Questions for the Record- Chairman Alexander Hoehn-Saric
U.S. Consumer Product Safety Commission

The Honorable Cathy McMorris Rodgers

1. **In the summer of 2018, the CPSC commissioned Dr. Erin Mannen who was then at the University of Arkansas for Medical Sciences to conduct a study the results of which were used to ban products. Since then, the CPSC has continued to engage with Dr. Mannen and awarded her nearly $4 million in no-bid taxpayer contracts to conduct several additional studies on various product categories, the results of which were not peer reviewed, but are being used to pass new stringent regulations. The CPSC has paid Dr. Mannen personally, through "Mannen Bio LLC," hundreds of thousands in taxpayer money to serve as the CPSC's expert witness.**

    a. **Why did the Commission not seek to hire an expert who could provide internal studies at a much more affordable rate?**

    To further the Commission's work to protect one of our most vulnerable populations – infants and children – from serious injury or death resulting from a consumer product, an extensive search was conducted to identify potential candidates that had both the necessary biomechanical expertise and the facilities necessary to conduct infant testing. As such, significant effort was required to set up a testing environment that not only answered the detailed and difficult research questions but also was absolutely protective of the test subjects. CPSC has neither the facilities nor the resources necessary to conduct such studies internally.

    Although I was not Chair when this contract was awarded (and do not agree with all the facts asserted in the question), my understanding is that CPSC staff identified Boise State University (BSU) and Dr. Mannen as having a unique capability to meet the above requirements.

    b. **Explain what due diligence was conducted on Dr. Mannen. Was it discovered that Dr. Mannen has been personally retained by dozens of plaintiffs in lawsuits across the country related to the work she has done for the CPSC?**

    As mentioned above, given the nature of the infant testing and the need for strong biomechanical expertise, an extensive search was conducted to identify potential candidates that had both. Dr. Mannen also served as the expert for the Commission in their litigation with Leachco. CPSC staff is not aware of Dr. Mannen's other representation work.

    c. **How do you reconcile Dr. Mannen's personal financial stake in the CPSC's continued rulemaking based on her CPSC contracted work and plaintiff work?**

The CPSC-contracted work provided by BSU is based on Dr. Mannen's scientific expertise as a biomechanical engineer and past research in this field. Dr. Mannen has the unique set of experiences and expertise in: infant biomechanics; leading a team within her university that includes pediatricians and pediatric pulmonologists; and testing young infants. She has completed groundbreaking research involving young infants (2-5 months) who were tested in inclined products. Dr. Mannen has developed widely regarded test methods and test equipment to monitor and record infant movement, muscle activity, and oxygen saturation while testing infants. She has also established safety protocols to end testing before the infant is distressed. Safely testing infants is a highly specialized field of study that requires experienced researchers, technicians, medical staff, and safety oversight.

d. **The CPSC's Statement of Principles: Integrity of the U.S. Consumer Product Safety Commission Staff's Scientific and Technical Work[1] states that "CPSC aims to conduct this work with an integrity that is beyond reproach because policy makers rely upon this work to make important decisions and because the public places its trust in the work of the Commission." Given the statement of principles, can you see how Dr. Mannen can be biased while both taking taxpayer funds to support your work and receiving payment from plaintiff attorneys who have a specific interest in litigating on the very same rules?**

My understanding is that CPSC staff has no reason to believe the assertions of bias made in the question, and that they are not aware of any conflicts of interest.

e. **According to your February 2024 Scientific Integrity Policy:**

CPSC employees and contractors are required to design, conduct, manage, evaluate, and report scientific research and other scientific activities honestly and thoroughly, and disclose any conflicts of interest (that the employee or contractor does not themselves resolve in accordance with applicable requirements) to their supervisor and the Office of the General Counsel (Ethics@cpsc.gov) for their determination as to whether a recusal, disclaimer, or other appropriate notification would be appropriate.

Why have Dr. Mannen's conflicts of interest not been publicly disclosed in the scientific research that CPSC relies upon for rulemaking?

See response to subpart d.

f. **It appears that Dr. Mannen has a professional history of failing publicly to disclose her conflicts of interest. On two occasions with peer reviewed articles associated with taxpayer-funded research, Dr. Mannen disavowed any conflicts of interest.[3, 4] Given Dr. Mannen's history of failing to disclose conflicts of interest in her published research and her CPSC-funded work,**

will you reconsider providing Dr. Mannen with no-bid contracts and instead follow open bidding in accordance with federal procurement policy?

See response to subpart d. CPSC followed all the requirements of the Federal Acquisition Regulations (FAR) here and will continue to comply with FAR.

g. **What will the CPSC Scientific Integrity Committee (SIC) and Scientific Integrity Official (SIO) do to ensure that highly influential contractor research is free from bias and conflict of interest?**

Research such as that conducted by Dr. Mannen and BSU – to inform staff's recommendations on rulemaking – is provided as part of the rulemaking record for public comment. As such, this research, along with staff's review, and the rest of the regulatory documents undergo extensive review. Under the Administrative Procedure Act, any assertions of flaws in that research, whether resulting from bias, conflict of interest or other causes, would be carefully reviewed and necessarily addressed as part of the rulemaking process.

h. **Please identify the CPSC SIO and members of the SIC who are responsible for ensuring contractor conflicts of interest are disclosed and the CPSC's Scientific Integrity Policy is followed.**

Mary Kelleher, the Associate Executive Director for Health Sciences, is the agency's SIO. The SIC is comprised of a rotating set of career staff representing various offices and specialties across the agency.

i. **Please provide a list of all the cases where Dr. Mannen has testified since 2018 as well as any additional lawsuits where Dr. Mannen has been retained as either a consulting or expert witness.**

CPSC staff does not have this information.

j. **Please identify all of Dr. Mannen's work that CPSC is relying upon as a basis for rulemaking and enforcement actions.**

Biomechanical Analysis of Inclined Sleep (2019); Crib Bumper Product Characterization and Testing (2021); Boise State University's Seated Products Characterization and Testing (2023); Pillows Products Characterization and Testing (2022).

k. **The CPSC's <u>Information Quality Guidelines</u> provide:**

> **On April 24, 2019, [the U.S. Office of Management and Budget (OMB)] issued updated guidance to federal agencies regarding the Information Quality Act (IQA). OMB Memorandum M-19- 15, Improving Implementation of the Information Quality Act**

(Apr. 24, 2019). CPSC is committed to complying with the IQA and to implementing the updates listed in M-19-15. CPSC revised certain provisions of the agency's guidance in response to M-19-15.

Guidance policy M-19-15 provides guidance on "influential" information that is disseminated by the CPSC. Specifically, it provides:

> **In the context of a policy decision, a specific piece or body of information is 'influential' when it is a principal basis for a decision by a federal decisionmaker, that is, if the same decision would be difficult to reach in that information's absence or if the decision would lose its fundamental scientific, financial, or statistical underpinnings absent the information.[6]**

The CPSC's Information Quality Guidelines, further deems "staff and contractor technical reports related to engineering, health science, or hazard analysis issues that potentially have impacts on important public policies and private sector decisions" as "influential" information.[7] Additionally, in Federal Register notices associated with two rulemakings, CPSC stated that the Infant Sleep Product Rule[8] and the proposed Safety Standard for Infant Support Cushions[9] are based on Dr. Mannen's CPSC- commissioned research. Yet neither of these two studies were peer reviewed.

i. **Please confirm that the CPSC deems Dr. Mannen's 2019 inclined sleeper study, which led to the final rule banning inclined sleepers as a product category, as "influential" information. If not, why not?**

The Commission's rule banning inclined sleepers codifies the ban enacted by Congress in the Safe Sleep for Babies Act, thereby aligning CPSC's regulations with the statute. The Commission did not rely on Dr. Mannen's work in that proceeding.

Before that statutory ban, in 2021, the Commission did adopt performance requirements for infant sleep products in the Infant Sleep Products Rule. Staff analysis, death and injury information, and the Mannen study were used to inform staff recommendations to the Commission on addressing the hazards associated with infant inclined sleep products, which at that time had been associated with 59 deaths. The staff briefing package, as well as Dr. Mannen's report, were put out for public comment. CPSC received extensive comments, including from those with advanced technical and medical degrees, and staff carefully considered the responses in crafting the proposed final rule.

ii. **What steps, if any, has the CPSC taken to have the results and conclusions with Dr. Mannen's studies verified by a qualified third party?**

As discussed above, all studies and other materials on which CPSC relies in its rulemakings are subject to full public review through the notice and comment process of the Administrative Procedure Act. In the case of Dr. Mannen's reports, CPSC has received extensive comment, including technical input from individuals with advanced technical and medical degrees.

l. **It is my understanding that your agency has rejected Freedom of Information Act (FOIA) requests to make public the data underpinning Dr. Mannen's "influential" research that the CPSC has relied upon for rulemaking. Your Scientific Integrity Policy identifies "transparency" as a "hallmark of scientific integrity." Furthermore, your Information Quality Guidelines recognize the critical importance of reproducible influential information, noting that "CPSC's influential information should be highly transparent and capable of being reproduced by qualified persons."**

i. **Has the data from Dr. Mannen's studies commissioned by the CPSC been made publicly available so that it can be reproduced by a qualified third party?**

See response to subpart k (ii).

1. **If so, has a qualified third party reproduced the data within any of Dr. Mannen's studies commissioned by the CPSC?**

See response to subpart k (ii).

2. **If not, will you commit to making publicly available Dr. Mannen's research data the CPSC has relied upon as "influential" information "to facilitate reproducibility by qualified parties" as provided in your Information Quality Guidelines, including, but not limited to, all measurements taken and/or collected by Dr. Mannen and her team during her testing of products, and all In-Depth Investigation (IDI) reports provide to her team for hazard analysis?**

As noted, any Commission reliance on Dr. Mannen's work for rulemaking was vetted through the notice and comment process of the Administrative Procedure Act, at the time of the rulemaking. Any future reliance on these materials to support Commission rulemaking would be similarly subject to public review.

2. **In relation to CPSC's Retailer Reporting Program, which the Committee understands is a voluntary program through which some retailers report product safety information to the Commission on a weekly basis:**

a. **How many companies currently participate in the Retailer Reporting Program?**

Seven companies participate in the Retailer Reporting Program. I do want to note that every manufacturer, retailer, and distributor has a duty under Section 15(b) of the Consumer Product Safety Act to immediately inform the Commission of information that reasonable supports the conclusion that a product creates an unreasonable risk of serious injury or death, contains a defect, fails to comply with a rule, standard or ban under the Act, or fails to comply with a rule or standard upon with the Commission has relied under Section 9. This obligation exists in addition to any reporting under the Retailer Reporting Program.

b. **How often does the CPSC add new participants to the program?**

CPSC has not added any new participants since 2009.

c. **What is the CPSC's criteria for selecting companies to participate in the program?**

CPSC has no present plans to expand the program and add additional participants.

The Honorable Gus Bilirakis

1. **I understand that the CPSC recently added guidance on their website explicitly stating that for purposes of CPSC phthalate regulations, commercial moon bounces should be treated as a toy. I have been told moon bounce manufacturers have been following ASTM voluntary standards in terms of phthalate content and that these are different from the requirements for toys.**

a. **Can you please explain the process the agency went through to update their website guidance, the notice they provided to industry, and the timing?**

Updated guidance was recently added to the CPSC website to clarify which consumer products are subject to the phthalates requirements after product testing revealed inflatables with unlawful levels of regulated phthalates. Children's toys "designed or intended by the manufacturer for a child 12 years of age or younger for use by the child when the child plays" are subject to the phthalates requirements under section 108 of the Consumer Product Safety Improvement Act of 2008 (CPSIA). Unlike toys defined under ASTM F963 (toy standard), the phthalates standard does not exclude constant air inflatables. Therefore, even though constant air inflatables are not subject to the toy standard, they are still required to meet the phthalates requirements if designed for use by a child 12 years of age or younger when the child plays.

The updated guidance provides clarification on the definition of children's toy and includes examples. The updated guidance to which you refer was reviewed

by multiple offices within the agency, including but not limited to the Small Business Ombudsman, Division of Human Factors, Office of Compliance and Field Operations, and Office of the General Counsel.

b. **Did the agency inform ASTM, the voluntary standards body?**

Yes, staff met with the ASTM F2374 Task Group on inflatable amusement devices to discuss industry's questions and concerns regarding the enforcement of the phthalates requirements.

c. **Are you aware of any illnesses that have resulted from current phthalate levels in moon bounces?**

No.

2. **In a standard case where section 6(b) would apply, what is the process for providing a company notice of public disclosure of information?**

The standard process for providing notice to a manufacturer or private labeler about public disclosure of information is outlined in CPSC's regulations at 16 C.F.R. part 1101. Subpart C – Procedure for Providing Notice and Opportunity to Comment under Section 6(b)(1) (16 C.F.R. § 1101.21-26) – outlines the procedures for disclosures when the information pertains to a specific product that can be readily ascertained by the public and has been obtained, generated, or received by those acting in their official capacities on behalf of the Commission. 16 C.F.R. § 1101.11(a). The Supreme Court has determined that the provisions under Section 6 also apply to disclosures under the Freedom of Information Act. *See GTE Sylvania, Inc. v. Consumers Union*, 100 *S. Ct.* 2051 (1980).

a. **How long does it take CPSC staff to provide notice to a company?**

CPSC staff provides notice to a firm once a legal determination is made that the proposed public disclosure of information is required and the information proposed to be disclosed is subject to the provision of section 6(b). In general, staff must provide this notice 15 days prior to public disclosure. The law allows the Commission to shorten the time for public disclosure based on a public health and safety finding; such a finding must be made by the Commission and is not delegated to CPSC staff.

b. **Have timeframes differed, and if so, why?**

See response to subpart a.

c. **Are there examples of a commissioner or staff using social media or other electronic communication outside of the proper reporting avenues to notify companies and the public? Please provide those examples.**

> Section 6(b) applies to all CPSC employees, including Commissioners, for all forms of communications. All employees receive annual training on procedures for disclosing information subject to section 6(b), and the agency's clearance procedures for providing information to the public are designed to minimize risk of inadvertent disclosure in any medium. Should a manufacturer, private labeler, distributor, or retailer believe that information has been publicly disclosed in violation Section 6(b), the Consumer Product Safety Act (CPSA) provides an administrative remedy to review such a claim. See 15 U.S.C. § 2055(6)(b)(7). The Commission has codified this retraction remedy at 16 C.F.R. § 1101.51.

3. **The CPSA restricts the CPSC from issuing mandatory rules unless it can prove that voluntary standards would not "adequately reduce the risk of injury." How does the Commission expect to withstand judicial scrutiny of its analysis of the effectiveness of voluntary standards under *Loper Bright*?**

   For consumer product safety standards promulgated under Sections 7 and 9 of the CPSA, the CPSA requires that:

   > The Commission shall rely upon voluntary consumer product safety standards rather than promulgate a consumer product safety standard … whenever compliance with such voluntary standards would eliminate or adequately reduce the risk of injury addressed and it is likely that there will be substantial compliance with such voluntary standards. 15 U.S.C. § 2056(b)(1).

   By law, Commission determinations concerning whether a voluntary standard would eliminate or adequately reduce the risk of injury are fact-based determinations based on the rulemaking record. The CPSA details the factual determinations CPSC must make in order to promulgate consumer product safety standards under Sections 7 and 9. Those findings are:

   - The degree and nature of the risk of injury the rule is designed to eliminate or reduce;
   - The approximate number of consumer products, or types or classes thereof, subject to such rule;
   - The need of the public for the consumer products subject to such rule, and the probable effect of such rule upon the utility, cost, or availability of such products to meet such need;
   - Any means of achieving the objective of the order while minimizing adverse effects on competition or disruption or dislocation of manufacturing and other commercial practices consistent with the public health and safety;
   - That the rule (including its effective date) is reasonably necessary to eliminate or reduce an unreasonable risk of injury associated with such product;
   - That the promulgation of the rule is in the public interest;
   - In the case of a rule declaring the product a banned hazardous product, that no feasible consumer product safety standard under this chapter would

adequately protect the public from the unreasonable risk of injury associated with such product;

- In the case of a rule which relates to a risk of injury with respect to which persons who would be subject to such rule have adopted and implemented a voluntary consumer product safety standard, that—
    - compliance with such voluntary consumer product safety standard is not likely to result in the elimination or adequate reduction of such risk of injury; or
    - it is unlikely that there will be substantial compliance with such voluntary consumer product safety standard;
- That the benefits expected from the rule bear a reasonable relationship to its costs; and
- That the rule imposes the least burdensome requirement which prevents or adequately reduces the risk of injury for which the rule is being promulgated.

15 U.S.C § 2058(f)(1), (3).

The Commission then publishes preliminary factual findings in a notice of proposed rulemaking issued under CPSA sections 7 and 9 and seeks public comment on those preliminary findings. The agency considers any comments received before issuing final findings in a final rule.

Therefore, the Commission's determination whether "voluntary standards would eliminate or adequately reduce the risk of injury" is based on a record of factual findings, following strict mandates from Congress. Under these circumstances, *Loper Bright* will have limited effect on such determinations. Of greatest importance, courts will still look to the rulemaking record in evaluating the adequacy of agencies' factual findings.

4. **We have heard concerns expressed about the agency's approach to data recently, specifically that there is not transparency in data cited by CPSC, that it is often incomplete and only details are included that would support a pre-drawn conclusion, that sometimes data is withheld until an NPR is released, that CPSC has become an agency driven by anecdotal information rather than science, and that the agency applies no or less weight to data submitted by industry sources. How do you respond to these concerns?**

CPSC is a data-driven agency that relies on a wide range of data sources and information to do our work. Consistent with Commission policy and in adherence to our statutes and regulations, we make data available to the public for review and analysis. National Electronic Injury Surveillance System (NEISS) data are downloadable and searchable and used by researchers, industry, and advocates. Similarly, the public elements of the consumer complaint database are downloadable and searchable.

Some of the information that CPSC relies upon – such as police reports and coroner's notes detailing injuries that led to death – are extremely sensitive and contain personally identifiable information (PII) including sensitive information about victims and their families. These are the details of the worst day of a family's life. CPSC must be diligent

and careful in ensuring that we protect the privacy of the individuals and families whose details are included in those reports, as the law requires.

Other data that we rely upon is statutorily protected from disclosure without consent from the company that submitted it to us. CPSC endeavors to release as much data as the submitting company will permit.

a. **What can you tell us that will assure us that integrity and completeness of data – and development of standards and regulations that have full access to relevant, analyzed, verified, timely and complete data (minus redacted details such as personal information and CBI, that we recognize must be protected) is paramount to the agency?**

   Following the decision in *WCMA v. CPSC* that was issued in September 2023, CPSC took steps to ensure that, consistent with statutory confidentiality requirements, we release detailed data regarding every incident that staff relies upon in developing proposed rules. For the proposed rules that were issued prior to the court opinion, we have been issuing Notices of Availability to give commenters time to review the data and provide additional comments on the rule based on that data. For proposals issued after the court opinion, we have included the data release as part of the Notice of Proposed Rulemaking.

b. **What are the ways you will work to ensure the agency's adherence to reliable, actionable data – and to processes that provide for, and adhere to, a scientific, risk-based approach?**

   CPSC takes pride in being a data-driven, scientific agency. We set regulatory priorities based on incident data, stakeholder input provided at our Priorities Hearing and throughout the year, staff research and recommendations, legislative direction, and the limitations of available resources. I am always happy to meet with stakeholders to discuss our priorities and the approach that we take toward regulation and enforcement.

5. **What is the CPSC's assessment of the likelihood of a web of patent issues arising from the proposed rule on table saws, potentially leading to lawsuits against other manufacturers in the table saw space? How might this affect the overall industry?**

   The Supplemental Notice of Proposed Rulemaking (SNPR) that was adopted by the Commission in November 2023 proposes a performance-based standard to address the hazards associated with blade-contact injuries caused by table saws. The SNPR would require table saws to limit the depth of cut to no more than 3.5 millimeters when a test probe (acting as surrogate for a human finger or other body part) approaches the spinning blade at a rate of 1 meter per second. The SNPR does not require a specific technology to achieve this result.

   CPSC staff believes that implementing an active injury mitigation (AIM) system would

meet the performance standard and proposed a three-year implementation period to give industry time to develop these systems.

The AIM technology developed by SawStop is one potential solution to the proposed rules' performance standard, but it is not the only one. CPSC sought comment on a range of issues related to the proposed rules and numerous companies and trade groups have provided information on market-related issues. Staff is currently assessing those comments.

a. **In the absence of licensing commitments from SawStop, how does the CPSC plan to foster and protect innovation within the table saw industry?**

   As mentioned above, the SNPR does not require a specific technology. It includes a proposed three-year implementation period to give industry time to develop AIM systems.

b. **If SawStop were to issue licenses, how would the CPSC ensure that the proposed rule does not unfairly disadvantage other manufacturers who might be unable to afford or obtain licenses?**

   See response to subpart a.

c. **Is the CPSC privy to data that shows the current voluntary standard lacks substantial compliance?**

   The SNPR includes incident data through 2021. The data confirm that CPSC staff has seen no decline in the number of injuries reported between 2010 and 2021. The voluntary standard became effective in 2010.

d. **In the Small Business Administration's comments on the proposed rule, SBA stated that the rule would have significant detrimental impacts on U.S. small businesses due to costs. Did the Commission review and consider SBA's comments?**

   CPSC staff is in the process of reviewing all comments to the SNPR, including any comments made by other federal agencies.

e. **Is there a viable explanation as to the claims between the CPSC estimates and expert review?**

   Unfortunately, I need additional background information in order to provide an answer to this question.

f. **Has the CPSC conducted a thorough analysis of the potential increase in costs for consumers if SawStop's technology becomes the mandated safety standard? If so, what were the findings?**

As mentioned above, the SNPR does not mandate a specific technology be used to meet the performance standard. According to the SNPR, the proposed rule would prevent or mitigate the severity of an estimated 49,176 injuries treated in hospital emergency departments or other medical settings per year. The Commission further estimates that net benefits would range from approximately $1.28 billion to $2.32 billion per year.

g. **How does the CPSC address concerns that the proposed rule might significantly increase costs for consumers and manufacturers without proportionate safety benefits?**

The SNPR predicts that the proposed rule would prevent or mitigate the severity of an estimated 49,176 injuries treated in emergency departments or other medical settings per year. The Commission further estimates that net benefits would range from approximately $1.28 billion to $2.32 billion per year.

h. **How can you confirm the accuracy and timeliness of the accident data sources the CPSC has used to justify the proposed rule?**

Data used in support of the proposed rule come from the National Emergency Injury Surveillance System (NEISS) and from a 2017 study of emergency department-treated table saw blade contact injuries. The NEISS consist of data on emergency room visits due to injuries caused by consumer products from a representative sample of hospitals.

i. **Has the CPSC separated incidents that occurred on consumer saws and contractor/cabinet saws? It is my understanding that CPSC does not have jurisdiction over saws that are used on job sites. Why hasn't the CPSC separated the incidents to get a true understanding of the safety concerns?**

The data used for the SNPR exclude data on workplace use of professional table saws – like bench saws, contractor saws, and cabinet saws. These types of saws are also widely purchased and used in consumers home shops, which is why they are covered in the SNPR. If the proposed rule becomes final, only those saws that meet the definition of a consumer product would fall within the scope of the rule.

j. **Can the Commission provide the Committee with a breakdown of where injuries are occurring segmented by category of table saw?**

The data in the SNPR are summary data. CPSC staff is currently working to provide more incident data for public review, but staff must first remove personally identifiable information. Upon completion of this effort – which is massive, given the large number of amputations and other serious injuries associated with table saws – more specific incident data will be made available to the public in a future notice of availability published in the Federal Register.

6. **The CPSC and U.S. Customs and Border Protection just recently expanded the Beta Pilot Test seeking up to 2000 participants to continue to test eFiling.**

   a. **What is the status of the Beta Pilot Test?**

   CPSC formally ended the first phase of its Beta Pilot on June 30th and has invited up to an additional 2,000 importers to join an expanded Beta Pilot. On June 4th, CPSC published a Federal Register Notice (FRN) (89 FR 47922) announcing the expanded pilot and the 60-day public comment period ended on August 5th.

   As of August 16th, 109 importers have requested to join the expanded pilot.

   b. **How many companies are participating in the pilot?**

   There are 37 importers that – with support from their trade partners (i.e., brokers and laboratories) – are participating in the pilot. As of August 16th, an additional 109 importers have requested to join the expanded pilot.

   c. **What are the key issues that have been identified during the pilot?**

   Importers, both large and small, have expressed concerns surrounding the time and resources needed to understand the eFiling requirements and update their systems in order to comply with the program. There is also uncertainty among importers about how the eFiling requirements apply to certain complex trade scenarios such as diverse product lines, direct import shipments, *de minimis*, and foreign trade zones. Finally, large importers have highlighted the need for more advanced technical solutions to manage data and automate processes in order to handle the high volume and complexity of product certificate compliance data that exists for their business.

   d. **How are those issues being addressed?**

   CPSC is committed to providing trade with clear and comprehensive guidance and resources to support the eFiling learning process and address key issues identified during the Pilot.

   CPSC published an eFiling Quick Start Guide, intended to support importers and their trade partners through the beginning stages of eFiling implementation. This document was informed by lessons learned throughout the Beta Pilot and highlights suggested best practices for new importers as they begin preparing for eFiling. Among these suggestions: considerations for time, resources, and advanced technical solutions needed to comply, especially when managing a high volume of products.

   The eFiling support team has also published improved training materials based on

Beta Pilot participant feedback to support advanced technical solution development such as an API Specifications document, a User Guide for CSV bulk upload, and Product Registry Training Videos, all available in the eFiling Document Library on our website.

Additionally, CPSC continues to provide an open-door policy to importers through our eFiling Beta Pilot Support Mailbox, participant feedback sessions, and ad-hoc one-on-one meetings with importers to understand the complex trade issues they are facing and how these issues are affecting their certificate filing capabilities. CPSC has a dedicated email inbox at eFilingSupport@cpsc.gov to serve as a direct line of communication, allowing both participants and non-participants to seek guidance on complex process and technical questions. Staff uses this inbox daily to support importers through their troubleshooting, development processes, and general eFiling process questions. Staff incorporates their feedback into our processes and applies a continuous feedback loop to ensure the program meets industry needs. Staff continues to review the comments filed in the rulemaking proceeding and is in the process of preparing for the Commission's consideration a draft final rule that is designed to product consumers and facilitate the inspection of consumer products imported in the U.S., taking into consideration the issues raised by industry.

e. **Can you please discuss how the CPSC is justifying the eFiling Beta Test Pilot as a ramp up period for both importers and the agency to test their systems before a final rule is published?**

CPSC staff is using the Beta Pilot as an opportunity to determine concerns from industry, understand potential roadblocks to implementation, and develop additional resources to address these issues. Participation is completely voluntary.

The expanded pilot allows interested importers to begin preparing for eFiling at their own pace, before being required to eFile certificate data for all of their products subject to a CPSC rule, ban, standard, or regulation. My understanding is that industry has expressed support for the Beta Pilot and expansion, so importers can prepare in advance, instead of waiting until publication of the final rule.

For instance, CPSC learned from the Beta Pilot that the preparation needed to eFile certificate data can take a significant amount of time. Customs brokers, who file on the importers' behalf, must update their software to submit data via CPSC's Partner Government Agency Message Set. When surveyed, these brokers took an average of nine months to update their software.

Furthermore, it became apparent during the Beta Pilot that importers need to collect their certificate information in a data format in order to eFile. Previously, many importers maintained certificates as PDFs. Many importer participants took several months to prepare before eFiling their certificate data as part of the Beta pilot.

f. **Does the CPSC not expect to make any changes to the requirements when a final rule is published?**

CPSC staff has reviewed all comments made during the rulemaking process and will provide recommendations on a final rule for Commission consideration.

g. **Does the CPSC plan to address the significant concerns that have been raised by importers and other stakeholders during the comment period? What about changes based upon lessons learned from the Beta Pilot?**

CPSC staff has reviewed all comments made during the rulemaking process and will provide recommendations on a final rule for Commission consideration. As mentioned earlier, staff has used lessons learned from the Beta Pilot to improve useability of Product Registry features and prioritize new development. That being said, a pilot used for testing and a proposed rule are two different things. While CPSC staff believes the Beta Pilot has helped them to inform the final rule that will go to the Commission, the Beta Pilot is not meant to continuously update the rule. Once the rule is finalized, that will become the standard. Finally, my understanding is that CPSC staff is specifically considering the time industry will have to develop tracking and reporting systems before the eFiling rules are effective and enforced.

h. **How has the CPSC addressed the technical issues and glitches that have occurred during the e-filing process, such as system outages, data errors, and delays?**

The Beta Pilot was designed to minimize any potential disruptions to importer participants as the eFiling system evolves. Any errors encountered as a result of ongoing development had no impact on trade operations.

Significant effort has been made to keep trade users informed of development progress. Any delays in implementation of specific features have been openly communicated via both public meetings and individualized support requests. To help with the prioritization of limited development resources, Beta pilot participants were also surveyed to determine which upcoming application features they were most interested in.

i. **How has the CPSC ensured the security and confidentiality of the sensitive data that is submitted electronically, such as trade secrets, proprietary information, and personal information?**

CPSC systems communicate with U.S. Customs and Border Protection (CBP) via two channels. In both cases, the contents of the communications are well-defined messages in Extensible Markup Language (XML) format. In the first channel, CPSC contacts CBP's Secure File Transfer Protocol (SFTP) service, which is a

secure, encrypted file transfer mechanism for the acquisition of Entry and Entry Summary XML files. CBP supplies credentials and handles authorizations for its SFTP server, and CPSC ensures that the provided credentials are both stored and supplied in an encrypted format with every connection.

The second channel uses CBP's Interoperability Web Services (IWS) Event Messaging architecture, through which CPSC and CBP participate in two-way communications of real-time updates of Entry statuses. All communication around IWS Events use encrypted channels. CBP and CPSC maintain shared secrets (encrypted in their respective systems) that are used only for this communication. With each request, the secrets are supplied by the requestor and validated by the receiver, who then generates a token for that communication exchange. This pattern ensures that every instance of communication between CBP and CPSC is secure.

In addition to the above mechanisms, CBP and CPSC use many other standard security techniques, such as: limiting the network addresses that are allowed to access hosts, firewall technologies, denial of service defenses, protocol scanners, and additional mandated defenses to detect and prevent a range of attacks that could be attempted on the networks of each organization or the communications between them.

j. **How is the CPSC evaluating the effectiveness and efficiency of the e-filing? What are the key performance indicators and metrics that are used?**

CPSC is tracking several metrics to evaluate effectiveness and efficiency, including: the number of message sets eFiled; activity by importer and broker; frequency of Harmonized Tariff Codes used; number and type of users in the Product Registry; and number of certificates entered into the registry by importer. Staff is also validating a random selection of eFiled certificates against testing laboratory reports to make sure that certificate data were properly entered. Staff informs importers of any errors found during validation.

k. **What are the main challenges or barriers that importers face in complying with the e-filing regulation? How is the CPSC working to address those issues?**

See response to subpart c.

l. **Do you believe that its system as well as CBP's Automated Commercial Environment will be fully ready for a January 1, 2025, implementation date for eFiling? If so, please explain.**

Should the proposed rule move to a final rule, CPSC staff will recommend an implementation period for the Commission's consideration.

m. **What consideration is the agency giving to difficulties that thousands of small businesses will have in transitioning to an eFiling system?**

As an initial matter, only companies that import products into the U.S. will be impacted by the eFiling system. Small businesses that manufacture domestically will not be affected by the implementation of eFiling.

With respect to businesses importing consumer products, CPSC's Product Registry was developed so that any business – small or large – can enter and maintain their certificate data. The Registry includes features for bulk certificate upload, trade party management, and creating new versions from existing certificates. These features will be particularly useful for small businesses, because there will be no requirement to invest in additional information technology internally. Staff has also developed guidance materials that will assist all importers and will work with our office of the Small Business Ombudsman should the proposed rule become final.

7. **In light of some of your recent public comments regarding online marketplaces and the need for greater cooperation with online retailers, particularly as it relates to foreign sellers selling on those marketplaces, what is the CPSC doing to coordinate with online marketplaces to address these challenges?**

CPSC's e-SAFE team regularly engages with online marketplaces to request the removal of hazardous products they identify online. In my time as Chair, we have issued more than 110,000 take down requests. However, online marketplaces are in the best position to prevent these listings from appearing to consumers in the first place.

8. **Is the Commission engaged in dialogue with these eCommerce marketplaces or seeking voluntary commitments? Does the Commission believe it has the authority to mandate certain actions from these parties with respect to products imported and sold by third- party retailers?**

Federal law prohibits the sale or re-sale of products that have been recalled. I have met with multiple online marketplaces in my time as Chair to discuss how online marketplaces can take accountability for the products they allow to be sold on their platforms, and the importance of preventing listings of hazardous, banned, and recalled products from appearing to consumers in the first place. At times, online marketplaces have contested the authority of the CPSC and the application of the CPSA to online marketplaces, particularly with respect to products sold by third-party retailers. Congress clarifying that all online marketplaces should be held to the same safety obligations as brick and mortar stores would go a long way to help CPSC work with industry to keep their sites safe from dangerous products.

9. **What is the Commission's view on the breadth or adequacy of its authority (under the CPSA or CPSIA) to hold online marketplaces legally responsible for the sales (or subsequent recall) of goods sold by third-party retailers on those marketplaces?**

Consumers don't distinguish online marketplaces from brick and mortar stores when it comes to safety. They expect the products they buy online to be just as safe. Under our statute, retailers, distributors, and manufacturers are required to report when they know of a dangerous or defective product. Most work cooperatively with CPSC to conduct a recall, when needed. Congress clarifying that all online marketplaces should be held to the same safety obligations would go a long way to help CPSC work with industry to keep their sites safe from dangerous products.

10. **How does the Commission plan to regulate or otherwise require participation with respect to recall and reporting obligations for online marketplaces in the absence of any clear indication that these marketplaces are acting as traditional manufacturers, distributors, retailers or importers of record?**

Today, online marketplaces are in the best position to prevent hazardous, banned, or recalled products from appearing on their sites. They have the resources to do it and those who fail to prioritize safety are undermining consumer trust for the entire industry. CPSC will take action to protect consumers where online marketplaces fail to meet their obligations under the law. Recently, the Commission found that Amazon acted as a distributor with respect to certain imported product sold on its site. The Commission, however, does not comment on any pending enforcement investigation. Here is a link to relevant filings and decisions in that matter.

11. **How does the Commission approach product history in conducting its review of products or regulations? Stated another way, what role or value does the Commission place on "experiential data"?**

    a. **For example, if 200,000 products are sold and there are less than 5 injuries or even deaths associated with that product, does the Commission consider that experiential data in its analysis? And if so, how?**

CPSC's mission is to protect the public from unreasonable risks of injury or death from consumer products. The statute does not suggest that the Commission should define "unreasonable risk" with a mathematical accounting of injuries and deaths (to the contrary, other factors like the product's utility and exposure to vulnerable populations like children may be highly relevant); it does not set a minimum number of incidents that must occur before action can be taken to protect consumers; and it does not tell the agency to refrain from addressing hazards presented by popular products. Under the law, CPSC does not need to wait for a body count and may act before injuries or deaths occur, depending upon severity of the risk of harm, the hazard pattern, and vulnerability of the potentially affected population.

In my experience the Commission exhaustively reviews and relies on death and injury data when considering potential new safety rules. CPSC spends considerable time and resources collecting and reviewing death and injury data that we receive from a variety of sources.

The Consumer Product Safety Act (CPSA), CPSC's primary authorizing statute, lays out different requirements for establishing safety standards across a class of products. As an illustrative example, CPSC applies the rulemaking provisions in Sections 7 and 9 of the CPSA for many consumer products. Those sections dictate that CPSC must make numerous findings before it can issue a final rule, including that the benefits bear a reasonable relationship to the costs. And the law requires that the Commission weigh the "degree and nature of the risk of injury the rule is designed to eliminate or reduce" as well as the probable effect of a rule on the "utility, cost, or availability" of the subject product.

However, another category of products, durable nursery products developed specifically for use by infants and toddlers, have a different standard established in Section 104 of the Consumer Product Safety Improvement Act of 2008. For these consumer products, the Commission is called upon to issue mandatory safety standards that are substantially the same as applicable voluntary standards or more stringent if necessary to further reduce the risk of injury associated with the product. After CPSC establishes these initial safety standards, the Commission is required to periodically review and revise them to ensure the highest level of safety that is feasible. Under the statute CPSC is also required to adopt revisions to applicable voluntary safety standards unless the Commission finds the revision does not improve the safety of a product. These obligations are placed on the Commission regardless of whether and how many injuries and deaths have been reported in the product.

12. **This question pertains to the Commission's enforcement practice, which includes pursuing civil penalties for late reporting of potential product safety hazards to the CPSC. The Committee is concerned with inconsistent enforcement against American businesses. In the past four years, the CPSC has levied 11 penalties against companies founded and operating in the United States. The CPSC recently targeted an Oklahoma family's small business that sells children's products, before an independent adjudicator dismissed the CPSC's case. You have praised CPSC's increased aggressiveness as "no small feat."**

a. **Out of concern of the cost to business, Congress has limited the maximum penalty that the Commission may impose at approximately $17 million for a related series of violations. You support efforts to increase that limit, and a bill to raise the limit has been introduced in Congress, but it is not the law. Despite this, we have heard concerning reports that your staff is demanding sums above the statutory cap to resolve matters.**

b. **Is this occurring? What is the Commission's authority for this?**

Commission staff is not demanding civil penalties above the statutory cap. All of CPSC's closed civil penalty cases and their amounts are posted publicly on our website.

13. **The Committee is aware that the CPSC requires laboratories that test consumer products to be accredited to ISO/IEC 17025 by an accreditation body recognized by the agency. Yet the CPSC's National Product Testing and Evaluation Center is not ISO-certified.**

a. **Why does the CPSC exempt its laboratory from meeting standards that it requires independent laboratories to meet? Should the CPSC laboratory meet ISO/IEC standards? Will you commit to having the CPSC laboratory ISO-accredited?**

As a regulator, CPSC's role in creating requirements and test methods differentiates it from labs that certify to children's product safety requirements. First and foremost, CPSC does not test products for manufacturers prior to their entering the stream of commerce. CPSC laboratories also have multiple functions, including forensic work related to product safety incidents and developing standards in rulemaking proceedings.

Regardless, CPSC has a long history of following the quality management systems approach incorporated in ISO-17025, including developing standard test procedures and test methods that assess technical capability, repeatability, and reproducibility. The process includes maintaining test procedures and data records and documentation, such as equipment calibration requirements, instrument performance checks, use of certified reference materials for batch run evaluation, staff training, and overall proficiency assessments. CPSC annually participates in external proficiency testing through the Institute for Interlaboratory Studies and has received certificates of excellence, the highest grade achievable, in all proficiency tests since 2017.

14. **This question pertains to the public's access to records of adjudications conducted by the CPSC. The Committee understands that the CPSC conducts proceedings where it attempts to compel manufacturers to conduct recalls of products. These proceedings effectively put companies on trial, and as a result, both the Administrative Procedure Act and your own regulations require the CPSC to make**

the Commission's decisions and reasoning for its actions publicly available. But last year, only 10 adjudications dockets were available on the CPSC website. In a recent Commission meeting, you said that the CPSC was working on uploading copies of historical documents online. Recently, the Commission posted documents from over 70 proceedings, including decisions in 63 cases, dating back to the 1970s.

a. **Why has the CPSC kept these rulings privileged from the public? Will you confirm that all of the Commission's decisional adjudication documents are now publicly available?**

As a small agency with very limited resources and a big safety mission, CPSC has not historically been able to devote sufficient resources to migrate all of its paper files to electronic records accessible to the public, absent a FOIA request. Over the last decade, as resources were available, and in line with records management regulations and Executive Orders, CPSC has been scanning its historical documents with an eye toward posting them online. After I became Chair, the agency directed funds toward developing an "archive" for the Office of the Secretary so that the public would be able to find historical Commission actions online. In January of 2024, we began to upload historical documents, including the decisions and orders made by the Commission and Administrative Law Judges since the Commission's inception, a process that has since been completed. Every such document identified by the Office of the Secretary is now available on our website by searching the Commission Action Documents page or through the agency's general Archive page.

15. **CPSC does not have blanket authority to order a product recall. It must first seek an order from an Administrative Law Judge declaring a product is unsafe and authorizing a recall. This is a long and uncertain process. As a result, CPSC seeks to get companies to voluntarily agree to recalls through incentives and collaboration. Repairs and replacements have historically and traditionally been accepted remedies, with refunds used when repair/replacement is not possible.**

Over the last several years, the voluntary recall process has appeared to shift from a collaborative process that quickly gets recall information to the public to a combative and antagonistic process in which CPSC uses threats and coercion to force recalls despite the factual record and obtain concessions in the recall negotiation process for which it has no statutory authority. This occurs at least in the areas of recall remedies and "Corrective Action Plan Agreements" setting out the actions a company will take in a voluntary recall.

The main coercive element is the "unilateral press release," in which CPSC publishes a warning to the public stating that a product is hazardous and should not be used—this often results in a de facto recall due to customer response, as well as a PR nightmare. Unilateral press release threats are being used to not only to coerce companies to agree to recalls, but also after a company has agreed to a voluntary recall but will not agree to certain conditions CPSC wishes to impose on the recall

process.

As to remedies, CPSC has started demanding that companies offer cash refunds for recalls in addition to appropriate repairs or replacement. This not only can lead to financial ruin, but also makes it impossible for recalling firms to model appropriate quantities of repair or replacement parts.

As to CAP Agreements, CPSC has insisted on requiring them, creating a separate contract between CPSC and the recalling company. Standard language applying broadly to the company and products unrelated to the recall (e.g., requiring that as a condition of a recall, a company must agree to maintain a compliance program for all products, identify a "Safety Officer" responsible for the company's compliance, and agree to provide documentation to CPSC regarding this).

There is no law, rule, or regulation requiring this otherwise.

a. **What is the statutory authority for obtaining voluntary recall agreements?**

Voluntary corrective action plans are undertaken by Firms voluntarily and "have no legally binding effect." 16 C.F.R. 1115.20(a). They provide a means to promptly protect the public from possible substantial product hazards without litigation under Section 15 of the CPSA and are entered into by Firms without any admission that the product at issue creates a substantial product hazard under Section 15. Though voluntary corrective action plans are not legally enforceable, Section 19 of CPSA makes it unlawful to sell, distribute or import any product that is known to be "subject to voluntary corrective action taken by the manufacturer, in consultation with the Commission…" 15 U.S.C. § 2068 (a)(2)(B).

b. **What is the statutory authority for obtaining concessions beyond agreement to recall (e.g., recall remedy, press release language, Corrective Action Plan (CAP) Agreements)?**

Section 15(c) and (d) of the CPSA sets out corrective action remedies authorized in mandatory recall actions, which are further specified in 16 C.F.R. 1115 Subpart C.

c. **What is the process by which unilateral press releases are authorized and how often are they issued?**

Unilateral press releases that pertain to a manufacturer or private labeler must comply with the process set out in Section 6(b) of the CPSA. These and any other unilateral notices are also reviewed and approved by the Director of Compliance, the Deputy Executive Director, the Executive Director, and the General Counsel before release.

The Commission issued 26 unilateral notices in FY 2023 and has issued 60 to date in FY 2024.

d. **Are the Commissioners aware that staff is using the threat of unilateral press release in routine corrective action plan negotiations with companies that have already agreed to recall products?**

Nearly every recall that firms conduct in coordination with the CPSC is voluntary. In negotiating a mutually agreed upon corrective action plan, CPSC staff are guided by internal procedures and guidance. Ultimately, staff seek to negotiate a recall that will address the identified safety problem in a product, effectively communicate the recall to consumers, and incentivize consumers to act upon the remedy or remedies offered by the company. A mutually agreed recall should provide the fast mechanisms to fix, replace or remove dangerous products from consumers' homes.

An inadequate recall may result in unsafe products remaining in consumers' homes, or ineffective remedies. As a result, consumers may suffer injuries and even deaths that might otherwise have been avoided. Thus, the CPSC must carefully review and consider each proposed voluntary recall individually before agreeing to a remedy so that consumer safety is prioritized.

A significant percentage of recalls are conducted through our "fast track" process under which a company approaches CPSC with information about a defect and a proposed remedy and the two entities work together to finalize the recall language and alert the public. Others are initiated by CPSC, but also move quickly toward resolution when the company takes responsibility for a safety hazard and proposes a reasonable recall remedy.

Companies are free to implement voluntary recalls without CPSC's participation. When they ask CPSC to join them in supporting the recall and yet are unwilling to provide remedies that fully address the hazard, CSPC is left with few options for protecting consumers. The agency may initiate litigation to compel a recall consistent with CPSC's authorizing statute, but this process is resource intensive and may take years to resolve. Alternatively, CPSC may itself warn consumers about the hazardous product, provided the agency complies with Section 6(b) of the Consumer Product Safety Act. The Section 6(b) process gives manufacturers the opportunity to review the safety warning prior to publication, raise any concerns regarding the accuracy of the release, provide the company's perspective in the release, and even seek a court order to prevent the CPSC's warning.

Many of the unilateral warnings that the commission has issued over the past three years have involved products sold by foreign companies that do not respond to CPSC's outreach and take no real responsibility for the safety of the products that they put into American commerce via the internet. Our statute does not

provide us with a means to reach these sellers and mandate a recall of these products, so the best we can do is issue a warning and urge the internet platforms that host the sales to take the products off their marketplaces and warn the individuals who have previously bought the products to dispose of them safely.

While the Commissioners are not briefed on, nor do they vote on, every recall, I am aware of numerous instances in which Commissioners were informed that staff was considering unilateral warnings when faced with an inadequate recall proposal from the company, including a company's refusal to offer a refund option. With respect to recalls the Commissioners have voted on, refunds in addition to repair or replacement remedies have been considered. In fact, recently, a Republican-led majority of Commissioners directed staff to seek a refund of the purchase price of an unsafe product even though staff had already secured a replacement remedy and did not believe a refund was necessary.

e. **If so, are the Commissioners authorizing or voting on the use of these threats by staff in all instances?**

See response to subpart d.

f. **Are the Commissioners aware that staff is requiring cash refunds as a remedy in addition to repair and replacement remedies?**

As discussed above, all voluntary recalls are negotiated and mutually agreed upon. As such, no specific remedies are "required." For additional background, see response to subpart d.

g. **What is the statutory authority for staff or Commissioners to mandate a cash refund in a voluntary recall if CPSC technical staff has deemed a repair or replacement to be acceptable?**

As discussed above, all voluntary recalls are negotiated and mutually agreed upon. No provisions are "mandated." For additional background, see response to subpart a.

h. **Has the Commission assessed or otherwise modeled the impact of mandating cash refunds as an alternative to repair/replacement in recalls in which technical staff has deemed repair/replacement acceptable, including as to financial impact to recalling firms, effectiveness in removing recalled products from use, and the creation of waste when products or their components could otherwise be repaired or replaced?**

CPSC's mission is to protect the public from unreasonable risks of death and injury associated with consumer products. CPSC staff assesses each product and proposed recall individually in order to address all identified hazards or defectives and to promote the efficacy of the recall remedy. A company may propose

different recall remedies based on the type of product, the nature of the hazard or defect and characteristics unique to the company, including its size and financial condition. In reviewing the firm's proposed remedy or remedies, CPSC staff and sometimes CPSC Commissioners may assess the impact or value of requesting a cash refund as an alternative or additional remedy. Part of that assessment would include the effectiveness of the proposed remedy as well as any issues raised by the company such as the financial impact to the firm. Unless there is a health and safety aspect to the creation of product waste, such concerns are generally not in-scope when CPSC staff reviews a recall remedy proposal.

i. **Are the Commissioners aware that staff is requiring Corrective Action Plan Agreements as a condition of accepting a voluntary recall?**

To the extent a voluntary recall is mutually agreed upon with a firm, Commissioners are aware that the terms of such a recall are memorialized in a Corrective Action Plan. In this way, the parties understand the specific commitments of both CPSC and the company.

j. **Are the Commissioners aware that the template Corrective Action Plan Agreement language requires a company to implement a compliance program for all CPSC laws and regulations for all products, identify a "Safety Officer or Safety Committee responsible for the firm's compliance," and require a recalling company to produce documents to CPSC in connection with this?**

I cannot confirm whether any individual Commissioner other than myself has read this standard Corrective Action Plan provision, which is available to them. Personally, I do not believe that asking a company that has sold a defective or hazardous product to document its program complies with federal product safety laws is an excessive or inappropriate request.

k. **What is the statutory authority for requiring a Corrective Action Plan Agreement as a condition of voluntary recall?**

See response to subpart a.

l. **What is the statutory authority for conditioning acceptance of a voluntary recall on agreement to implement a compliance program, identifying a Safety Officer or Safety Committee, and requiring production of documents to CPSC?**

See response to subpart a.

m. **Has the Commission published guidance or otherwise made consumers and industry aware of these demands and the risk of unilateral press releases if they are not agreed to?**

See response to subparts c and d.

n. **Have these processes been subject to public review and comment?**

The Commission's regulations pertaining to corrective actions in 16 C.F.R. Part 1115 went through the notice and comment process prior to issuance.

o. **Has the Commission assessed the amount of delay caused on average in its effort to extract these concessions from recalling companies in connection with voluntary recalls?**

The Commission works to finalize effective voluntary corrective actions as expeditiously as possible so consumers can be informed of potential product hazards and be encouraged to take appropriate action. Each corrective action plan discussion is different due to the nature of the product, hazard, and firm. Accordingly, staff has not determined the time devoted to the discussion of any particular provision or type of provisions in voluntary corrective action plans.

p. **What does the Commission view as the acceptable number of days or weeks for a recall to be delayed in order for it to negotiate, threaten, or coerce these concessions?**

The Commission works to finalize effective voluntary corrective actions as expeditiously as possible so consumers can be informed of potential product hazards and be encouraged to take appropriate action.

q. **Has your compliance office threatened unilateral action without performing a safety assessment or determining a safety hazard or defect? What protocols or procedures are in place to ensure that all threats of action are backed by thorough and objective safety assessments? Is your agency following those procedures?**

Section 6(b) of the CPSA requires that any Commission safety notice pertaining to manufacturers or private labelers be "accurate, and that such disclosure is fair under the circumstances and reasonably related to effectuating the purposes" of the Act. Commission staff performs sufficient investigation and analysis of the product at issue to meet this standard before issuing unilateral safety notices.

16. **In November 2020, the Government Accountability Office ("GAO") released a report on the CPSC's processes for addressing defects in consumer products. The GAO report stated that the CPSC uses the "correction rate"—which represents the "proportion of product units recalled that have been refunded, replaced, or repaired"—to evaluate the effectiveness of product recalls. The correction rate for CPSC recalls is disappointingly low: in 2017, the correction rate for recalls announced by the CPSC through a press release was approximately 6 percent.**

a. **What is the CPSC's current definition of "correction rate"? Has the CPSC changed how it calculates the correction rate since you became Chair? How? Why does that make sense?**

Until recently, the definition of "correction rate" reflected the percentage of all recalled products that were remedied (refund, repair, or replacement) and that concluded monitoring during the fiscal year. Beginning in FY 2024, the method for calculating the recall correction rate, as reported in performance metric KM2.3.1, was changed to more accurately report the average correction rate for all recalls, taking into account high-volume recall outliers. Further information on this topic is available in the Commission's 2024 Proposed Operating Plan Alignment and Midyear Review.

17. **The Committee understands that the CPSC requires companies that conduct product recalls to submit monthly progress reports to the agency. But the GAO's 2020 report found that the CPSC does nothing with that data:**

a. **What is the purpose of expecting companies to fill out reports if staff don't do anything with the information? Has the CPSC's practice of tracking those reports changed since the GAO's report? How?**

In response to GAO's 2020 recommendation related to Monthly Progress Reports (MPRs), Commission staff developed tracking mechanisms to identify overdue or missing reports and a notification program to facilitate firm compliance with MPR obligations. Presently, staff (1) tracks submissions of MPRs and communicates with firms that have failed to submit reports or are delayed in their submissions; and (2) reviews the information in the MPRs, including the correction rate and post-recall incident information, to determine whether additional action may be needed. In some instances, recalls have been reannounced to expand consumer awareness and modifications made to the remedies offered to reduce the risk of future injuries and deaths.

18. **The GAO report also concluded the CPSC does not follow its own procedures for "prioritizing resources for newly opened cases based on the potential risk to consumer safety associated with a product."**

a. **How does staff decide which cases to prioritize? Has the CPSC's procedures on determining what cases to prioritize changed since the GAO's report? How?**

Following the GAO report, CPSC staff formalized a Standard Operating Procedure (SOP) establishing prioritization factors in response to the GAO Report. As reflected in the SOP, staff prioritizes and tracks defect matters considering a number of factors, including the likelihood a product creates a substantial product hazard, known death and injury information, the number of

incidents, and any vulnerability of the population exposed to the product.

19. **I have one more question regarding this GAO report. The GAO highlighted that the CPSC does not account for the complexity of product defect investigations in creating so- called "timeliness goals" for those investigations.**

    a. **How much variance is there in the length of time that it takes for CPSC staff to conduct investigations? Are CPSC staff subject to performance metrics based on how quickly they can complete investigations?**

    CPSC is responsible for the investigation of thousands of different types of products that present a myriad of hazard scenarios. As such, investigations are highly differentiated and not conducive to uniform timelines. However, as reflected in performance metric KM2.1.01 of CPSC's FY 2024 Operating Plan, staff strives to make a preliminary determination of a substantial product hazard within 85 business days of case opening in 70% of cases.

20. **What is CPSC currently doing to ensure the independence of third-party testing labs abroad, including countries like China that don't always respect the rule of law and whistleblower protections of foreign jurisdictions.**

    a. **Can CPSC guarantee the independence of these third-party labs?**

    CPSC's program as promulgated at 16 CFR 1112, relies on the established international system for accreditation of laboratories and as bound by mutual recognition and trade agreements under ILAC. The underlying statute prescribes the approval process and is focused on evidentiary documentation reviews of approved scopes of the lab's accreditation by a recognized accrediting body. CPSC believes there is a high level of compliance given the observed scrutiny of in-country Accrediting Bodies (ABs) and other in-country local governmental regulatory bodies.

    b. **What type of due diligence is done when granting initial and renewal applications?**

    CPSC's lab approval system includes two independent staff reviews of the lab's application of CPSC scope requests to be approved. Each reviewer assesses the scope requested in the application and compares the documentation the lab has provided with the accrediting body's online listing of that lab's approval by the accrediting body (AB). If reviewers find discrepancies or inconsistencies the lab and/or AB will be contacted by the CPSC staff to address these issues.

    In cases where misconduct by a laboratory is suspected or found, CPSC can take and has taken action under 16 CFR 1112, Subpart D, "Adverse Actions: Types, Grounds, Allegations, Procedural Requirements, and Publication." In 2023,

CPSC removed 19 labs provisionally due to alleged misconduct, and two remain withdrawn after misconduct was found. CPSC's website was updated to list Labs with Adverse Action Taken by CPSC.

c. **Historically, application renewals were delegated to career staff, not requiring a Commission vote, and reviewed as a matter of course. Do you support automatic renewals by career staff?**

Renewal should not be "automatic." Firewalled labs require a Commission order to be accepted and firewalled lab renewals that are not delegated to staff by the Commission require subsequent re-approval by the Commission for renewal. When the Commission has seen fit, it has delegated certain renewals to staff. Many of the renewals deal with routine updates of reviews by Accrediting Bodies, with limited changes. Others deal with updates to align accreditations to the most recent versions of standards. These and others are routine in nature and are already governed by extensive rules issued by the Commission, and therefore are most efficiently handled by staff.

The Honorable Kelly Armstrong

1. **As was reported by North Dakota's KX News, Temu is the "sister company" of the massive Chinese company Pinduoduo and "the cheap prices are explained by poor quality items." KX's reporting goes on to state that according to customer complaints filed to the Better Business Bureau there "is no phone # and 'chatting' has proved futile as there is an obvious language barrier", when it comes trying to contact Temu's customer service.**

Temu claims that it is a Boston-based company, doing business as WhaleCo, Inc., though those claims are debatable, at best.

a. **For the various recalls that the Commission has issued for products sold exclusively by Temu, has it ever communicated with an Temu employee based in Boston?**

Yes, CPSC has communicated with a Temu employee based in Boston concerning recalls.

i. **If not, what are the names, titles, and business addresses of the Temu employees it has communicated or engaged with?**

N/A

The Honorable Russ Fulcher

1. **What alternatives or flexibilities have you presented, given the concern that**

imposing a mandatory rulemaking on the industry at this stage could cause a shutdown of side-by- side manufacturing, meaning that police, fire, EMS, Park Service, Forest Service, BLM, agricultural, and recreational users would not have access to buy new vehicles for a year or possibly longer?

Assuming this question concerns CPSC's pending Notice of Proposed Rulemaking establishing a Safety Standard for Debris Penetration Hazards, CPSC's preliminary assessment is that the costs to manufacturers of protecting against deaths and injuries from debris penetration would amount to far less than one percent of the cost of the vehicles. CPSC's Initial Regulatory Analysis considered two illustrative compliance approaches for industry. First, manufacturers could redesign floorboards where most of the material in the original floorboard is redistributed into a new shape and thickness that addresses the debris penetration hazard. Alternatively, manufacturers could redesign floorboards to add a 2' x 2' x 0.19" aluminum piece that acts as a guard to prevent debris penetration.

CPSC staff performed a full benefit-cost analysis on both potential compliance approaches and found that redesigning the original floorboard would be less costly than adding a floorboard guard, adding $10.68 and $18.71 per vehicle respectively. This equates to 0.07 percent and 0.13 percent of the average retail price of a vehicle. Given the small marginal cost of compliance per vehicle, this rule would not have a disruptive effect to side-by-side manufacturing or the industry overall and the benefits of either approach meet or exceed the costs.

2. **In our discussion during the hearing, I mentioned that the time to step away from the traditional approach in working with industry on safety issues in connection with design approaches was during the meetings in which CPSC staff participated.**

    a. **Can you explain why that doesn't appear to have been the case?**

    CPSC staff continues to work with industry in the voluntary standards process, during public meetings, and in public requests for comments for all of our rulemakings. In the context of debris penetration, CPSC staff has been meeting and communicating to voluntary standards development organizations ROHVA and OPEI since 2018. Further, CPSC staff has repeatedly urged industry to develop a voluntary standard to adequately address the hazard. Further information on CPSC's work with these voluntary standards organizations is available in the agency's Annual Voluntary Standards Activities Reports.

    b. **Or, if it was, then what draft conclusions did the CPSC share with industry during this process to indicate to industry the CPSC was going to propose a rule?**

    After industry proposed a performance requirement and test method to address debris penetration hazards, CPSC sponsored research that included an evaluation of these proposals. The report, which was made available for public comment in

the Federal Register, found the industry standard to be insufficient. Further, CPSC's interest in a debris penetration rulemaking has been known to industry since the Commission published an Advanced Notice of Proposed Rulemaking (ANPR) in 2021 and has been included in the Agency's Regulatory Agenda and annual Operating Plans for several years. As early as 2018, industry was provided with CPSC staff's views through the voluntary standards process.

3. **The D.C. Circuit recently vacated a mandatory rule for window coverings that disregarded the industry's voluntary standard, *Window Covering Mfrs. Ass'n v. Consumer Prod. Safety Comm'n*, 82 F.4th 1273 (D.C. Cir. 2023). The court found that CPSC failed to provide sufficient notice and comment on the underlying incident data, conducted a flawed cost-benefit analysis, and imposed an arbitrary effective date. Despite evidence that there was substantial compliance with the voluntary standard and that it improved product safety, CPSC plowed ahead with a flawed mandatory rule that circumvented the process established by Congress in the Consumer Product Safety Act.**

    a. **Is it your viewpoint that CPSC safety rules are always better than industry standards that are developed by engineers and safety experts in consultation with CPSC? Why/Why not?**

    No. CPSC mandatory safety standards are often based on an underlying voluntary industry standard. Recent examples of this approach include our mandatory safety rules on Adult Portable Bed Rails, magnets, and multiple durable nursery product regulations.

4. **A bipartisan group of Senators recently wrote to your agency, pointing out that the proposed mandatory rule for ROV debris penetration suffers from many of the same flaws as the vacated window coverings rule. Like the window coverings industry, the ROV industry followed the process set out by Congress. The ROV industry developed a consensus voluntary standard for debris penetration that has been reviewed and published by the American National Standards Institute. The revised voluntary standards reflect input from a broad array of stakeholders including industry, rider, and consumer-safety voices. This new product safety standard is based on real-world field data involving hundreds of thousands of hours of actual ROV usage.**

    a. **Does CPSC intend to press ahead with its proposed mandatory rule despite the new voluntary standard for ROV debris penetration in FY 2024?**

    The Commission will soon issue a notice of availability (NOA) with request for comment on the data underlying the proposed rule.

    b. **What about FY 2025?**

The Commission has not yet voted on the FY 2025 Operating Plan which sets the rulemaking agenda for the fiscal year.

c. **If CPSC proceeds with a rule, will it follow the important teachings of the window coverings case on notice and comment, cost-benefit analysis, and effective dates?**

Yes.

5. **The timing for a potential ROV debris-penetration rule is unclear. CPSC's Spring 2024 Unified Agenda of Regulatory and Deregulatory Actions states that "[s]taff is directed to prepare a final rule briefing package for submission to the Commission in fiscal year 2024," which ends on September 30, 2024. However, the Agenda also states that staff will send the Commission a notice of availability of additional data for public comment in September 2024.**

a. **Does CPSC still intend to send the notice of availability of additional data – and provide a public comment period on that new data – before issuing a debris- penetration rule?**

Yes.

b. **When does CPSC intend to send the notice of availability?**

The Commission will soon issue a NOA with request for comment on the data underlying the proposed rule.

c. **Will CPSC commit to providing the public with sufficient time to analyze and provide meaningful comments on the new data?**

Yes.

d. **Will CPSC commit to waiting for those comments and analyzing them before preparing the briefing package for a final debris-penetration rule?**

The comments on the notice of availability will be analyzed before a briefing package recommending a final rule is presented to the Commission.

e. **When does CPSC plan to issue a final debris-penetration rule?**

The Commission has not yet established its operating plan for FY 2025.

6. **In the proposed rule, CPSC found that ROVs and UTVs present an unreasonable risk of injury because debris penetrates certain ROV floorboards at speeds as low as 2.5 mph. Our understanding is that this conclusion was based on simulated,**

third-party testing in which sleds fitted with ROV floorboards were driven on a linear track to collide with stationary wooden dowels. That sort of controlled-environment testing does not reflect real-world conditions. For example, CPSC's linear-track test cannot account for vehicle motion and branch movement, breakage, and deflection when there is vehicle-branch contact.

a. **Is CPSC aware of real-world incidents where debris penetrated ROV or UTV floorboards at speeds as low as 2.5 mph? If in-depth investigation reports were conducted for any such incidents, please share those reports with the subcommittee.**

CPSC staff examined incident data that showed debris penetrations occur at reported speeds as low as 2 mph. This data will be available for public for review and comment as part of the NOA.

The Honorable Diana Harshbarger

1. **Chair Hoehn-Saric, according to a poll by a baby safety group, BabyCenter, nearly 38% of parents have purchased or received items from Temu, which is owned by China-based PDD Holdings Inc., raising consumer alarm bells. BabyCenter warned against purchasing unsafe baby products from the retailer – toys, cribs, bassinets, play yards, infant teethers, thermometers, strollers, car seats. The article by BabyCenter raised concerns that the items could be counterfeit, knock off, or recalled products, and could circumvent U.S. product safety and manufacturing standards and safety features.**

a. **With Temu's products coming into the U.S. via U.S. Customs and Border Protection's (CBP) Section 231 de minimis framework, how is the Commission working with CBP and its Partner Government Agency program to ensure all of these infant and children's products have the appropriate certifications?**

The SNPR for eFiling addresses *de minimis* shipments with its proposed importer definition. The SNPR explains, "for direct-to-consumer imports not involving a broker, the party with financial interest in the product being offered for import and who effectively caused the consumer product to be imported into the United States, which could be the foreign manufacturer or the seller who sold the product on an online marketplace, would be considered the importer and the party responsible for certifying." Should the proposed rule become finalized and upon implementation of eFiling, CPSC will be better able to target and review potentially violative *de minimis* shipments, which will improve CPSC and CBP's current targeting at express consignment facilities, airports, and truck ports.

The Honorable Robin Kelly

1. **Chair Hoehn-Saric, according to a poll by a baby safety group, BabyCenter, nearly**

38% of parents have purchased or received items from a foreign-owned online marketplace, raising consumer alarm bells. BabyCenter warned against purchasing unsafe baby products from the retailer – toys, cribs, bassinets, play yards, infant teethers, thermometers, strollers, car seats. The article by BabyCenter raised concerns that the items could be counterfeit, knock off, or recalled products, and could circumvent U.S. product safety and manufacturing standards and safety features. With foreign-owned online marketplace products coming into the U.S. via U.S. Customs and Border Protection's (CBP) Section 231 de minimis framework, how is the Commission working with CBP and its Partner Government Agency program to ensure all of these products have the appropriate certifications?

The SNPR for eFiling addresses *de minimis* shipments with its proposed importer definition. The SNPR states, "for direct-to-consumer imports not involving a broker, the party with financial interest in the product being offered for import and who effectively caused the consumer product to be imported into the United States, which could be the foreign manufacturer or the seller who sold the product on an online marketplace, would be considered the importer and the party responsible for certifying." Should the proposed rule become finalized and upon implementation of eFiling, CPSC will be better positioned to target and review potentially violative *de minimis* shipments, which will improve CPSC and CBP's current targeting at express consignment facilities, airports, and truck ports.

2. **Chair Hoehn-Saric, this past March, an article in Business Insider raised concerns about the safety of pajamas, cribs, bassinets and other children's sleeping spaces, as well as other products shipped directly to consumers from China by online marketplaces like Temu and Shein. What is the Commission doing to ensure that products such as pajamas and children's sleeping spaces products shipped directly to consumers from China and other countries are safe? Are there things Congress could do to help you make sure such products are safe?**

The convenience of shopping online should not mean sacrificing safety. Consumers expect that the products they buy online are just as safe as those they buy in brick-and-mortar stores, but, as you point out, that is not always the case. Under our statute, retailers, distributors, and manufacturers are required to report when they know of a dangerous or defective product. Most work cooperatively with CPSC to report and conduct a recall when appropriate. Congress clarifying that all online marketplaces should be held to the same safety obligations would go a long way to help CPSC work with industry to keep their sites safe from dangerous products. Outside of that, CPSC staff at our ports of entry work every day to ensure that children's products that violate CPSC regulations do not make it into consumers homes. Thus far in FY 2024, port staff have screened over 56,000 products for possible violations of CPSC mandatory rules.

The Honorable Darren Soto

1. **The United Kingdom's Office for Product Safety and Standards recently issued a product recall for the Wireless Microphone HIFI Speaker sold on Temu, a "new**

entrant" online marketplace that you specifically called out, because of a "serious risk of fire and explosion." How is the Commission working with its UK counterparts to ensure that this product is also not sold on the Temu marketplace website here in the United States?

CPSC often seeks to coordinate and collaborate with our international product safety counterparts, and I believe it is important to do so. CPSC staff is currently reviewing the recent UK recall of this product.