The SUNSET provisions inevitably have varied
14 effects for each of the thousands of rules under
15 consideration. Yet, the proposed rule makes a blanket
16 claim that the risk of a regulation inadvertently
17 expiring is outweighed by the benefit of
18 institutionalizing retrospective review. The proposed
19 rule offers no evidence that HHS has made any
20 individualized recent assessment as to each of the
21 thousands of regulations impacted by the proposal.
22 But that is what the APA requires. By issuing a

1 single rulemaking to amend thousands of HHS rules
2 without considering the impacts on each, the proposed
3 rule violates the requirements of the APA. Moreover,
4 the APA will be violated every time a rule
5 automatically expires because the expiration will
6 occur without the required notice and comment
7 opportunity, and without an examination by the Agency
8 if whether expiration of the rule is justified by the
9 relevant science.

10 The ensuing litigation could clog the court
11 and paralyze the Agency. Therefore, because the
12 proposed rule imposes extraordinary burdens on FDA and
13 its regulation of tobacco products with no benefits to
14 the public health, and because it violates the APA,
15 the Campaign for Tobacco-Free Kids urges HHS to
16 withdraw the proposed rule. Thank you. That
17 concludes my comments.

18 MR. HECHT: Thank you very much, Ms. Rawani.
19 Next up is Debra Miller, senior vice president for
20 Scientific & Regulatory Affairs at the National
21 Confectioners Association. Ms. Miller, you have 10
22 minutes.

1 MS. MILLER: Thank you very much. Can you
2 hear me okay?

3 MR. HECHT: Yes, we hear you great. Thank
4 you.

5 MS. MILLER: Great. Well, good afternoon,
6 everyone. Or just on the cusp of afternoon. I'm here
7 representing the National Confectioners Association.
8 NCA is the leading trade association representing the
9 nearly \$45 billion U.S. confectionary industry.

10 NCA represents nearly 200 companies that
11 manufacture chocolates, confectionary, gum and mint in
12 the United States. And we represent another 200
13 companies that supply those manufacturers. Chocolate
14 and candy are produced in all 50 states, employing
15 approximately 54,000 workers in nearly 1,300
16 manufacturing facilities across the country. And the
17 vast majority of our members are small and medium-
18 sized companies, many of which are family-owned
19 businesses that pass on the art of candy-making
20 expertise from generation to generation. NCA and our
21 members thank HHS for the opportunity to provide these
22 comments today on this important issue.

1 First, it gives me great pleasure just to
2 note how much consumers love the products our member
3 companies produce. Our members in turn are committed
4 to providing consumers with quality and safe
5 confectionary products in a way that's been prepared
6 and helpful to ensure that people understand and
7 appreciate that unique role that chocolate and candy
8 can play in a happy and balanced lifestyle. Since
9 March of this year, most, if not all of us, have been
10 unable to travel, congregate, or even go to many of
11 our own workplaces due to the COVID-19 epidemic.
12 Given this unique time, small celebrations have meant
13 more to Americans than perhaps at any other time in
14 our country's history.

15 And candy and chocolate have been a trusted
16 and welcome part of these small celebrations for
17 families and couples and even individuals during this
18 time. NCA members, those hands-on makers of those
19 small candy and treats that are part of those
20 celebrations are an important group of stakeholders
21 who supply those little moments of happiness during
22 this time of social distance, isolation, and indeed

1 all times. This proposed rule is enormous, and so
2 sweeping in nature. Our members, those who make those
3 small moments of happiness, will simply be unable to
4 review and consider this proposed rule in a thoughtful
5 manner if given only 30 days to do so.

6 We respectfully request that the comment
7 period for this proposed rule be extended from 30 days
8 to 100 -- an additional 150 days. As noted by other
9 speakers, this proposal would require FDA to analyze
10 and justify all of its substantive regulations
11 promulgated over the past 80-plus years. Of
12 particular concern to NCA members are the regulations
13 regarding product safety, such as FSMA, the Food
14 Safety Modernization Act; food manufacturing
15 processes, practices, DMPs, and the status of
16 important exported products.

17 Also, we are concerned about nutrition
18 labeling and standards of identity and a host of
19 others. These regulations are intended to protect the
20 public health and are driven by science. For example,
21 there are extensive nutrient reviews by the National
22 Academy of Science, Engineering, and Medicine

1 (phonetic). To suddenly change or remove such
2 requirements could have unintended public health
3 repercussions. The confectionary industry and the
4 entire food industry rely on consistent and lasting
5 federal regulations.

6 FDA regulations establish a level playing
7 field and uniform federal standards are vastly
8 preferable to a patchwork of 50 different state
9 requirements which would be costly and highly
10 burdensome to industry. Companies have also built
11 compliance programs around the existing legal
12 requirement. And while there are -- there may be some
13 regulations that our industry would like to see
14 reviewed, the process outlined in this proposal would
15 be very burdensome for our industry to keep up with
16 and would likely create widespread consumer confusion
17 and a decrease in consumer confidence and trust, here
18 both in the United States and with our trading
19 partners abroad.

20 Finally, in this regulation as proposed, all
21 federal agencies, including FDA, would be required to
22 conduct detailed reviews and assessments of

1 regulations under the Regulatory Flexibility Act
2 within a 2-year period to prevent their automatic
3 expiration. We are concerned that this rather short
4 timeframe for this review will pull resources from
5 FDA's core purpose of protecting the nation's food and
6 pharmaceutical supply and thus endangering public
7 health.

8 In closing, NCA believes that this rule, if
9 implemented as proposed, would have sweeping and
10 potentially unintended consequences that would not
11 benefit our industry or the consumers we serve. We
12 also support the request for extension of the comments
13 already made which would be -- we believe will be
14 necessary for industry to review the proposed rule and
15 respond in a meaningful way. We also plan to submit
16 our comments in writing. Thank you.

17 MR. HECHT: Thank you very much, Ms. Miller.
18 Next is Katherine Lundie, a state and local policy
19 analyst at the National Immigration Law Center. Ms.
20 Lundie, you have 5 minutes.

21 MS. LUNDIE: Thank you. My name is Katherine
22 Lundie, and I'm presenting on behalf of the National

1 Immigration Law Center. Our organization's core
2 mission is to defend and advance the rights and
3 opportunities of low-income immigrants. I'm here
4 today to ask the Department of Health and Human
5 Services to abandon this unnecessary and reckless rule
6 because of the increased chaos and ultimate harm it
7 will inflict on communities. If implemented, the rule
8 will consume resources the Agency should be using to
9 limit the harm of the coronavirus pandemic and to
10 otherwise serve the public.

11 The burdens of the SUNSET rule will be
12 particularly heavy in the next 2 years when by its own
13 count, the Agency would need to review over 2,400
14 regulations, consuming time and resources that could
15 be used to help distribute a coronavirus vaccine or
16 related outreach.

17 And there are three key issues I bring before
18 you today. First, under the SUNSET -- or under the
19 proposed SUNSET rule, regulations that are not
20 reviewed will simply terminate. Among the regulations
21 approaching the 10-year mark is the 2009 rule that
22 removed HIV from the definition of communicable

1 disease of public health significance which made it
2 possible for HIV-positive individuals to be admitted
3 to the U.S.

4 Second, the important work of the HHS Office
5 of Refugee Resettlement could also be harmed by this
6 diversion of resources. In addition to what is needed
7 to rebuild our nation's refugee program, ORR will rely
8 on the stability of HHS to continue to provide housing
9 for children separated from their families under the
10 administration's zero-tolerance policy. Some 600
11 children still remain separated from their families,
12 and precious ORR resources will be needed to locate
13 their parents.

14 And third, the proposed rule would decimate
15 the regulatory framework that makes the Affordable
16 Care Act work. Heavy restrictions have always
17 complicated immigrants' eligibility for public
18 program, such as the ACA or Medicaid. For example,
19 only certain lawfully present immigrants are eligible
20 for Medicaid, and in many cases, only after a 5-year
21 waiting period. The procedures and standards that
22 govern the complex web of eligibility determinations

1 are set forth in essential regulations. In the field,
2 service providers already have to navigate a confusing
3 system in order to serve immigrants and mixed
4 immigration status families.

5 Immigrant communities are already being
6 deterred from seeking healthcare services because of
7 the DHS public charge regulation and other fair-based
8 policies. HHS is being willfully ignorant to the fact
9 that this change will create real life and death
10 consequences for families that need all of the
11 resources of a well-functioning Health and Human
12 Services agency to overcome the public health crisis.
13 So we ask, and we strongly ask that you abandon this
14 rule. Thank you.

15 MR. HECHT: Thank you very much, Ms. Lundie.
16 Next up is Sara Brown, director of government affairs
17 at Prevent Blindness. Ms. Brown, you have 5 minutes.

18 MS. BROWN: Thank you, everyone. Good
19 afternoon. My name is Sara Brown. I am director of
20 government affairs at Prevent Blindness. We
21 appreciate the opportunity to address this important
22 proposed rule and the issues that would be of

1 consequence should this proposal move forward.

2 Prevent Blindness is the nation's leading
3 nonprofit voluntary vision and eye health and safety
4 organization in the country. Since 1908, we've made
5 it our mission to extend access to vision and eye
6 health care and treatment to Americans across the age
7 spectrum, no matter the socio-economic, racial or
8 ethnic backgrounds or health circumstances.

9 This proposed rule is a major importance to
10 us on behalf of those who face blinding eye diseases,
11 low vision, and vision loss or impairment,
12 specifically as the ramifications in Medicaid and
13 Medicare pose major threats to children in their
14 development and school-readiness, working adults who
15 need their sight to earn a productive living, and
16 aging Americans who seek to maintain independent and
17 quality of life with healthy eyesight.

18 Firstly, we echo the comments of others
19 regarding the substantial and unnecessary
20 administrative burden required to administer this rule
21 and its implications for achieving goals that we all
22 share of lowering cost to our national healthcare

1 system, making healthcare affordable and accessible,
2 and provide care based on value patient-centered care
3 and healthy outcomes. The eleventh (phonetic) out-
4 nature of this proposed rule also undermines any
5 meaningful effort to update regulations where needed
6 in the future, and it would impede true stakeholder
7 engagement as the public would be directed to address
8 unnecessary reviews instead of working with HHS to
9 (inaudible).

10 Staffing across organizations such as the CDC
11 are absolutely necessary to conduct sufficient
12 surveillance and community health strategies. We have
13 significant concerns that this rule, if implemented,
14 could impede the acquisition of data needed to
15 contribute to policies that would improve access to
16 vision and eye care.

17 Third, Medicaid and relatedly CHIP, is in
18 many cases, the only source of visual care and eye
19 disease prevention and treatment that many Americans
20 have. As we've observed in the current pandemic, many
21 of the circumstances that surround vision loss and eye
22 disease, including the presence of chronic disease,

1 disparities along racial and ethnic lines, socio-
2 economic circumstances and age are at the intersection
3 of COVID-19 and its most serious consequences.

4 In addition, several conditions that are
5 associated with the most serious conditions of COVID-
6 19 are analogous to vision and eye health, including
7 diabetes, heart problems, depression and social
8 isolation, long-term hospitalization and readmission
9 and the need for long-term care.

10 This rule as finalized will need states
11 without critical guidance needed to continue their
12 Medicaid programs at sufficient level to account for
13 all of Americans' needs, including their vision and
14 eye health, which could mean permanent and
15 irreversible vision loss and damage if not addressed
16 in a timely manner. All of this during a devastating
17 pandemic.

18 Finally, HHS already has the opportunity to
19 periodically review and update its regulations,
20 especially in the Medicare program. And this provides
21 the opportunity for frequent public input and comment,
22 processes that we feared the SUNSET would bypass. We

1 urge this rule to be withdrawn, it seems to be
2 abandoned and not implemented. Prevent blindness
3 looks forward to working with HHS through the avenues
4 already established for public comment to achieve the
5 shared goal of preventing vision impairment and
6 blinding eye disease. Thank you.

7 MR. HECHT: Okay. Thank you very much, Ms.
8 Brown. Once again, please mute your phone if you're
9 not speaking. You know, during last few comments, the
10 sounds of what sounds like typing on a keyboard in the
11 background. So, if you could please mute your phone
12 when you're not talking, that would be very
13 appreciated.

14 Next up is Leah Wilkinson, vice president for
15 public policy and education at the American Feed
16 Industry Association. Ms. Wilkinson, you have 5
17 minutes.

18 MS. WILKINSON: Thank you very much and good
19 afternoon. The American Feed Industry Association is
20 the world's largest organization devoted exclusively
21 to representing the business and the legislative and
22 regulatory interests of the U.S. animal food industry

1 and its suppliers. Our almost 700 member companies
2 are livestock feed and pet food manufacturers,
3 pharmaceutical company, ingredients suppliers,
4 equipment manufacturers, and other companies which
5 supply other products, services and supplies to the
6 animal food industry, which encompasses feed, pet
7 food, and all of the ingredients that go into making
8 our products.

9 AFIA supports sound science-based regulations
10 that will allow for innovation and growth while
11 producing safe, nutritious and high-quality animal
12 feed and pet food products. Our association
13 appreciates the intent behind the notice of proposed
14 rulemaking for the review of regulations for the
15 animal food industry. However, we have some concerns
16 about the potential impact of this proposal.

17 There are regulations that do need updating
18 and attention, could be given that would benefit the
19 Agency and the industry without creating some undue
20 burdens or a new review system. For example, in
21 February of 2017, our association filed a citizen's
22 petition asking to remove some outdated recordkeeping

1 requirements. And again, in February 2018, we
2 commented to the Food and Drug Administration Center
3 for Veterinary Medicine on regulations that were
4 outdated or needing improvement. No action has been
5 taken to-date.

6 AFIA, in general, supports the review of the
7 current animal food regulations and 21 CFR 500 for
8 their appropriateness, redundancy and completeness.
9 However, this effort should not be rushed without
10 proper review and stakeholder input. Also, a thorough
11 plan should be developed that details how the review
12 would happen without diverting current staff resources
13 from programs that are already understaffed and
14 struggling to meet regulatory timeframe.

15 As written, the review system would entail
16 all regulations under 21 CFR. It's unclear if the
17 exemptions provided would apply to the hundreds of
18 animal food ingredients that are approved with a
19 published regulation such as a food additive generally
20 recognized as safe, flavorings, or color additives.

21 With the limited resources within the Center
22 for Veterinary Medicine dedicated to animal food, we

1 would urge that proper care and planning be taken to
2 ensure that the regulatory system which protects
3 consumers and industry can continue to function with
4 reviewing, updating and approving new ingredients and
5 technologies. We do not want the system to be bogged
6 down more than it already is, which would further slow
7 innovation and threaten our ability to complete -- to
8 compete in the global marketplace.

9 Thank you for hearing our initial concerns
10 during this public meeting, and we will be submitting
11 further detailed written comments by your December 4th
12 deadline.

13 MR. HECHT: Okay. Thank you very much, Ms.
14 Wilkinson. Next is Tim Gardner, legal director at the
15 Disability Rights New Mexico. Mr. Gardner, you have
16 10 minutes.

17 MR. GARDNER: Thank you. Good morning or
18 good afternoon. I will say at the outset I don't
19 anticipate needing the full 10 minutes. Everything I
20 had planned to say has been expressed more
21 articulately than I would have said it.

22 Want to point out that people with

1 disabilities are very much overrepresented in programs
2 administered by HHS, and of course, people with
3 disabilities face the most challenges in participating
4 in regulatory review.

5 This proposal is illegal. That's been
6 explained. At best it would create massive litigation
7 and bog down the system. If this SUNSET provision
8 were to ever be implemented, it would create
9 regulatory chaos. This would be a total distraction,
10 diverting time and energy from protecting Americans to
11 chasing SUNSET, as has been much discussed, this
12 minimal comment period.

13 Over this holiday season, during a pandemic
14 in an administrative transition for this massive
15 overhaul of the entire regulatory approach is rather
16 absurd. I would like to say that I do see value to
17 the careful attention to regulatory retrospective
18 review. I think Chief of Staff Harrison at the outset
19 of this hearing had some important points that
20 warranted careful consideration. And while he was
21 speaking, I was scribbling in my notes that he was
22 calling out for a scalpel but not the sledgehammer,

1 and then the American Frozen Food Institute used that
2 same analogy.

3 And, you know, I just have to point out that
4 if, with one proposal, you've managed to alienate the
5 American Frozen Food Institute, Disability Rights
6 advocates, Consumer Brands Association, Lambda Legal,
7 consumer advocates, American Feed Industry Association
8 and everyone in between, and pretty much everyone is
9 in between the entities in that group, you're clearly
10 peddling a bad idea.

11 And I'll just sort of close by saying, I
12 understand that this SUNSET demolition of HHS
13 regulations can't fly, it won't fly. And I understand
14 this desire to make a political point. I get that. I
15 understand the game. But this proposal, which is
16 illegal, which would be self-destructive of the
17 regulatory system, with this fast-track, minimal
18 comment period, at this height of a deadly pandemic,
19 in this time of great need for regulatory structures
20 around emerging vaccines, during this short window of
21 a transition of presidential administration, is not
22 just tone deaf to this moment. This is a malicious

1 distraction from the vital purpose that HHS serves.

2 So, that concludes my oral remarks, which I
3 will expand on in written comment. So thank you very
4 much for hearing me out.

5 MR. HECHT: Thank you very much, Mr. Gardner.
6 Next is Dana Brooks, president and CEO at the Pet Food
7 Institute. Ms. Brooks, you have 5 minutes.

8 MS. BROOKS: Thank you. Many thanks to the
9 Department of Health and Human Services for convening
10 today's public meeting to comment on the recently
11 issued notice. The Pet Food Institute, which
12 represents U.S. dog and cat food makers, appreciates
13 this opportunity to share a perspective on this
14 important proposed rule. I also truly appreciate The
15 Barking Dogs (phonetic) joining the call today as they
16 are our consumers.

17 Our members, who account for well over 90
18 percent of U.S. dog and cat food production and feed
19 the vast majority of the 180 million pets in the U.S.
20 households, operate under regulation promulgated by
21 the FDA and enforced by both federal and state
22 officials. This means dog and cat owners throughout

1 the U.S. and around the world benefit from science-
2 based regulation that provide the safest animal food
3 supply available anywhere.

4 We recognize and generally agree with the
5 proposed rules goal of requiring some form of
6 retrospective regulatory review for the Department and
7 the agencies under it. However, the proposed rule
8 will cast a long shadow of uncertainty over entire
9 swath of U.S. food and drug regulations at a time when
10 more, not less, trust and confidence in the federal
11 food and drug regulation is desperately needed.

12 And we will take a second to ask the person
13 typing, if they would either mute their phone or stop
14 talking during my comments, I really appreciate it.
15 As we enter a crucial period of pandemic response with
16 coronavirus vaccines on the verge of receiving federal
17 regulatory approval, we urge HHS to extend the comment
18 period for this proposed rule to a full 6 months.
19 This extension will allow the broad range of affected
20 stakeholders and consumers to provide thoughtful
21 comment and to facilitate a meaningful dialogue of
22 regulatory reform that satisfies the statutory intent,

1 inspires consumer confidence and provides regulatory
2 certainty for all affected stakeholders.

3 The proposed rule would require HHS and its
4 agencies to conduct detailed reviews and assessments
5 of all regulations within a 2-year period to prevent
6 their automatic expiration. The scope of this
7 proposed rule would include FDA regulations
8 promulgated under Section 21, 42 and 45 of the Code of
9 Federal Regulations, as well as virtually all human
10 and animal food offered for sale in the United States.
11 Dog and cat food is subject to regulation under
12 Section 21. These regulations were recently updated
13 pursuant to legislation passed in Congress and signed
14 into law in early 2011.

15 The Food Safety Modernization Act, or FSMA,
16 required FDA to update its regulations of human and
17 animal food, specifically to employ a science-based
18 proactive approach to food safety with the objective
19 of identifying and eliminating foodborne hazards
20 before they pose a risk to human and animal health.

21 PFI estimates that our member-driven
22 committee cumulatively spent more than 3,000 hours

1 over a 5-month comment period analyzing the proposed
2 rule, drafting and reviewing response, and consulting
3 with our U.S. food and agriculture partners to align
4 our messaging to FDA. Our comment alone with those of
5 hundreds of food producers, food safety experts and
6 consumers, prompted FDA to make substantial changes to
7 the rule. This helped result in a final proposed rule
8 that is generally regarded as advancing the safety of
9 animal food, while acknowledging the unique
10 characteristics of animal food production.

11 The entire FSMA rulemaking process I've just
12 described took 2 years. The proposed rule at issue
13 today would require FDA to analyze and justify in just
14 2 years virtually all substantive regulatory
15 regulations that have been promulgated over the past
16 80-plus years.

17 FDA officials would have to curtail or stop
18 their current enforcement activity and devote all
19 their energy to review of those same regulations they
20 are charged with enforcing. This review would create
21 tremendous uncertainty here and abroad regarding the
22 safety and oversight of the U.S. food, drug and

1 medical device supply.

2 So, our request is twofold. First, we
3 respectfully request HHS to extend by 150 days the
4 comment period for this proposed rule in order to
5 allow all stakeholders to provide thoughtful review
6 and comment. Second, we urge HHS to consider that
7 rather than require a wholesale review of all
8 regulations issued by the Department and its agencies,
9 it should modify this proposed rule to instead seek
10 input from regulated community and consumers as to
11 which regulations require review with an eye towards
12 eliminating, consolidating and updating such
13 regulations.

14 The regulated community and consumers can
15 provide HHS with valuable input that can facilitate a
16 more efficient use of resources and effort to achieve
17 meaningful regulatory reform. Thank you for this
18 opportunity to share our views on behalf of PFI
19 members. There's nearly 25,000 employees in 32
20 states, provide safe food for hundreds of millions of
21 dogs and cats in the United States and around the
22 world. We will be submitting our comments in writing.

1 Thank you.

2 MR. HECHT: Thank you very much, Ms. Brooks.

3 Next on the agenda was J. Mason Weeda. But he has
4 informed the Department he no longer wishes to speak
5 at this meeting.

6 Dr. McEntire has already spoke. And so,
7 well, and the last speaker was Brian Scarpelli, who
8 has also informed the Department that he no longer
9 wishes to speak today.

10 So we have gone through all the folks who
11 requested to speak at this meeting. Are there other
12 folks on the line who did not register, but who would
13 like to make a statement? If so, if you could please
14 let us know now your name, and if there's an
15 organization you're affiliated with, let us know that
16 as well, and we can try to divide up the remaining
17 time in an equitable manner.

18

19 Other Public Comments

20

21 MR. KENT: Hey, this is Matt Kent with Public
22 Citizen. I have something to add to the record.

1 It'll take 2 seconds.

2 MR. HECHT: Okay. We'll get to you. But I
3 think we'd just like to get a full list of all the
4 folks who would like to speak, so --

5 MR. KENT: Sounds good.

6 MR. HECHT: -- are there other folks who
7 would like to say something who have not yet spoken?

8 MS. LUTHULI: Hi.

9 MR. THOMSON: Hi. Yeah, this is Kyle
10 Thomson. Sorry. Kyle Thomson from the American
11 Medical Association.

12 MR. HECHT: Okay. Did I hear another voice?

13 MS. LUTHULI: Hi. This is Ahimsa Luthuli
14 from SEIU.

15 MR. HECHT: Okay. Anyone else? Okay. Well,
16 in that case, I will turn it over to Matt Kent from
17 Public Citizen.

18 MR. KENT: Yeah. Listen, I'll -- I've
19 listened to this entire hearing, and I won't
20 reiterate, you know, the huge legal issues that this
21 proposal -- the practical issues, you know, all the
22 problems that folks have really put a pin in here.

1 I'd just like to point out, you know, by my
2 count, we had 17 comments requesting a comment period
3 extension, a revision of the rule, or a complete
4 withdrawal of the rule. I haven't heard any comments
5 to move this rule forward as it is. And as pointed
6 out before, that's not -- that's across the spectrum.
7 We're dealing with public interest groups who're
8 saying that, but also major trade associations who are
9 asking for that.

10 So, I don't think it can be any more clear
11 from this hearing what the regulatory community and
12 just the larger public consensus is on this. I mean,
13 this is a really problematic proposal. And, you know,
14 it's incumbent on HHS to withdraw this thing. That's
15 all I have.

16 MR. HECHT: Okay. Thank you very much. Next
17 is Kyle Thomson. Mr. Thomson, you have 5 minutes.

18 MR. THOMSON: Hi, there. Thank you very
19 much. As I said, this is Kyle Thomson speaking on
20 behalf of the American Medical Association. I'd also
21 like to keep this short because we agree with many of
22 the comments that have already been made about the

1 ill-timing of this proposal and many of the legal
2 concerns that have been discussed thus far.

3 In particular, speaking from the AMA's
4 perspective, I think we, like a lot of the
5 organizations and stakeholders on this call, and maybe
6 others who are considering issuing comments, have been
7 focused almost solely on the COVID-19 pandemic. Our
8 resources have gone into advocating for appropriate
9 policies during the pandemic, and appropriate policies
10 that would address the pandemic as it continues. We
11 think HHS should be doing the same thing, and
12 diverting their resources accordingly.

13 This proposal with only 30 days to review the
14 proposal and in the midst of everything else that's
15 going on, it's extremely difficult for organizations
16 and interested parties to evaluate it and meaningfully
17 comment on it. So we would echo request to extend the
18 comment period from 30 days to 180. But we would also
19 suggest respectfully that HHS should withdraw this
20 rule and focus its efforts instead on the continuing
21 pandemic. Thank you.

22 MR. HECHT: Okay. Thank you very much, Mr.

1 Thomson. Next is Ahimsa Luthuli from SEIU. You have
2 5 minutes.

3 MS. LUTHULI: Thank you. My name is Ahimsa
4 Luthuli, and I'm a senior policy analyst at the
5 Service Employees International Union, which is the
6 largest union representing healthcare workers in the
7 United States, representing more than 1 million
8 healthcare workers, which are hospital workers,
9 homecare workers and nursing home workers. SEIU
10 opposes this regulation, and respectfully requests for
11 HHS to decline to pursue finalization of the rule.

12 This regulation would result in catastrophic
13 consequences by imposing SUNSET timelines on 18,000
14 HHS regulations that millions of individuals and
15 families rely upon for their health care. For
16 example, the Affordable Care Act was signed into law
17 in 2010, and many provisions that were implemented in
18 subsequent years will soon be approaching their 10-
19 year anniversaries and these provisions would be in
20 jeopardy through this blanket SUNSET rule.

21 Additionally, this rule is not necessary
22 because agencies can already review rules that have

1 become outdated or in the need of improvement. And
2 this rule burdens a smooth transition to a new
3 presidential administration.

4 And finally, this regulation would divert
5 critical resources away from addressing the
6 devastating COVID-19 pandemic that is now on the rise
7 all across this nation. Thank you.

8

9 Adjournment

10

11 MR. HECHT: Thank you much -- thank you very
12 much, Ms. Luthuli. So, just one last chance. Is
13 there -- are there other folks on the line who have
14 not yet spoken who would like to say something?

15 Okay. Great. Well, that concludes today's
16 public hearing. As a reminder, this hearing was
17 recorded and it will become part of the administrative
18 record. The comment period for much of this rule
19 remains open until December 4th and -- as of now. And
20 the comment period on the remainder of the rule
21 remains open to January 4th.

22

 The Department will consider the comments

1 expressed today as well as those expressed in writing.
2 And once again, we thank you all very much for
3 participating in this public hearing today and we hope
4 everybody has a great Thanksgiving. Thank you very
5 much.

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December 9, 2020

DATE WINJOY VIJAYAN

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