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

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P R O C E E D I N G S

Introduction

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

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

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

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

Overview of the Notice of Proposed Rulemaking

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

should be amended or rescinded, consistent with the stated objectives of applicable statutes to minimize any significant impact of the rules upon a substantial number of small entities.

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

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 Therefore, in order to ensure evidence-based regulation that does not become outdated as conditions change, HHS issued this notice of proposed rulemaking.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Public Comments

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.

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

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

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

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

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

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

it Medicaid or some other program.

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

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

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

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

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

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

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

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

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

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

So, Congress has already spoken to this issue

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

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

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

And of course these numbers and these

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

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

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

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

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

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

SPEAKER: Yes. Yes, we can.

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

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

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

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

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

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

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

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

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

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

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

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

and a number of groups participated in that.

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

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

The stated intention of completing this rule

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

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

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

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

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

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

This is an anti-regulation proposal. And so,

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

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

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

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

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

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

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

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

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

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

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

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

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

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

particular regulation.

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

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

I question whether HHS has estimated the

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

MR. HECHT: You have 1 minute left.

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

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

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

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

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

MR. HECHT: Yes. Thank you.

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

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

In fact, we did not even have an adequate

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

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

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

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

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

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

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

CDC data shows an increase in the number of reported multi-state food-borne illness outbreaks from 28 in 2014 to more than double that, 58, in 2018. The agency, FDA, is critical for food safety efforts, inspecting food facilities to both ensure food safety and compliance with regulations. Recently the Food Safety Modernization Act enabled FDA to focus more on preventing food safety problems by amending the Food, Drug and Cosmetic Act to increase the frequency of inspections of domestic food.

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

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

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

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

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

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

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

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

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

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

To that end, there are already measures in

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

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

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

At a minimum, there should be additional time

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

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

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

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

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

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

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

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

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

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

Thank you.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

UNIDENTIFIED SPEAKER: Probably waiting till 11:40.

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

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

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

BREAK

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

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

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

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

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

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

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

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

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

from tobacco products.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

for the passage of the Food Safety Modernization Act.

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

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

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

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

opportunity to comment. This concludes my remarks.

MR. HECHT: Thank you very much, Ms. McEntire. Ms. Musheno from the Autism Society of America, are you on the line now? Okay. Well, then we will proceed down the agenda.

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

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

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

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

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

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

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

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

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

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

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

SPEAKER: Sorry.

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

the test of time.

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

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

Thank you.

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

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

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

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

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

Since 2009 when the Family Smoking Prevention

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

consequence should this proposal move forward.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Want to point out that people with

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

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

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

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

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

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

distraction from the vital purpose that HHS serves.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

medical device supply.

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

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

Thank you.

MR. HECHT: Thank you very much, Ms. Brooks. Next on the agenda was J. Mason Weeda. But he has informed the Department he no longer wishes to speak at this meeting.

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

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

Other Public Comments

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

It'll take 2 seconds.

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

MR. KENT: Sounds good.

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

MS. LUTHULI: Hi.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Adjournment

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

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

The Department will consider the comments

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

CERTIFICATE OF TRANSCRIBER

I, WINJOY VIJAYAN, do hereby certify that this transcript was prepared from audio to the best of my ability.

I am neither counsel for, related to, nor employed by any of the parties to this action, nor financially or otherwise interested in the outcome of this action.

December 9, 2020

DATE WINJOY VIJAYAN

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