UNITED STATES OF AMERICA
CONSUMER PRODUCT SAFETY COMMISSION

In the Matter of Amazon.com, Inc., Respondent.	CPSC Docket No. 21-2 Hon. Carol Fox Foelak Presiding Officer

DECLARATION OF JOHN MIZERAK
IN SUPPORT OF AMAZON'S MOTION TO EXCLUDE
THE REBUTTAL EXPERT REPORT AND TESTIMONY
OF MS. SHARON R. WHITE

I, John Mizerak, hereby declare:

1. I am an attorney for Respondent Amazon.com, Inc. ("Amazon") in the above-captioned matter.

2. I am over the age of 18 and I am competent to make this declaration.

3. Attached as Exhibit 1 is a true and correct copy of the email sent by Amazon counsel Sarah Wilson to Complaint Counsel on May 9, 2022.

4. Attached as Exhibit 2 is a true and correct copy of the expert report of Joseph P. Mohorovic that was submitted by Amazon counsel to Complaint Counsel on May 9, 2022. This document is designated Confidential and will be submitted for in camera review pursuant to the Protective Order.

5. Attached as Exhibit 3 is a true and correct copy of the email sent by Complaint Counsel Liana Wolf to Amazon counsel on June 30, 2022.

6. Attached as Exhibit 4 is a true and correct copy of the transcript of the deposition of Sharon R. White taken on August 9, 2022. This document is designated Confidential and will be submitted for in camera review pursuant to the Protective Order.

7. Attached as Exhibit 5 is a true and correct copy of the Consumer Product Safety Commission's "Recall Effectiveness Workshop Report" dated February 22, 2018.

8. Attached as Exhibit 6 is a true and correct copy of the U.S. Government Accountability Office's report titled "Consumer Product Safety Commission - Actions Needed to Improve Processes for Addressing Product Defect Cases" dated November 2020.

9. Attached as Exhibit 7 is a true and correct copy of the email sent by Complaint Counsel Serena Anand to Amazon counsel on August 8, 2022.

10. Attached as Exhibit 8 is a true and correct copy of the article authored by Jennifer A. Cowley and Michael S. Wogalter titled "Analysis of Terms Comprising Potential Names for a Recall Notification Campaign" that was published in Volume 52, Issue 21 of *Proceedings of the Human Factors and Ergonomics Society Annual Meeting* in September 2008.

11. Attached as Exhibit 9 is a true and correct copy of the rebuttal expert report of Sharon R. White that was submitted by Complaint Counsel to Amazon counsel on June 30, 2022. This document is designated Confidential and will be submitted for in camera review pursuant to the Protective Order.

12. Attached as Exhibit 10 is a true and correct copy of the U.S. Consumer Product Safety Commission's Directive Order No. 9010.34 titled "Initiating and Monitoring Corrective Action Plans" and dated July 15, 1992. This document is

designated Confidential and will be submitted for in camera review pursuant to the Protective Order.

I declare under penalty of perjury that the foregoing is true and correct.

Executed on September 22, 2022.

/s/ John Mizerak
John Mizerak

CERTIFICATE OF SERVICE

I hereby certify that, on September 22, 2022, a true and correct copy of the foregoing documents were, pursuant to the Order Following Prehearing Conference entered by the Presiding Officer on October 19, 2021:

- filed by email with the Secretary of the U.S. Consumer Product Safety Commission, Alberta Mills at amills@cpsc.gov, with a copy to the Presiding Officer at alj@sec.gov and to all counsel of record; and
- served to Complaint Counsel by email at jeustice@cpsc.gov, lwolf@cpsc.gov, and sanand@cpsc.gov.

/s/ Sarah L. Wilson
Sarah L. Wilson

Exhibit 1

From: Wilson, Sarah
Sent: Monday, May 9, 2022 8:02 PM
To: Eustice, John; Wolf, Liana; Anand, Serena
Cc: Anthony, Stephen; Mizerak, John; Cavataro, Benjamin; Ramirez, Diane
Subject: In the Matter Amazon.com, Inc.; CPSC Docket No.: 21-2 (Expert Report)
Attachments: 22.5.09 Mohorovic Report Final.pdf

Counsel,

On behalf of Amazon, please see the attached expert report of Joseph Mohorovic.

We will be sending under cover of a separate email a Kiteworks link containing the attachments.

Sarah Wilson

Covington & Burling LLP
One CityCenter, 850 Tenth Street, NW
Washington, DC 20001-4956
T +1 202 662 5397 | swilson@cov.com
www.cov.com

COVINGTON

This message is from a law firm and may contain information that is confidential or legally privileged. If you are not the intended recipient, please immediately advise the sender by reply e-mail that this message has been inadvertently transmitted to you and delete this e-mail from your system. Thank you for your cooperation.

Exhibit 3

From: Wolf, Liana <LWolf@cpsc.gov>
Sent: Thursday, June 30, 2022 8:19 PM
To: Wilson, Sarah; Anthony, Stephen; Brugato, Thomas; Cavataro, Benjamin; Griepsma, Nick; Ramirez, Diane
Cc: Eustice, John; Anand, Serena
Subject: In the Matter of Amazon.com, Inc. (CPSC Docket No. 21-2)
Attachments: Rebuttal Expert Report of Sharon White 6.30.2022.pdf

[EXTERNAL]
On behalf of Complaint Counsel, attached please find the Rebuttal Expert Report of Sharon White.

You will receive a separate email to access the attachments via WatchDox.

Best regards,
Liana

Liana G.T. Wolf
Trial Attorney
U.S. Consumer Product Safety Commission
Division of Enforcement and Litigation | Office of Compliance and Field Operations
4330 East West Highway | Bethesda, MD 20814
(240) 743-8559 | lwolf@cpsc.gov | www.cpsc.gov

*****!!! Unless otherwise stated, any views or opinions expressed in this e-mail (and any attachments) are solely those of the author and do not necessarily represent those of the U.S. Consumer Product Safety Commission. Copies of product recall and product safety information can be sent to you automatically via Internet e-mail, as they are released by CPSC. To subscribe or unsubscribe to this service go to the following web page: http://www.cpsc.gov/en/Newsroom/Subscribe *****!!!

Exhibit 5

Recall Effectiveness Workshop Report

CPSC in Cooperation with Stakeholders

February 22, 2018

Office of Compliance and Field Operations
Joseph F. Williams, CFEI
Compliance Officer

This document was prepared by CPSC staff and has not been reviewed or approved by, and may not necessarily represent the views of the Commission.

Recall Effectiveness Workshop Report

Introduction

The CPSC is charged with protecting consumers from unreasonable risks of injury or death associated with the use of thousands of types of consumer products. One way to protect consumers is to conduct a product recall. CPSC's recalls are generally executed cooperatively with affected companies. Although there are mandatory recalls, the vast majority of CPSC's recalls are voluntary. During the voluntary recall process, the CPSC works with companies that agree to provide notice to consumers and a remedy for potentially hazardous products. This cooperative process facilitates the ability of the CPSC and the recalling company to reach affected consumers.

In furtherance of that cooperation, on July 25, 2017, the CPSC hosted a Recall Effectiveness Workshop. The goal of the workshop was to explore and develop proactive measures that CPSC and stakeholders can take to improve recall effectiveness. Seventy-nine external stakeholders attended the workshop, including various retailers, manufacturers, law firms, consumer interest groups, third party recall contractors and consultants, testing laboratories, and other interested parties. The CPSC facilitated an open discussion among these participants about ways to increase recall effectiveness and also gathered feedback on how CPSC can potentially improve its recall efforts.

Workshop Summary

During the workshop registration and welcome process, participants had an opportunity to post their expectations for the day. Stakeholders said they wanted to learn more about CPSC's procedures and learn about innovative ways to increase recall effectiveness. Stakeholders also said they wanted to discuss the role of technology and social media in recalls, and to address how to achieve consistency between recalls and recalling firms. Several stakeholders expressed interest in the action items that would result from the workshop.

CPSC opened the program with three presentations related to the recall process: (1) "Review of Recall Process and Standard Notifications," (2) "Intro to OCM [Office of Communications Management] and Goals for CPSC Press Releases," and (3) "Recall Data." The first presentation offered an overview of CPSC's standard processes and recall notifications; the second introduced OCM's role in the recall process, and offered information on the goals and guidelines for CPSC press releases. The third presentation supplied statistical analysis of recall results from FY 2014 through FY 2016 for 865 closed Section 15 cases. This analysis demonstrated an overall correction rate of 65 percent, including corrections from manufacturers, distributors, retailers and consumers from CPSC recalls. The presentation provided correction rates based on distribution level, retail price, product category, type of remedy, and recall type. These presentations can be found online at:

- CPSC Defect Recall Data - https://www.slideshare.net/USCPSC/cpsc-recall-effectiveness-workshop-recall-data;
- Review of Recall Process and Standard Notifications - https://www.slideshare.net/USCPSC/cpsc-recall-effectiveness-workshop-recall-process; and
- Goals for CPSC Recall Press Releases - https://www.slideshare.net/USCPSC/cpsc-recall-effectiveness-workshop-goals-for-cpsc-recall-press-releases.

After these background presentations, CPSC encouraged open-forum discussions on the recall process. The first open forum was titled, "What is an effective recall?" Some stakeholders said they were interested in considering multiple factors to measure the effectiveness of a recall. In addition to consumer return rates, some of these stakeholders recommended considering incident rates.

The second open forum was titled, "Communicating the Hazard." Over the past 20 years, the means of communicating recalls has changed substantially and continues to change rapidly as technology evolves. Widespread use of the Internet, email, social media, and other forms of instant communication have changed the ways companies can reach consumers. This session focused on communication channels, the use of marketing strategies, language in recall notices, recall best practices, and limitations and barriers to effective communication. It appeared from the discussions that very few firms develop a marketing strategy for recalls.

The third and fourth forums (held simultaneously as breakout sessions) focused on "Consumer Motivation" and "Technological Advances to Improve Recall Effectiveness." The "Consumer Motivation" forum discussed consumer behavior, challenges to motivating consumers to participate in recalls, incentives, and designing notices to encourage participation. The forum on "Technological Advances to Improve Recall Effectiveness" discussed technological improvements to consumer notification and the effectiveness of recalls, improving direct notification and challenges acquiring and implementing new technology to support more effective recalls.

Reaction to the Workshop

The workshop received positive feedback from stakeholders. Follow-up survey results showed that:

- Respondents felt that the information was useful and that they can share the workshop information with others;
- Ninety-six percent of respondents believed the workshop format helped engage stakeholders in discussion;
- Eighty-eight percent of respondents felt their opinion was heard;

- Ninety-six percent of respondents would like additional workshops on this topic; and
- Suggestions from respondents included: offering workshops in this format on other topics; continuing discussion on recall effectiveness during ICPHSO; encouraging additional manufacturers to attend future workshops; and webcasting future workshops.

Stakeholder Suggestions

The workshop resulted in valuable feedback and ideas for improving recall effectiveness. The consolidated notes from the workshop can be found here (Workshop Notes). Key ideas and suggestions from stakeholders included:

- **Explore ways to increase direct notice to consumers**

  The "Recall Data" presentation demonstrated that direct notice has a substantial impact on consumer return rates. Stakeholders noted that improved product registration methods (*e.g.*, retailer opt-in at checkout, home voice assistants, photo texting, QR codes, and incentives) could lead to higher consumer participation.

- **Expand the use of marketing strategies and technology**

  Marketing and technology can play a pivotal role in getting a recall message to consumers. Stakeholders discussed how using marketing and technology (*e.g.*, social media, the use of apps, and targeted messaging) might heighten effectiveness, and several suggested that CPSC share effective practices to a wider audience.

- **Consider consumer and business incentives to promote effective recalls**

  Stakeholders discussed exploring incentives for consumers to participate in recalls, and examine whether it would be helpful to incentivize recalling firms to be creative in their recall efforts.

- **Consider greater differentiation of recalls**

  Stakeholders suggested evaluating whether differentiating between recalls with more and less significant hazards would improve overall effectiveness. Several stakeholders suggested reviewing systems other agencies use to develop and release recalls for possible guidance on whether and how to differentiate actions.

- **Consider disseminating additional information on best practices**

  Stakeholders saw value in dissemination of best practices in addition to existing recall information, including information related to the use of marketing, social media, and product registration.

Key Findings for Further Consideration with Stakeholders

We considered these suggestions for follow-up with stakeholders and intend to prioritize the following:

1. **Collaborating on ways to improve direct notice to consumers**

   Direct notice recalls have proven to be the most effective recalls. We intend to work with consumer and industry stakeholders on registration methods or other improvements (*e.g.*, retailer opt-in at checkout, home voice assistants, photo texting, QR codes, and incentives for product registration) to promote direct notice recalls.

2. **Collaborating with firms engaged in recalls to use marketing strategies to promote consumer response**

   We will continue to explore how technology can be used to enhance recall response in appropriate cases, including enhancing firms' recall marketing strategies, use of social media, and improved methods for in-store communication. We intend to identify and share examples of future recall marketing strategies that are innovative and/or successful.

Exhibit 6

United States Government Accountability Office

Report to Congressional Requesters

November 2020

CONSUMER PRODUCT SAFETY COMMISSION

Actions Needed to Improve Processes for Addressing Product Defect Cases

GAO-21-56

GAO Highlights

Highlights of GAO-21-56, a report to congressional requesters

November 2020

CONSUMER PRODUCT SAFETY COMMISSION

Actions Needed to Improve Processes for Addressing Product Defect Cases

Why GAO Did This Study

CPSC is responsible for ensuring the safety of thousands of consumer products ranging from children's toys to off-road recreational vehicles.

GAO was asked to review CPSC's processes for addressing product safety hazards. Among other objectives, this report examines the extent to which CPSC has (1) taken steps to prioritize and address product safety hazards in a timely and efficient manner; (2) overseen firms' compliance with corrective action plans and taken steps to address noncompliance; and (3) taken steps to assess the effectiveness of different types of corrective actions.

GAO reviewed CPSC policies and procedures, prior GAO reports, and other published studies. GAO also interviewed CPSC commissioners and staff, legal experts, and representatives from consumer and industry organizations.

What GAO Recommends

GAO is making five recommendations to CPSC to improve its processes for prioritizing resources, overseeing firms' compliance, measuring recall effectiveness, and managing the timeliness of product defect cases. CPSC generally agreed with GAO's findings and said it supported the recommendations.

View GAO-21-56. For more information, contact Alicia Puente Cackley at (202) 512-8678 or cackleya@gao.gov.

What GAO Found

The Consumer Product Safety Commission (CPSC) has recently taken steps intended to strengthen its processes for addressing consumer product defect cases, such as by developing a web portal to facilitate firms' participation in its Fast Track program for expedited recalls. However, GAO found several areas in which CPSC could improve how it responds to consumer product hazards:

- **Prioritizing resources**. CPSC does not follow steps described in its procedures for prioritizing resources for newly opened cases based on the potential risk to consumer safety associated with a product. Establishing and following specific procedures for prioritizing new cases based on relevant case-specific factors, such as the potential risk to consumer safety, could help ensure CPSC staff consistently allocate staff resources to cases based on these factors. CPSC staff conduct "recall effectiveness checks," such as by confirming that recalled products were removed from shelves and that appropriate signage was placed in stores for consumers to see. However, GAO found that CPSC does not consistently assign more checks to higher-risk recalls. By developing more formal written procedures on how to determine how many checks to assign, CPSC could provide staff with tools to more effectively prioritize resources to higher-risk cases.
- **Ensuring compliance with reporting requirements**. CPSC does not centrally track whether firms undertaking recalls have submitted required monthly progress reports. GAO found that only 61 percent of firms had submitted their progress reports more than 75 percent of the time for recalls closed between February 2016 and May 2020. Taking steps to ensure firms' compliance with the monthly reporting requirement could improve CPSC's ability to monitor the status of product recalls.
- **Measuring recall effectiveness.** CPSC uses one performance metric to assess the effectiveness of recalls—the correction rate. This metric represents the proportion of product units recalled that have been refunded, replaced, or repaired. However, using a single measure may not allow CPSC to accurately gauge the effectiveness of all its recalls—for example, for cheap products consumers may simply throw away (rather than seek a refund or replacement) in response to the recall. Using additional performance measures could help CPSC more accurately assess the effectiveness of product recalls.
- **Managing timeliness**. CPSC uses the same timeliness goals for all of its product defect cases, although complex cases take significantly longer. These timeliness goals do not account for the significant variability in how long it takes staff to conduct key stages of a product defect investigation. As a result, CPSC's timeliness goals for certain stages of product defect cases may not be an effective tool for managing more complex cases.

Contents

Figures

Abbreviations

CAP	corrective action plan
CPSA	Consumer Product Safety Act
CPSC	Consumer Product Safety Commission
Compliance	Office of Compliance and Field Operations
PD	preliminary determination
REC	recall effectiveness check
section 15 manual	Section 15 Defect Investigation Procedures Manual

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U.S. GOVERNMENT ACCOUNTABILITY OFFICE
441 G St. N.W.
Washington, DC 20548

November 19, 2020

The Honorable Richard Blumenthal
Ranking Member
Subcommittee on Manufacturing, Trade, and Consumer Protection
Committee on Commerce, Science, and Transportation
United States Senate

The Honorable Edward Markey
United States Senate

The Consumer Product Safety Commission (CPSC) is charged with protecting U.S. consumers from unreasonable risks of injury and death from consumer products. CPSC has broad jurisdiction over thousands of types of consumer products representing $1.6 trillion in consumption, including off-road recreational vehicles and hazardous substances. Some products under CPSC's jurisdiction are regulated—that is, subject to mandatory standards established by CPSC through regulations. Many other products are subject to voluntary standards, which are generally determined by standard-development organizations, with input from government representatives and industry groups.

To address product safety hazards it identifies, CPSC can establish new standards, recall hazardous products, engage in consumer outreach, or take legal action against product manufacturers. In fiscal year 2019, CPSC coordinated 259 voluntary recalls affecting approximately 20 million product units.[1] Despite its broad jurisdiction, CPSC is a relatively small agency with just over 500 full-time equivalent employees as of September 2020.

You asked us to review CPSC's processes for addressing product safety hazards, including its development and oversight of corrective action plans, which document the actions firms are to take to carry out a product recall. Specifically, this report examines the extent to which CPSC has (1) taken steps to prioritize and address product safety hazards in a timely and efficient manner; (2) used different types of corrective actions, enforcement actions, and standards; (3) overseen firms' compliance with corrective action plans and taken steps to address noncompliance; and

[1]Consumer Product Safety Commission, *Fiscal Year 2019 Annual Performance Report* (Bethesda, MD: Feb. 10, 2020).

(4) assessed the effectiveness of different types of corrective actions and incorporated best practices.

To address our first objective, we reviewed CPSC's policies and procedures, such as CPSC's manual that outlines its processes for managing product defect cases. We also reviewed CPSC's performance goal reports for fiscal years 2016–2019 that showed how CPSC performed relative to its timeliness goals. To obtain additional information and perspectives on CPSC's process and practices, we interviewed CPSC staff responsible for managing key aspects of its product recall processes.

To address our second objective, we reviewed CPSC data and documentation for CPSC's use of corrective actions and standards. To describe CPSC's use of corrective actions from 2016 through 2019, we reviewed product defect case data from CPSC's Dynamic Case Management System. To describe how frequently CPSC participated in developing voluntary standards and promulgated new mandatory standards, we reviewed CPSC operating plans for fiscal years 2016 through 2020 and documentation on mandatory product rulemakings from January 2016 through June 2020. To identify factors that may have affected CPSC's use of corrective actions, enforcement actions and standards, we reviewed CPSC's annual operating plans, performance reports, and other relevant documentation. We also interviewed CPSC officials and staff.

To address our third objective, we reviewed CPSC's policies and practices for monitoring firms' compliance with corrective action plans, such as relevant sections of CPSC's manual that describe how staff should manage recalls. To obtain information about steps CPSC has taken to monitor corrective action plans in accordance with its policies, we analyzed CPSC's recall monitoring data for cases closed between January 2016 and May 2020. In addition, to describe whether recall effectiveness checks were conducted appropriately, and whether all monthly progress reports were submitted, we selected a non-generalizable sample of 25 recall cases and reviewed monthly progress reports and data on recall effectiveness checks for these cases. We selected this sample from a data set of 78 recall cases closed between January 2016 and May 2020.

To address our fourth objective, we reviewed CPSC's Annual Performance Reports and other documentation related to CPSC's assessment of recall effectiveness. We reviewed documentation on

CPSC's efforts to consider and incorporate best practices for implementing recalls, such as presentations by the National Highway Traffic Safety Administration, Federal Trade Commission, Department of Agriculture, and Food and Drug Administration from a 2017 workshop CPSC hosted. We interviewed CPSC officials for information and perspectives about CPSC's efforts in these areas.

We assessed the reliability of CPSC data by reviewing relevant documentation, interviewing CPSC officials about steps taken to ensure the accuracy of the data, and testing the data for omissions and errors. We found these data reliable for obtaining information about CPSC's efforts to manage the timeliness of its process phases and activities and assessing how staff monitor recall cases. Appendix I provides additional details on our scope and methodology.

We conducted this performance audit from November 2019 to November 2020 in accordance with generally accepted government auditing standards. Those standards require that we plan and perform the audit to obtain sufficient, appropriate evidence to provide a reasonable basis for our findings and conclusions based on our audit objectives. We believe that the evidence obtained provides a reasonable basis for our findings and conclusions based on our audit objectives.

Background

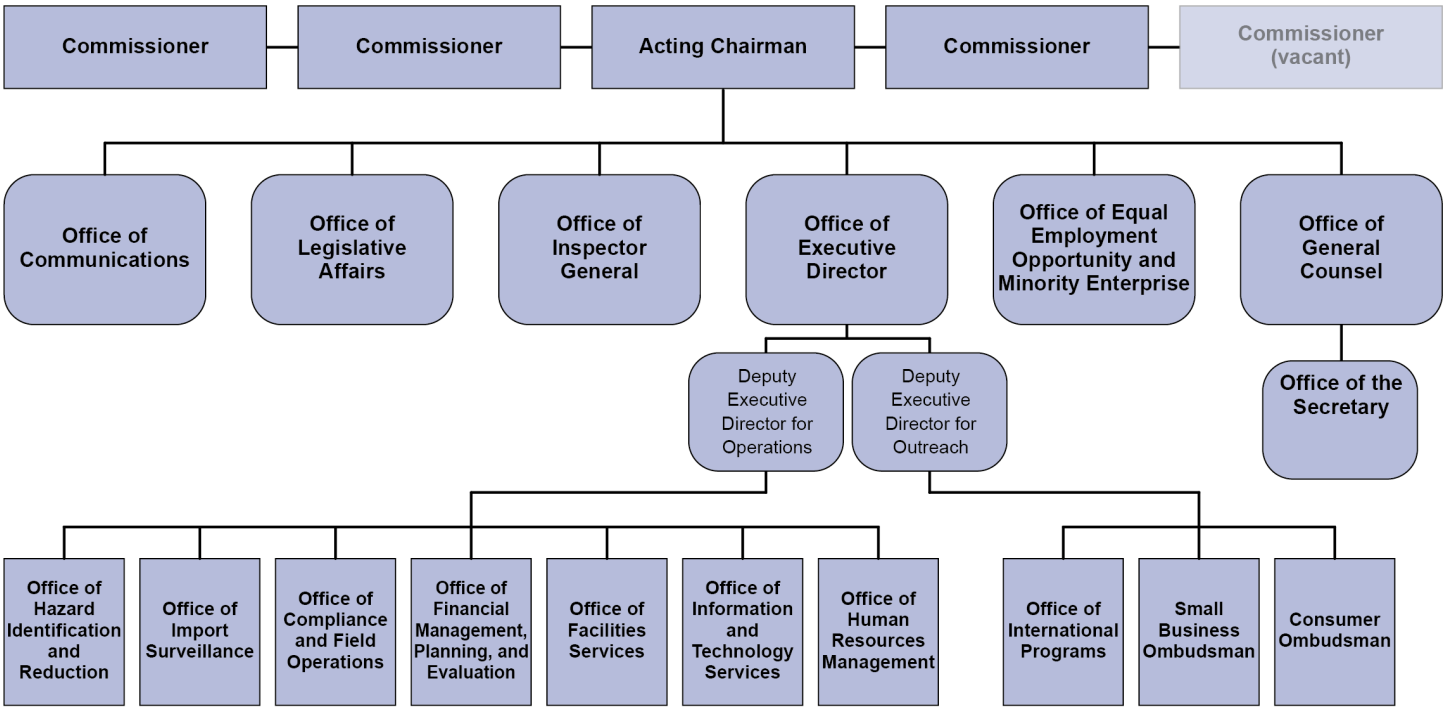
The Consumer Product Safety Act (CPSA) created CPSC to regulate consumer products and address those that pose an unreasonable risk of injury; assist consumers in evaluating the comparative safety of consumer products; and promote research and investigation into the causes and prevention of product-related deaths, injuries, and illnesses.[2] CPSC is empowered to carry out these goals through a combination of monitoring, research, standard-setting, and enforcement.

CPSC is an independent regulatory commission with a maximum of five members, one of whom serves as the Commission's Chair.[3] The Commission's staff are organized into six main offices and a number of suboffices (see fig. 1).

[2]15 U.S.C. §§2051-2089.

[3]15 U.S.C. § 2053(a). As of October 2020, CPSC was led by four commissioners, one of whom was serving as the Acting Chairman.

Figure 1: Consumer Product Safety Commission Organizational Chart, as of September 2020



Source: GAO adaptation of Consumer Product Safety Commission graphic. | GAO-21-56

In fiscal year 2020, CPSC's budget was $132.5 million, which provided funding for 539 full-time equivalent employees.[4] Table 1 shows CPSC's budgetary appropriations and authorized staffing levels from 2015-2020.

[4]Consolidated Appropriations Act, 2020, Pub. L. 116-93, Division B, Title V, 133 Stat. 2459-60 (2019).

Table 1: CPSC Congressional Appropriations and Funded Staffing Levels, Fiscal Years 2015–2020

Fiscal year	Appropriations ($ millions)	Full-time equivalent employees
2015	123	535
2016	125	549
2017	126	552
2018	126	530
2019	127	520
2020	132.5	539

Source: Consumer Product Safety Commission (CPSC) | GAO-21-56

In addition to authorities granted under the CPSA, CPSC has broad authority to identify, assess, and address hazards associated with consumer products under laws that include the following:

- **The Consumer Product Safety Improvement Act of 2008** amended the CPSA to expand CPSC's authorities to address consumer product safety risks by strengthening CPSC's authority to enforce product safety standards and increasing civil penalties for statutory violations.
- **The Flammable Fabrics Act** authorizes CPSC to prescribe flammability standards for clothing, upholstery, and fabrics.[5]
- **The Federal Hazardous Substances Act** establishes the framework for the regulation of substances that are toxic, corrosive, combustible, or otherwise hazardous.[6]

[5]15 U.S.C. §§ 1191-1204. The authority for enforcing the Flammable Fabrics Act was transferred to CPSC by the CPSA in 1972. Pub. L. No. 92-573, § 30, 86 Stat. at 1231 (1972).

[6]15 U.S.C. §§ 1261-1278a. Under the Federal Hazardous Substances Act, CPSC is authorized to declare a substance to be hazardous and regulate the labeling of substances declared to be hazardous. 15 U.S.C. §§ 1261-1262. The authority for enforcing the Federal Hazardous Substances Act was transferred to CPSC by the CPSA in 1972. Pub. L. No. 92-573, § 30, 86 Stat. at 1231 (1972).

Other laws provide CPSC with authorities to prescribe performance standards for specific consumer products.[7]

When carrying out activities under the authority of these laws, CPSC is concerned with products that may pose a substantial product hazard to the public. The CPSA defines a substantial product hazard as a failure to comply with an applicable consumer product safety rule under the CPSA or a similar rule, regulation, standard or ban under any other act administered by the Commission that creates a substantial risk of injury to the public, or a product defect that creates "a substantial risk of injury to the public."[8] Manufacturers, importers, distributors, and retailers of consumer products must notify the Commission immediately if they obtain information that reasonably supports the conclusion that a product fails to comply with a product safety standard on which the Commission has relied; fails to comply with any rule, regulation, standard, or ban under the CPSA or any other act enforced by the Commission; contains a defect that could create a substantial product hazard; or creates an unreasonable risk of serious injury or death.[9] CPSC also can identify products that may pose a substantial product hazard from other sources, such as reports of injuries from hospitals and consumer complaints.

When working to identify, assess, and address substantial product hazards, CPSC generally handles two types of cases:

- **Regulated product cases.** These involve products under CPSC's jurisdiction that are subject to mandatory standards prescribed in statutes and regulations.[10] These include federal rules that define requirements certain consumer products must meet before they may

[7]These additional laws include the Poison Prevention Packaging Act of 1970, 15 U.S.C. §§ 1471-1477; the Refrigerator Safety Act of 1956, 15 U.S.C. §§ 1211-1214; the Virginia Graeme Baker Pool and Spa Safety Act of 2007, 15 U.S.C. §§ 8001-8008; the Children's Gasoline Burn Prevention Act of 2008, 15 U.S.C. § 2056 note; and the Child Safety Protection Act of 1994, 15 U.S.C. §1278.

[8]15 U.S.C. § 2064(a).

[9] 15 U.S.C. § 2064(b).

[10]See app. II for an overview of CPSC's process for addressing hazards associated with regulated products.

be manufactured, imported, distributed, or sold in the United States.[11] Examples of products with such requirements include children's toys (which must meet standards for chemical and lead content) and garage door operators (which must employ entrapment protection mechanisms).[12] In a regulated product case, CPSC is authorized to initiate a recall when the agency determines that the firm's product constitutes a substantial product hazard through violation of an existing statute or regulation.

- **Product defect cases.** These involve products that are not covered by specific regulations and may be subject to voluntary product safety standards.[13] Most voluntary standards are developed by private sector standard-developing organizations with input from industry stakeholders, consumer advocates, and government agencies. In a product defect case, CPSC must demonstrate, through the collection of evidence, that a product presents a substantial product hazard. Product defect cases are generally more complex than regulated product cases because CPSC lacks the clear evaluative criteria of a mandatory regulation.

CPSC's Section 15 Defect Investigation Procedures Manual (section 15 manual) prescribes the process CPSC staff should follow when managing product defect cases. According to this manual, this process has five key stages:

1. opening a case after a product hazard is identified;
2. evaluating evidence to make a preliminary determination, which is the staff's assessment that a product has a defect that creates a substantial product hazard;
3. negotiating with the firm to develop a corrective action plan;
4. monitoring the firm's implementation of the corrective action plan; and
5. closing a case after CPSC determines that the firm has adequately implemented the corrective action plan.

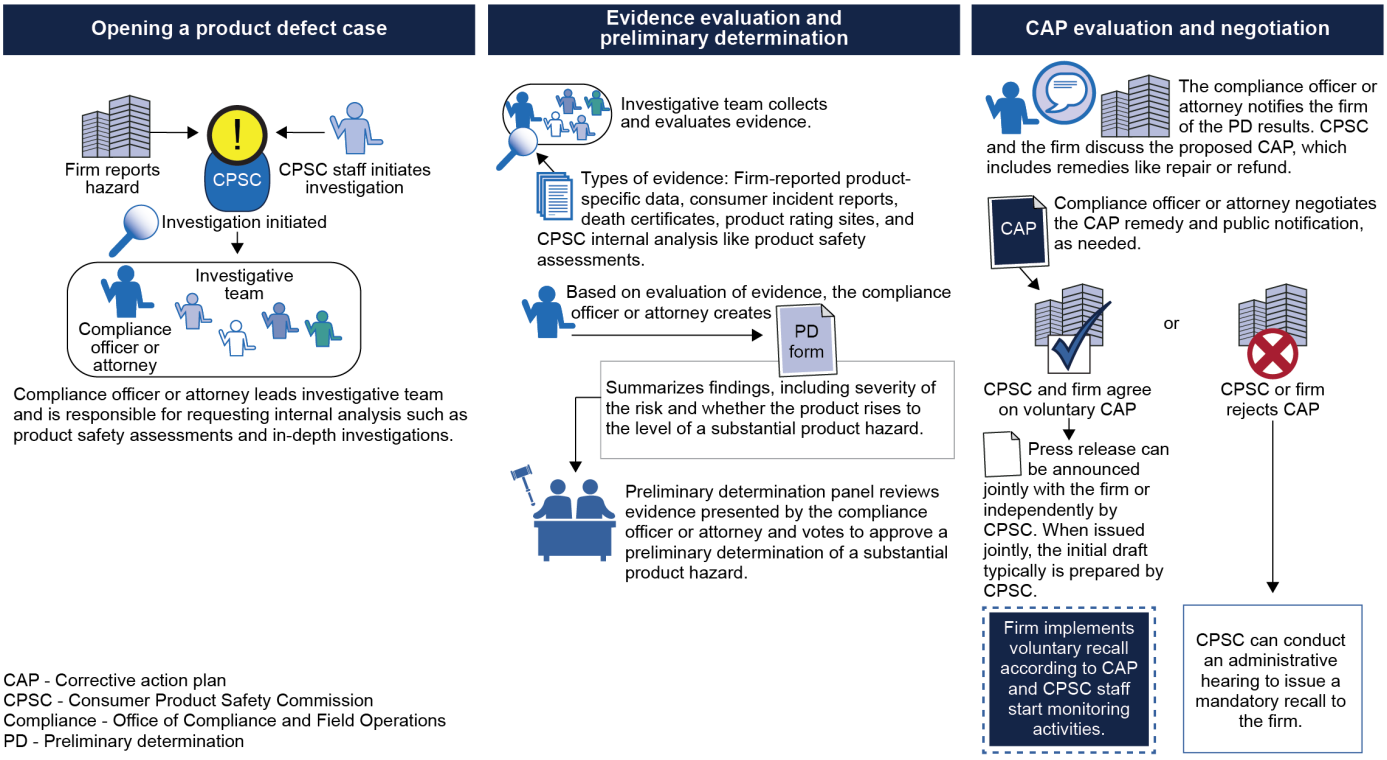
[11]CPSC is statutorily restricted from issuing mandatory safety rules except in instances in which voluntary standards would not "eliminate or adequately reduce the risk of injury" and where it is unlikely there "will be substantial compliance with such voluntary standards." (15 U.S.C. § 2056(b)).

[12]See 15 U.S.C. § 2056b; 15 U.S.C. § 2056 note.

[13]CPSC alternately refers to cases involving unregulated products as "section 15 cases," in reference to section 15(a) of the CPSA, which defines a substantial product hazard.

Time frames associated with the first three stages influence the length of time that passes before firms initiate steps to mitigate product safety hazards (see fig. 2).

Figure 2: Overview of Decision Making-Process for Product Defect Cases



CAP - Corrective action plan
CPSC - Consumer Product Safety Commission
Compliance - Office of Compliance and Field Operations
PD - Preliminary determination

Source: GAO analysis of CPSC policies and procedures. | GAO-21-56

This manual also defines hazard classifications, which group the severity of product hazards (see table 2).[14]

[14]The section 15 manual states that the hazard priority serves as the guide for determining the level and intensity of corrective action and public notice.

Table 2: Hazard Classifications and Definitions for CPSC Product Defect Cases

Classification	Description
Class-A	A risk of death or grievous injury or illness is likely or very likely, or serious injury or illness is very likely. Voluntary corrective action plans involving class-A hazards require a Commission vote.
Class-B	Risk of death or grievous injury or illness is not likely to occur but is possible; serious injury or illness is likely; or moderate injury or illness is possible.
Class-C	Risk of serious injury or illness is not likely but is possible; moderate risk of injury or illness is not necessarily likely, but is possible.
Class-D	Defect exists; risk of injury does not rise to the level of a substantial product hazard; company voluntarily has taken action to address the risk.

Source: Consumer Product Safety Commission (CPSC) | GAO-21-56

CPSC has a number of tools available to respond to substantial product hazards. CPSC has authority to order companies to engage in various corrective actions—including refunds, replacements, or repairs of products.[15] However, CPSC generally may only exercise this authority after conducting an administrative hearing, and any entity that is adversely affected by such an order can challenge the action in federal court. Because of this, in most circumstances CPSC negotiates corrective actions with firms on a voluntary basis and will pursue mandatory compliance only if CPSC and the firm fail to reach a voluntary agreement. In addition, in cases in which CPSC finds that a firm's product is in violation of a statute or regulation, it can issue a notice of violation letter and request corrective actions, such as stopping sale of the product or correcting future production.

CPSC may also pursue enforcement actions—such as civil or criminal penalties—for violations such as the sale of a consumer product subject to voluntary corrective taken by the manufacturer. According to CPSC officials, mandatory compliance actions require additional time and resources to pursue and may lead to lengthy delays in removing hazardous products from the market. As a result, according to officials, CPSC pursues these actions only as a last resort.

[15]15 U.S.C. § 2064(d).

CPSC Has Taken Steps Intended to Improve Efficiency but Issues Remain with Timeliness Goals and Prioritization for Product Defect Cases

CPSC Has Taken Steps Intended to Improve Efficiency

CPSC has planned or taken several process-related steps intended to address consumer product safety hazards in a more efficient and timely manner.

- **Restructuring the Office of Compliance and Field Operations.** In January 2020, CPSC's Office of Compliance and Field Operations created the Enforcement and Litigation Division to bring compliance and legal staff working on preliminary determinations and corrective action plans into one division.[16] CPSC officials noted that an intended benefit of this restructuring was to ensure that CPSC teams working on product defect cases have increased access to staff resources, such as staff attorneys who previously were in a separate division.
- **Developing a web portal for Fast-Track program.** CPSC plans to develop an electronic submission portal to facilitate firms' submission of information to the Fast-Track program. CPSC introduced the Fast-Track recall program in 1995 to quickly remove potentially hazardous products from the U.S. market—eliminating the need for CPSC staff to make a preliminary determination. CPSC officials noted that the new portal is intended to help ensure that firms more consistently and completely submit the data needed to participate, helping reduce processing delays. The officials told us they began collecting input from external stakeholders on the portal in fiscal year 2020 and a contractor will begin building the portal in fiscal year 2021.
- **Updating the product defect case management system.** As of 2016, CPSC uses a new product defect case-management system that allows staff to enter and track case-management information

[16]The Enforcement and Litigation Division is also responsible for administrative litigation and imposition of enforcement actions such as civil penalties.

electronically, which could improve the agency's ability to manage key process stages for product defect cases.[17] CPSC officials told us that previously these processes relied on paper documentation.

In addition, CPSC recently increased its use of unilateral press releases to notify the public more quickly of a potential hazard posed by a product or product category. When CPSC makes a preliminary determination of a substantial product hazard but a firm is unwilling or unable to conduct a voluntary corrective action, CPSC may consider issuing a unilateral press release to warn the public of the hazard.[18] CPSC officials told us that if they are confident that staff can reach a voluntary agreement with the firm, they generally do not pursue a unilateral press release.

CPSC has issued four unilateral press releases since October 2019, but before that had issued only two since 2010.[19] CPSC Commissioners as of September 2020 had mixed views on the use of unilateral press releases. Three have supported their use, while one other expressed concern they could be used inappropriately to embarrass a firm or create leverage in corrective action plan negotiations.

CPSC's Timeliness Measures Do Not Account for Variability among Cases

CPSC has established time frames and related performance goals staff should meet for key stages of its process for product defect cases, but time frames can vary significantly across product defect cases, with complex cases taking more time. For example, CPSC's section 15 manual recommends that staff should make a preliminary determination within 3 months of opening a case for products that pose a high risk of harm to consumers. In addition, CPSC sets annual performance goals related to the timely management of cases, including a goal related to making a preliminary determination within 85 days of opening an investigation (see table 3). However, CPSC officials told us that complex cases can take more time because they often require new or in-depth technical analysis by CPSC staff or external contractors that can cause delays. For example, our analysis of product defect case data from 2016

[17]CPSC officials stated that they started implementing the new system in 2013 but did not fully implement it until 2016.

[18]Unilateral press releases must adhere to the requirements of section 6(b) of the CPSA and the regulations established in 16 C.F.R. part 1101, which require that CPSC provide firms with at least 15 days to comment on the accuracy of the information in a unilateral press release.

[19]The four unilateral press releases in 2020 were related to infant sleepers, hover boards, cedar chests, and a cooking tool.

through 2019 found 60 percent (78 of 131) took longer than 3 months to make a preliminary determination, with a few taking more than a year (6 of 131).

Table 3: Key CPSC Timeliness Goals for Product Defect Cases, Fiscal Year 2019

Product defect case process stage	Annual timeliness goals
Opening a case	Percentage of cases for which a request for all required information to evaluate a potentially hazardous consumer product is sent within 5 business days of case opening
Evidence evaluation	Percentage of cases for which a preliminary determination is made within 20 business days of completed product safety assessments
Evidence evaluation	Percentage of cases for which a preliminary determination is made within 85 business days of the case opening
Corrective action plan negotiation	Percentage of cases for which a corrective action is accepted within 90 business days of preliminary determination

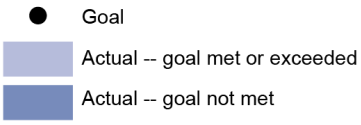
Source: Consumer Product Safety Commission (CPSC). | GAO-21-56

Additionally, section 6(b) of the CPSA requires CPSC to provide a firm advance notice and opportunity to comment on the accuracy of any information related to a potential product hazard before that information is disclosed to the public. CPSC officials and external stakeholders told us that satisfying this requirement may delay agreement on language for notifying the public of a product recall.

CPSC has faced challenges consistently meeting two of its timeliness goals related to evidence evaluation and reaching a preliminary determination. As shown in figure 3, in fiscal years 2018 and 2019, CPSC missed its goal to reach a preliminary determination within 20 business days of completing a product safety assessment. In addition, in fiscal year 2019, CPSC fell significantly short of reaching its goal to make a preliminary determination within 85 business days—this occurred in only 12.5 percent of product defect cases compared to a goal of 65 percent. While CPSC officials noted that the government shutdown from December 2018 to January 2019 affected their ability to meet timeliness goals in 2019, time frames can vary significantly across product defect cases and these goals are not useful for cases with certain characteristics, such as those that required complex technical analysis or interviews with affected consumers.

Figure 3: Timeliness Performance Goals and Results for Product Defect Cases (Fiscal Years 2016–2019)

Process stage	Performance measure description	Goal and actual (percentage)	Goal	Actual
Opening a case	Percentage of cases where a request for all required information to evaluate a potentially hazardous consumer product is sent within 5 business days of case opening	2017	None[a]	91.0
		2018	90	93.1
		2019	90	91.8
Evidence evaluation	Percentage of cases for which a preliminary determination is made within 20 business days of completed product safety assessments	2017	None	35.0[b]
		2018	60	42.8
		2019	50	25.6
Evidence evaluation	Percentage of cases for which a preliminary determination is made within 85 business days of the case opening	2017	None	74.0
		2018	70	75.0
		2019	65	12.5
Corrective action plan negotiation	Percentage of cases for which a corrective action is accepted within 90 business days of preliminary determination	2017	None	52.0[a]
		2018	60	92.7
		2019	60	76.9
Fast-Track recall program	Percentage of Fast-Track cases with corrective actions initiated within 20 business days	2017	90	98.0
		2018	90	95.9
		2019	90	97.4



N/A = Not applicable (CPSC did not have this performance measure in this fiscal year)
None = CPSC did not have goals for the applicable performance measure in this fiscal year

Source: Consumer Product Safety Commission (CPSC). | GAO-21-56

Note: CPSC calculated its performance metrics based on product cases assigned one of the three highest hazard classifications (A, B, or C) based on CPSC's determination of the risk posed to consumers.

[a]For fiscal year 2017, CPSC's performance goal for accepting corrective actions after making a preliminary determination had a target of 60 business days instead of 90 business days.

[b]For fiscal year 2017, CPSC's performance goal for making a preliminary determination after completing a product safety assessment had a target of 10 business days instead of 20 business days.

In prior work, we reported that a set of successful performance goals and measures is balanced to address varied aspects of program performance.[20] However, by using the same timeliness measures for cases, CPSC does not account for the significant variability in the time it takes staff to conduct key stages of a product defect investigation. CPSC officials acknowledged that these timeliness goals may not be useful, but have not taken steps to update or revise these goals. As a result, CPSC's product defect investigation time frames may not be an effective tool for managing more complex cases and its performance goals may not be an effective measure of timeliness overall.

CPSC Does Not Follow Steps Described in Policy to Prioritize Product Defect Cases Based on Potential Risk to Consumer Safety

The section 15 manual describes steps CPSC staff should take to prioritize resources for newly opened product defect cases. According to the manual, when CPSC opens a new product defect case, staff are to assign a tentative hazard classification to help prioritize cases. These classifications are based on criteria for potential risk to consumer safety in the section 15 manual—for example, a tentative class-"a" rating would be assigned where evidence indicates the product may pose a class-A safety hazard (likely risk of death or serious injury).[21] According to the section 15 manual, an economic or health sciences product safety assessment should be completed within 2 weeks for a case with a tentative class-a rating and within 3 weeks for cases with all other classifications.

However, CPSC does not follow these risk-based steps for prioritizing cases. Specifically, compliance officials told us that staff do not rely on the tentative hazard classifications for prioritizing resources, such as assigning additional technical or legal staff to product defect cases that pose the highest risk of harm to consumers.[22]

CPSC officials told us that rather than using tentative hazard classifications to prioritize resources upon opening a case, they instead rely on management and staff experience in addressing product safety

[20]GAO, *Agency Performance Plans: Examples of Practices That Can Improve Usefulness to Decision Makers*, GAO/GGD/AIMD-99-69 (Washington, D.C.: Feb. 29, 1999).

[21]CPSC uses a lowercase letter to indicate a tentative hazard classification, and changes it to an uppercase letter once staff finalize a preliminary determination.

[22]CPSC's product defect case management system automatically labels cases as "high priority" if the product causes internal organ injuries, suffocation risk, has any death reported, has over 100 incidents reported, or was assigned a tentative Class-a hazard classification. However, CPSC officials told us that this automatic designation is primarily used for tracking serious cases, not resource prioritization.

hazards to make decisions on a case-by-case basis. Specifically, CPSC officials told us that Office of Compliance and Field Operations management review staff workload reports and case timeliness reports to assess whether CPSC should assign additional resources to a case or reassign a case to other staff. However, the section 15 manual does not describe this approach for prioritizing cases based on potential risk to consumer safety associated with a product, or other factors, such as units sold. Establishing and following procedures for prioritizing new cases based on relevant case-specific factors, such as the potential safety risk, could help ensure CPSC staff consistently allocate staff resources to cases based on these factors.

CPSC Relies on Voluntary Corrective Actions More Frequently Than Mandatory Corrective or Enforcement Actions

CPSC Has Relied Principally on Voluntary Agreements with Firms for Recalls and Pursued Few Mandatory Recalls

CPSC principally has relied on voluntary corrective actions for product defect cases or to address violations of statutes or implementing regulations.

Product Defect Cases

For product defect cases between 2016 and 2019, CPSC had 1,000 active product defect investigations, 131 of which resulted in voluntary corrective actions.[23] By comparison, CPSC brought six administrative cases for mandatory recalls since 2010. CPSC has authority to issue mandatory recalls but only after the involved firm is given the opportunity for an administrative hearing, and the firm can subsequently challenge the recall in federal court. Furthermore, CPSC generally only exercises its authority to impose mandatory recalls if the Commission determines that

[23]CPSC officials stated that product defect case data were not reliable before full implementation of the product defect case management system in 2016.

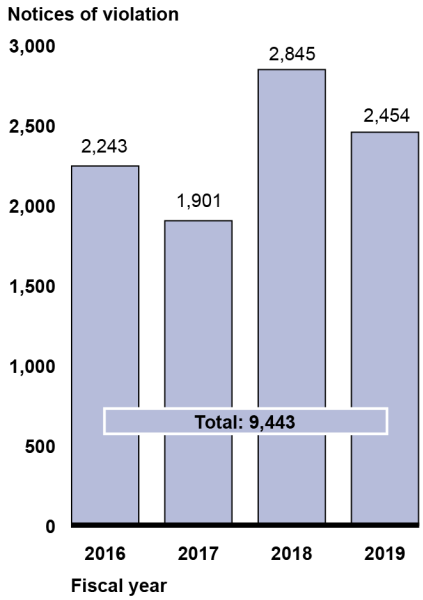
voluntary actions are insufficient, product hazards are particularly acute, or safety standard violations are egregious.

CPSC officials said that negotiating a voluntary corrective action plan is typically more efficient than a mandatory action for achieving the goal of quickly removing hazardous products from the U.S. market. CPSC Commissioners and officials told us that pursuing mandatory recalls is resource-intensive and time consuming. We found that most cases in which CPSC pursued a mandatory recall took more than 1 year to finish, with one taking almost 7 years. Furthermore, hazardous products stay on the market while CPSC pursues the recall unless the agency takes a separate legal action, such as seeking a court injunction to stop the sale of the product.

Products in Violation of the Law

Similar to product defect cases, in recent years CPSC relied on voluntary actions by firms to address products that violate the CPSA or other acts CPSC enforces. From 2016 through 2019, CPSC issued 9,443 notice of violation letters describing the violation and CPSC's proposed corrective action to firms with a product found to be in violation of applicable statutes and regulations (see fig. 4).

Figure 4: Notices of Violation Sent by CPSC, 2016–2019

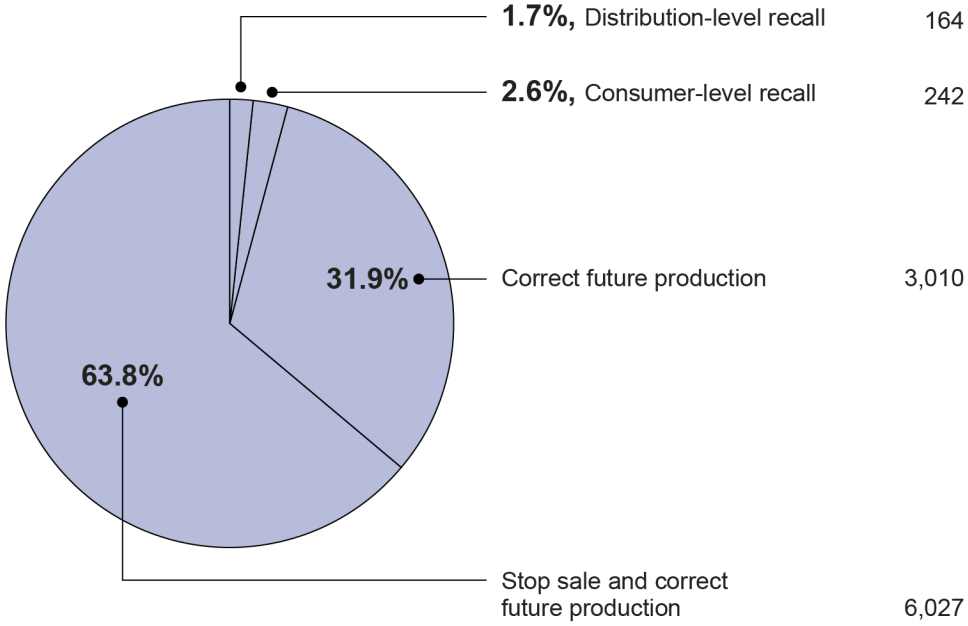


Source: GAO analysis of Consumer Product Safety Commission (CPSC) data. | GAO-21-56

Corrective actions proposed by CPSC in notices of violation include (1) stop sale and correct future production, (2) correct future production, (3) recall the product at the consumer level, and (4) recall the product at the distribution level. Consumer-level recalls made up 2.6 percent and distribution-level recalls made up 1.7 percent of all such corrective actions from 2016 through 2019 (see fig. 5). Firms agreed to implement CPSC's proposed corrective action in 81 percent of regulated product cases in that period.

Figure 5: CPSC Proposed Corrective Actions for Regulated Product Violations, 2016–2019

The Consumer Product Safety Commission (CPSC) can propose four types of corrective actions to firms whose products have safety hazards in violation of law or regulation.



Source: GAO analysis of Consumer Product Safety Commission data. | GAO-21-56

From 2016 through 2019, CPSC identified 82 percent of its regulated product violations through its import surveillance program, which works closely with U.S. Customs and Border Protection to identify and examine imported shipments of consumer products. China was the place of origin for 72 percent of these products. Five violation types accounted for approximately 66 percent of all notices of violation CPSC sent to firms in that time period: violations related to tracking label requirements (26 percent), lead in children's products (20 percent), third-party certificate

requirements (11 percent), art material labeling requirements (5 percent), and products containing small parts (4 percent).

CPSC Has Taken Few Enforcement Actions, Such as Imposing Civil Penalties

CPSC has pursued few enforcement actions in recent years. As stated previously, CPSC has authority to take enforcement actions, such as imposing civil penalties and seeking injunctions and seizures. CPSC Commissioners and officials told us that priorities established by agency leadership drive CPSC's propensity to pursue enforcement actions. For example, most CPSC Commissioners (three of four) and officials said staff would pursue more civil penalties if the Chair signaled that doing so was a priority. Commissioners and officials cited resource constraints as another factor in deciding whether to pursue enforcement actions, which are resource-intensive and time-consuming.

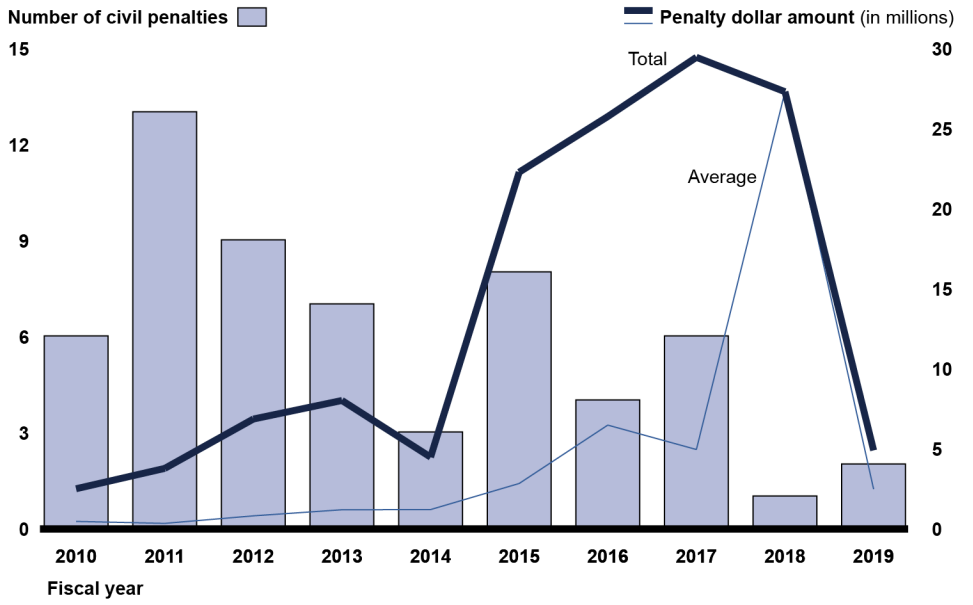
Civil Penalties

Civil penalties are monetary fines that CPSC can impose for violation of prohibited actions defined by statutes such as the CPSA or the Federal Hazardous Substances Act.[24] CPSC imposed 59 civil penalties from 2010 through 2019 (see fig. 6). CPSC officials told us that civil penalty settlement agreements negotiated by CPSC staff contain provisions requiring firms to implement and maintain an internal compliance program and a system of internal controls, in addition to paying a civil penalty.[25] Since 2016, CPSC has accepted nine such agreements.

[24]Prohibited actions include selling a consumer product that violates CPSC regulations or rules or is subject to voluntary corrective action taken by the manufacturer. 15 U.S.C. § 2068.

[25]In the event that CPSC and a subject company cannot agree on civil penalty settlement terms, CPSC may refer the matter to the Department of Justice to initiate civil penalty litigation.

Figure 6: Consumer Product Safety Commission Civil Penalties, 2010–2019



Source: GAO analysis of Consumer Product Safety Commission (CPSC) data. | GAO-21-56

Criminal Penalties

Criminal penalties include monetary fines, imprisonment of individuals, and forfeiture of assets for violating statutes such as those mentioned above.[26] Criminal matters are referred to the Department of Justice. CPSC has had significant involvement in 12 criminal penalty cases prosecuted from fiscal years 2007 to 2019, with the most recent case occurring in 2011.[27]

Injunctions and Seizures

Other enforcement actions CPSC can take against firms include injunctions and seizures of products. From 2016 through 2019, CPSC was granted nine court injunctions, which can order firms to take specific actions. For example, an injunction can prohibit the manufacture or sale of certain consumer products. Products in violation of an applicable statute or regulation enforced by CPSC are subject to seizure and

[26]See, e.g., 15 U.S.C. 2070(a),(c) [CPSA],15 U.S.C. 1264(a) [FHSA], and 15 U.S.C. 1196 [FFA].

[27]CPSC officials stated that there are pending criminal penalty matters that cannot be made public as of July 2020.

condemnation proceedings. However, CPSC did not seek any seizures through federal courts from 2016 through 2019.

CPSC Promulgates Mandatory Standards Less Frequently Than It Participates in the Development of Voluntary Standards

CPSC is statutorily restricted from issuing mandatory consumer safety rules in instances in which compliance with voluntary standards would eliminate or adequately reduce the risk of injury and it is likely there will be substantial compliance with such voluntary standards. CPSC officials and other stakeholders in the development of voluntary product standards told us that the process for developing mandatory standards can be lengthy, often lasting several years.[28] Amendments to the CPSA passed in 1981 added new steps that CPSC must follow to issue mandatory consumer safety rules.[29] For example, before implementing a mandatory consumer safety rule, CPSC must conduct a cost-benefit analysis, assess alternatives to the final rule, and justify why these alternatives were not adopted.[30] In addition, CPSC must substantiate a number of findings, including that the rule is reasonably necessary to eliminate or reduce an unreasonable risk of injury associated with the product, and that the rule is the "least burdensome" that will adequately reduce the risk.[31]

Between 2016 and 2020, CPSC finalized 35 mandatory product safety standards, more than half of which were revisions to existing standards. Of the 35 standards, none was promulgated using the rulemaking process required by the 1981 amendments to the CPSA.

Because of statutory restrictions and difficulties promulgating mandatory standards, CPSC actively participates in the development of voluntary product safety standards. CPSC staff told us that because the agency has limited resources, CPSC tries to participate in the development of voluntary standards that align with agency priorities or for products that may pose the greatest risk. Since 2016, CPSC has participated in the development of between 71 and 78 voluntary standards per year, including for high chairs, candles, and fuel containers.

[28]According to CPSC, over 250 products are currently regulated and subject to mandatory standards.

[29]Pub. L. No. 97-35, § 1203, 95 Stat. 703, 704-13 (1981) (codified as amended at 15 U.S.C. § 2058).

[30]15 U.S.C. § 2058(f)(2)(A),(B).

[31]15 U.S.C. § 2058(f)(3).

CPSC staff involved in the development of voluntary standards told us that teams throughout the agency make recommendations for potential product categories to participate in voluntary standards activities. Those recommendations are vetted by CPSC management. CPSC staff told us that criteria the agency considers when making decisions on involvement in voluntary standard development include the likelihood the voluntary standard will adequately reduce the risk of injury, result in substantial compliance, and be developed in a timely manner. See appendix III for more details on CPSC's participation in voluntary standards development.

CPSC's Oversight of Firms' Compliance with Corrective Action Plans Could Be Improved

CPSC's two primary mechanisms for overseeing firms' compliance with corrective action plans are recall effectiveness checks and monthly progress reports. Recall effectiveness checks are conducted by CPSC staff or delegates to determine if the corrective action plan is being carried out, while monthly progress reports are completed by firms and submitted to CPSC for review.[32]

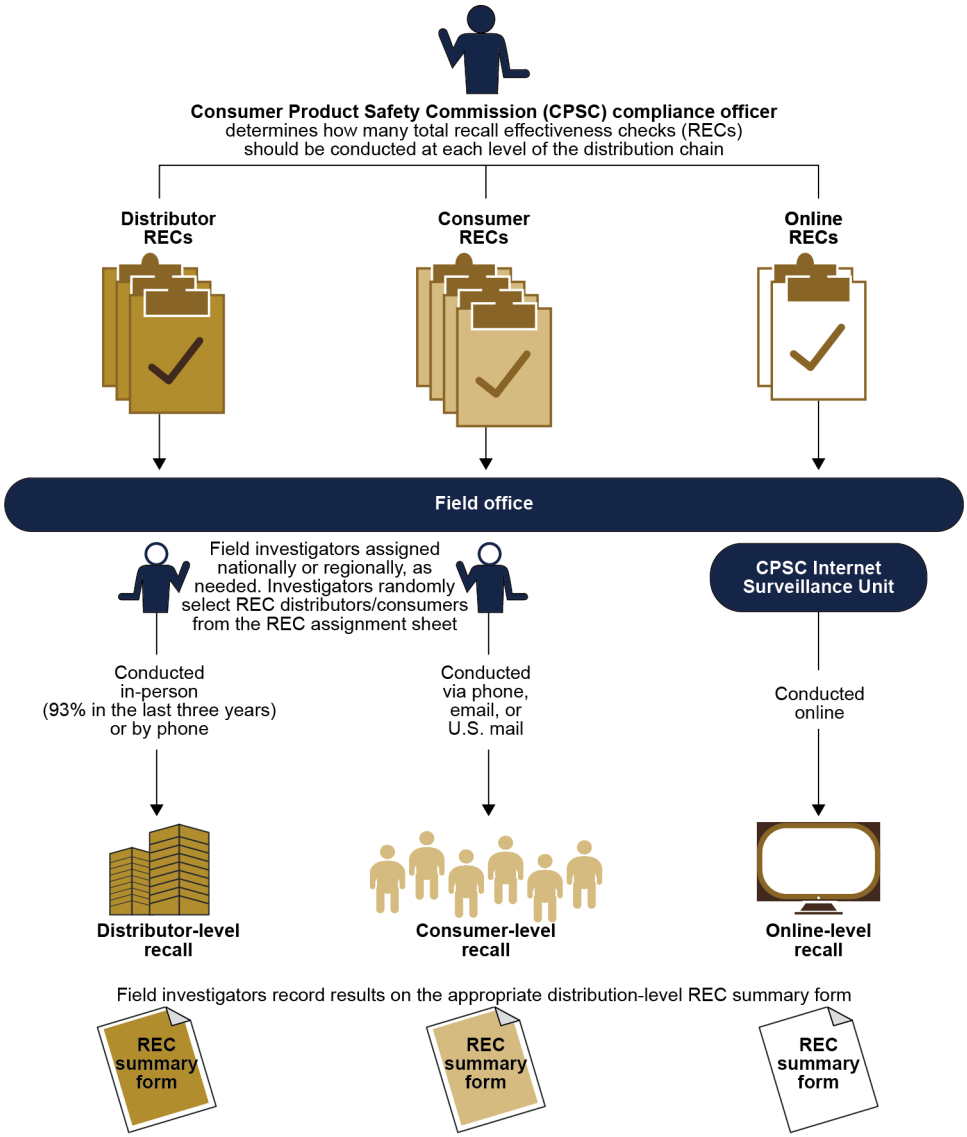
CPSC Does Not Allocate Resources to Recall Effectiveness Checks Based on Key Risk Factors

In the event of a recall of a hazardous product, CPSC field staff conduct recall effectiveness checks to determine if the recall is being carried out according to the agreed upon corrective action plan at all levels of the distribution chain (see fig. 7).[33] At the direction of CPSC compliance officers, field staff check to ensure that the recalling firm has carried out its responsibilities under the corrective action plan. For example, staff may check that distributors (wholesalers, retailers) have removed recalled products from shelves and placed any appropriate signage in stores for consumers to see.

[32]CPSC officials stated that about 1 month after reaching a corrective action plan agreement field investigators also conduct corrective action plan inspections at firms to confirm that firms are properly executing recalls. During a corrective action plan inspection, a field investigator visits a firm to check that the firm's recall documentation and practices align with the corrective action plan agreement.

[33]CPSC officials told us that under the Office of Compliance's new structure case management duties performed by compliance officers may also be performed by attorneys within that office.

Figure 7: Recall Effectiveness Check Process



Source: GAO analysis. | GAO-21-56

Note: In this context, distributors refer to wholesalers and retailers that distribute products.

CPSC's section 15 manual states that compliance officers should consider factors such as hazard classification when determining how many checks to assign, because higher risk cases require more rigorous

monitoring.[34] Additionally, CPSC officials stated that compliance officers should take into account risk factors such as hazard classification, deaths, injuries, and number of products being recalled when determining the number of recall effectiveness checks to conduct.

However, our analysis of CPSC's data shows that compliance officers did not consistently assign more checks to higher-risk recalls between February 2016 and May 2020. Instead, compliance officers assigned varying numbers of checks to cases with similar risk profiles, or assigned similar numbers of checks to cases with very different risk profiles (see table 4). For example, in two cases with the same hazard classification, similar numbers of products being recalled, and similar numbers of injuries, compliance officers assigned 70 checks to one case and 11 to the other. In a separate instance, compliance officers assigned 20 checks to a case with a C hazard classification, fewer than 2,000 products being recalled, and two injuries reported, while assigning 15 checks to a case with a B hazard classification (indicating higher risk than a C hazard), more than 200,000 products being recalled, and 115 injuries reported.

Table 4: Examples of Product Recall Cases that Illustrate Variation in Number of Recall Effectiveness Checks by Recall Characteristics

Example	Hazard classification	Number of products recalled	Injuries reported	Total number of recall effectiveness checks conducted
Example Case 1a	C	1,942,466	27	**70**
Example Case 1b	C	1,487,129	30	**11**
Example Case 2a	C	1,807	2	**20**
Example Case 2b	B	217,633	115	**15**
Example Case 3a	B	86,800	0	**5**
Example Case 3b	B	86,752	11	**0**
Example Case 4a	C	317,282	27	**0**
Example Case 4b	C	25,602	0	**25**

Source: Consumer Product Safety Commission (CPSC) | GAO-21-56

Note: We selected the cases in the table as illustrative examples of variance in the number of recall effectiveness checks assigned in CPSC Section 15 Recall Cases opened between June 2013 and November 2019 with hazard classifications A, B, and C. Examples were selected for similarities in risk factors but high variance in the number of checks conducted, or for similarities in numbers of checks assigned but high variance in risk factors.

[34]We define one recall effectiveness check as a single visit to a distributor, call or email to a consumer, or online check. If the compliance officer assigned 10 consumer-level checks, the field officer would contact 10 separate consumers.

While the section 15 manual does not contain written instructions on how many checks compliance officers should assign, CPSC officials told us that it is standard for compliance officers to assign 10 checks per recall and increase or decrease this number based on the recall's risk profile and other factors. Our analysis of CPSC's data shows that on average 8.57 checks were conducted per recall, for product defect recalls closed between January 2016 and May 2020 with hazard classifications of A, B, and C.

Federal internal control standards state that management should design control activities to achieve objectives and respond to risks.[35] This includes designing procedures to achieve the agency's objectives. Although the section 15 manual provides general instructions that compliance officers should consider risk factors when assigning recall effectiveness checks, these instructions do not specify how to consider risk factors. Instead, determining the number of checks is left to the judgment of individual compliance officers.

In our review of a sample of recall cases, we did not identify any documentation by compliance officers that provided their justification for the numbers of checks they assigned. As a result, we could not determine if compliance officers consistently used the same approach across recalls.[36]

CPSC told us it has not considered revising the manual to include more specific instructions for how many recall effectiveness checks should be conducted based on the characteristics of recalls. CPSC officials noted that they have not considered issuing more guidance on how checks should be assigned, and any additional instructions on assigning effectiveness checks would need to allow for flexibility, given the wide variety of products being recalled. As seen above, the lack of specific instructions in the section 15 manual or elsewhere on assigning recall effectiveness checks likely has contributed to inconsistencies, and the rationales for these inconsistencies are unknown. By providing more formal written guidelines or procedures for how compliance officers should determine how many recall effectiveness checks to assign, CPSC

[35]See GAO, *Standards for Internal Control in the Federal Government*, GAO-14-704G (Washington, D.C.: Sept. 10, 2014).

[36]We reviewed a random sample of 25 cases from a population of 78 Section 15 recall cases closed between February 2016 and May 2020 with hazard classifications of A, B and C, and in the top 80 percent of cases by recall volume.

could position compliance officers to prioritize resources effectively to more closely monitor recall cases that are higher risk.

CPSC Does Not Systematically Track Firms' Submission of Monthly Progress Reports, and Firms Do Not Submit Them Consistently

Monthly progress reports are standardized, one-page forms that recalling firms submit to CPSC on a monthly basis, typically per a clause in their corrective action plan. These forms provide CPSC with information on the recall's performance in various areas, such as the number of products corrected, notifications made to consumers, advertisement of the recall, and social media and web engagement with recall content.

The section 15 manual states that monthly progress report forms are to be submitted by the recalling firms. These forms provide CPSC staff with specific information on how many units of the defective product have been repaired, replaced, or refunded by the firm each month, as well as how many consumers contacted the firm about the recall announcement. In cases in which monthly progress reports indicate a slowdown in the recall's progress, the section 15 manual directs compliance officers to consider whether such a slowdown indicates a problem with the recall. CPSC also uses the information from these forms to determine when a corrective action plan should remain open or be closed.

However, CPSC does not track global submission of progress reports across all recalls, so it does not always know that not all firms are submitting them monthly. When a firm is late to submit a progress report, a CPSC system alerts the responsible compliance officer so they can contact the firm and attempt to correct the issue. However, CPSC does not have a systematic approach for globally tracking submission of monthly progress reports. According to our analysis of CPSC's data (for product defect case recalls closed between February 2016 and May 2020 with hazard classifications of B and C), over half of firms did not submit all monthly progress reports to CPSC. Our analysis of data in these cases shows that about 61 percent of firms achieved a monthly progress report submission rate greater than 75 percent, while 25 percent of firms submitted their monthly progress report for less than half of the months in which a report was required.[37]

In a random sample of 25 product defect case recalls from January 2016 to May 2020, we found that all of the cases had monthly progress reports

[37]We define this submission rate as the number of monthly progress reports a firm submitted for a given recall over the number of months in which a firm would have been expected to submit a monthly progress report for that recall.

required in their corrective action plan, but 12 of the 25 had a report submission rate of 75 percent or lower.[38] CPSC officials stated that in cases in which a firm missed a number of months in a row, the next report submitted typically included up-to-date numbers that included information from the missed months. In one case, a report covered from June 26, 2018, through April 30, 2019, a period during which CPSC had received no updates on the status of the recall. These delays in reporting could result in CPSC not being informed in a timely manner about potential problems with recall implementation, such as delays in removing potentially hazardous products from the market.

CPSC has goals for ensuring the submission of monthly progress reports. CPSC's 2018–2022 Strategic Plan includes a performance goal of improving the effectiveness of corrective actions, which notes the importance of working with firms to ensure the accuracy and timeliness of their progress reports.

Monthly progress reports are an important source of quality information for CPSC to monitor recall effectiveness, but CPSC lacks a mechanism to systematically track report submission rates across all recalls. CPSC recently created the position of Recall Monitor in the Office of Compliance. This position is responsible for periodically checking with compliance officers to discuss firms' monthly progress, among other duties. However, the creation of this position does not address CPSC's inability to systematically track progress report submission rates. While compliance officers may track the submission rates of monthly progress reports for individual recalls, CPSC's lack of a measure of overall submission rates means it does not have visibility into the extent to which firms have not been complying with the monthly progress report requirement.

If CPSC does not regularly receive reports from firms, compliance officers may miss signs that a recall is ineffective, or that it has been effective and is ready to be closed. Systematically tracking progress report submission rates would allow the Office of Compliance to better identify and address firms' noncompliance with the requirement to submit monthly progress reports for recalls. In turn, better compliance with this monthly reporting

[38]We reviewed a random sample of 25 cases from a population of 78 product defect case recalls closed between February 2016 and May 2020 with hazard classifications of B and C, and in the top 80 percent of cases by recall volume.

requirement would improve CPSC's ability to monitor the status of product recalls.

CPSC Has Identified Best Practices for Recalls but Its Efforts to Assess the Effectiveness of Corrective Actions Have Limitations

CPSC Primarily Relies on One Measure of Recall Effectiveness That Has Limited Usefulness for Recalls with Certain Characteristics

CPSC uses one performance measure to assess the effectiveness of recalls—the correction rate. Corrected products are those for which consumers have utilized a firm-provided recall remedy (for example, a repair kit, replacement, or refund). Since fiscal year 2017, CPSC has used the correction rate—the total number of recalled products corrected divided by total number of products recalled—as the key performance indicator for recall effectiveness in its strategic plan. According to CPSC, this performance measure is intended to improve understanding of the overall effectiveness of product recalls at all levels (manufacturer, distributor, retailer, and consumer).

However, using the correction rate as the only measure of recall effectiveness may not allow CPSC to accurately gauge the effectiveness of all its recalls. Various recall characteristics can contribute to lower consumer participation in a particular corrective action. For example, when a firm recalls, and offers to replace, a product that has a very low dollar value, like a fast food meal toy, consumers aware of the recall may throw away the product rather than take the corrective action (return it for replacement). In this case, the recall is effective in alerting the consumer and removing the hazard, but this would not be reflected in CPSC's correction rate because the consumer did not use the firm-provided remedy. Thus, the correction rate may not fully reflect a recall's success at mitigating product hazards.

CPSC has not recently updated the recall performance data it collects or the way it collects recall effectiveness data. CPSC last updated its monthly progress report form in 2015, and the form does not include some fields that could be useful indicators of recall effectiveness. In July

2020, CPSC officials said that CPSC does not have plans to update its progress report forms to include additional data fields.

In prior work, we reported that a set of successful performance goals and measures is balanced to address varied program priorities.[39] For example, an agency might have one primary goal and measure of performance in a particular area that is then balanced by other goals and measures that help depict the complex performance they are intended to assess.

In addition, CPSC's most recent strategic plan stated intent to consider additional evaluation tools and metrics to assess recall effectiveness. However, the agency made no additions to its key performance indicators in this area in its 2018, 2019, and 2020 operating plans.

If CPSC were to develop alternative measures of recall effectiveness, it might see different results in analyses of relative effectiveness of corrective actions with varying characteristics, which could enable it to improve recall effectiveness. For example, other measures of recall effectiveness that CPSC could explore include measures of consumer engagement (e.g., counts of the number of consumers who engaged with a social media post or video) or measures of direct notice contacts to consumers. Measures of consumer engagement could provide information about the effectiveness of different kinds of strategies in achieving consistently higher levels of consumer engagement.

While correction rate— how many products were corrected using the firm-provided remedy— measures an important dimension of recall effectiveness, it does not capture other ways that a recall might be effective in reaching consumers. Using additional measures of recall effectiveness could provide for a more comprehensive assessment of the effectiveness of recalls and help identify strategies for improving them. By exploring the use of measures of recall effectiveness beyond the correction rate, CPSC could better assess and, in turn, improve the effectiveness of product defect recalls.

[39]GAO, *Tax Administration: IRS Needs to Further Refine Its Tax Filing Season Performance Measures*, GAO-03-143, (Washington, D.C.: Nov. 22, 2002); and GAO/GGD/AIMD-99-69.

CPSC Has Identified Best Practices for Recalls and Has Been Taking Steps to Encourage Firms to Adopt Them

CPSC has collected best practices from other government agencies that conduct recalls and from nongovernment stakeholders and made efforts to incorporate best practices into consumer product recalls. For example, in 2018, CPSC organized and hosted a meeting to discuss recall best practices with other agencies that conduct recalls.[40] At this meeting CPSC collected best practices for recalls that the other agencies use, including strategies for improving consumer response to recalls using direct notice, and discussed shared challenges, such as negotiating voluntary recalls. CPSC has made efforts to incorporate some of these practices by ensuring firms use social media and other methods of communication as much as possible to reach consumers.

In 2017, CPSC organized and hosted a workshop on recall effectiveness with external, nongovernment stakeholders to collect recall best practices, and CPSC has worked to implement practices it identified. At this meeting, CPSC identified five key ideas and suggestions from stakeholders, selecting two as priorities: improving direct notice to consumers and expanding the use of marketing strategies and technology.[41] CPSC officials stated that they have worked toward these priority goals by creating a working group to explore how data on consumer purchases might be used more frequently to enhance direct notice. CPSC officials stated they have also tried to formulate corrective action plans to maximize actions taken to publicize recalls on social media and other electronic sources. Additionally, CPSC has posted the meeting's documentation to its Recall Guidance webpage, giving firms conducting recalls access to information about the effective practices identified.

In July 2020, CPSC officials said they plan to incorporate a best practices section into the update of the Recall Handbook, a document that CPSC makes available on its website to help guide firms through the recall process.

Conclusions

CPSC is a small agency with broad jurisdiction over product safety. In carrying out its mission of protecting consumers from unreasonable risks posed by hazardous products, it is critical for CPSC to prioritize and focus

[40]The meeting included attendees from CPSC, National Highway Traffic Safety Administration, Federal Trade Commission, Department of Agriculture, and the Food and Drug Administration.

[41]Direct notice to consumers refers to a firm reaching out to consumers who purchased a recalled product directly, by mail, email, or phone, rather than more indirectly through public notification such as advertisements and signage in retail locations.

its limited resources so that it can act quickly and effectively to address the most serious product hazards. While CPSC has taken steps to improve its processes for responding to product safety hazards, we identified additional opportunities for CPSC to better manage the timeliness of product defect cases and its oversight of product recalls:

- CPSC's time frames can vary significantly across product defect cases, with complex cases requiring more time. By using the same time frames for all cases, CPSC does not account for the significant variability in how long it takes staff to conduct key stages of a product defect investigation. As a result, CPSC's time frames for certain stages of product defect cases may not be effective tools for managing more complex cases and its related performance goals may not be effective measures of timeliness overall.
- CPSC does not follow the process described in the section 15 manual for prioritizing newly opened product defect cases based on the potential risk to consumer safety associated with a product. Establishing and following specific procedures that instruct staff on prioritizing new cases based on case-specific factors, such as the potential risk to consumer safety, could help CPSC more consistently allocate staff resources to cases based on these factors.
- CPSC does not have specific instructions for how compliance officers should determine how many recall effectiveness checks should be assigned in the event of a recall. By issuing more formal written guidelines or procedures on how compliance officers should determine how many recall effectiveness checks to assign, CPSC could provide compliance officers with tools to more effectively prioritize resources and to more closely monitor cases that are higher risk.
- In recent years, nearly 40 percent of firms have not consistently submitted monthly progress reports to CPSC as stipulated in their corrective action plans, and CPSC does not track the extent to which firms are submitting their reports systematically across all cases. By not systematically tracking progress report submission rates, CPSC may miss opportunities to better identify and address firms' noncompliance with the submission requirements and to improve CPSC's ability to monitor the status of product recalls.
- CPSC measures recall effectiveness by a single metric that may not accurately measure the effectiveness of recalls for certain types of products. Developing and implementing additional measures of recall effectiveness could provide for a more comprehensive assessment of the effectiveness of recalls and help CPSC identify strategies for

improving future recalls.

Recommendations for Executive Action

We are making the following five recommendations to CPSC:

- CPSC's Assistant Executive Director of the Office of Compliance and Field Operations should establish a policy or procedure that sets forth specific steps CPSC staff should take to manage timeliness for product defect cases with varying characteristics. As CPSC develops this policy or procedure, CPSC should consider whether updates or revisions are needed to existing timeliness goals to make them more useful for the purpose of managing the timeliness of cases with varying characteristics. (Recommendation 1)
- CPSC's Assistant Executive Director of the Office of Compliance and Field Operations should develop and follow a documented policy or procedure for prioritizing resources based on case-specific factors, such as the potential risk to consumer safety associated with a product. This policy or procedure should include specific steps staff should take to prioritize resources to cases based on factors such as likelihood and severity of harm or number of injuries related to the product hazard. (Recommendation 2)
- CPSC's Assistant Executive Director of the Office of Compliance and Field Operations should develop procedures for how compliance officers should determine how many recall effectiveness checks to assign to recalls based on risk factors, such as product volume and injuries. (Recommendation 3)
- CPSC's Assistant Executive Director of the Office of Compliance and Field Operations should systematically track the global submission of recalling firms' monthly progress reports to better identify and address firms' noncompliance with the submission requirements and to improve CPSC's ability to monitor the status of product recalls. (Recommendation 4)
- CPSC's Assistant Executive Director of the Office of Compliance and Field Operations should explore measures of recall effectiveness to use in addition to correction rate, which could provide for a more comprehensive assessment of the effectiveness of recalls. (Recommendation 5)

Agency Comments

We provided a draft of this report to CPSC for review and comment. We received written comments from CPSC that are reprinted in appendix IV.

CPSC also provided technical comments that we incorporated, as appropriate.

In its written comments, CPSC stated that it generally concurs with our findings and supports the recommendations to improve CPSC's processes for prioritizing resources, overseeing firms' compliance, measuring recall effectiveness, and managing the timeliness of product defect cases.

We are sending copies of this report to the appropriate congressional committees, the Acting Chairman of CPSC, and other interested parties. In addition, the report is available at no charge on the GAO website at https://www.gao.gov.

If you or your staff have any questions about this report, please contact me at (202) 512-8678 or cackleya@gao.gov. Contact points for our Offices of Congressional Relations and Public Affairs may be found on the last page of this report. GAO staff who made key contributions to this report are listed in appendix V.

Alicia Puente Cackley
Director, Financial Markets and Community Investment

Appendix I: Objectives, Scope, and Methodology

This report examines the extent to which the Consumer Product Safety Commission (CPSC) has (1) taken steps to prioritize and address product safety hazards in a timely and efficient manner; (2) used different types of corrective actions, enforcement actions, and standards; (3) overseen firms' compliance with corrective action plans and taken steps to address noncompliance; and (4) assessed the effectiveness of different types of corrective actions and incorporated best practices.

To address our first objective, we obtained and reviewed documentation on CPSC's process for investigating potential product hazards and administering voluntary recalls for what are known as product defect cases.[1] For example, we reviewed CPSC's Section 15 Defect Investigation Procedures Manual, which describes how staff should manage product defect investigations, Dynamic Case Management User Manual, and standard operating procedures for investigation and corrective action plan approval. To obtain additional information and perspectives on CPSC's process and practices, we interviewed CPSC staff responsible for investigating potentially defective or violative consumer products, negotiating corrective actions with firms, and pursuing enforcement actions. We also interviewed CPSC's Acting Chair and three Commissioners as of July 2020.

We also reviewed CPSC's performance goal reports and summaries for fiscal years 2016–2019 that showed how CPSC performed relative to its timeliness goals. We obtained and analyzed active product defect case data from 2016 through 2019 to determine how long staff typically took to complete key process stages and activities. Specifically, this analysis focused on product defect cases to which CPSC staff assigned one of the three highest hazard classification ratings (class A, B, or C).[2] From 2016 through 2019, 131 of 1,000 product defect cases met these criteria. To determine the reliability of these data, we reviewed related documentation, tested the data for missing data and errors, and interviewed CPSC officials about steps taken to ensure data quality. We found the data reliable for the purposes of selecting product defect cases to review and assessing these cases to determine how long staff take to

[1]CPSC may also refer to these cases as "section 15" or "unregulated product" cases.

[2]CPSC officials stated that they started implementing a new product defect case management system in 2013 (the Dynamic Case Management System) and fully implemented it in 2016. According to CPSC staff, once fully implemented, the system improved the quality and reliability of CPSC's voluntary recall data. Based on this information, we requested and reviewed active case data available from January 2016 through December 2019.

complete key process phases and activities. We also interviewed external stakeholders such as industry organizations, consumer advocacy groups, and legal experts who had experience working on product safety issues to obtain their perspectives on how CPSC addresses product safety hazards.

To address our second objective, we obtained and reviewed data and documentation for CPSC's use of corrective and enforcement actions and standards. As stated above, we requested and reviewed data on active product defect cases from 2016 to 2019 to which CPSC staff assigned one of the three highest-risk classification ratings (class A, B, or C). These data were stored in CPSC's Dynamic Case Management System. Examples of variables we reviewed in this data set included risk classifications, process milestone dates, and corrective action plan information. We reviewed documentation showing how often CPSC pursued administrative hearings for mandatory recalls since 2010. We also obtained and analyzed data for products that violated specific statutes or regulations, such as the Consumer Product Safety Act or Federal Hazardous Substances Act, from 2016 through 2019. In addition, we requested and reviewed documentation associated with CPSC's use of enforcement actions, such as civil and criminal penalties, injunctions, and seizures of hazardous products. To describe how frequently CPSC participated in the development of voluntary standards, we reviewed CPSC operating plans for fiscal years 2016–2020, which report the voluntary standards the agency participates in developing every year. To describe how frequently CPSC promulgates mandatory standards, we reviewed documentation on mandatory product rulemakings from January 2016 through June 2020 and the statutory authorities under which those rulemakings were promulgated.

To identify factors that may have affected CPSC's use of corrective or enforcement actions and standards, we reviewed CPSC's annual operating plans, performance reports, and other relevant CPSC documentation. We also interviewed CPSC Commissioners and CPSC staff involved in the development of voluntary standards and spoke with CPSC general counsel about CPSC's rulemaking authorities and reviewed relevant documentation on those authorities. In addition, we interviewed external stakeholder groups, such as industry organizations, consumer advocacy groups, and legal experts with experience working on product safety issues to obtain their perspectives on CPSC's use of corrective and enforcement actions in recent years.

To address our third objective, we reviewed CPSC's policies and practices for monitoring firms' compliance with corrective action plans, including relevant sections of CPSC's Section 15 Defect Investigation Procedures Manual, which describes how staff should manage a recall through all of its phases, and CPSC's recall handbook, which guides firms through the recall process. In addition, we reviewed documents relevant to CPSC's primary recall monitoring tools, monthly progress reports, and recall effectiveness checks and interviewed CPSC officials about how staff administer monitoring policies.

To determine whether CPSC monitors corrective action plans in accordance with its policies and whether firms comply with monitoring requirements, we analyzed CPSC's recall monitoring data for cases closed between January 2016 and May 2020. We assessed the reliability of CPSC's monitoring data by reviewing related documentation, testing the data for omissions and errors, and interviewing CPSC officials about steps taken to ensure data quality. We found the data reliable for reviewing and assessing how staff monitor recall cases and how firms comply with monitoring aspects of corrective action plans. Additionally, to describe whether recall effectiveness checks were conducted appropriately, and whether all monthly progress reports were submitted, we reviewed recall effectiveness checks and monthly progress reports of a non-generalizable sample of 25 recall cases. We selected this sample from a data set of 99 section 15 recall cases closed between January 2016 and May 2020 with risk classifications of A, B and C. We further narrowed the population by number of products being recalled, keeping only the top 80 percent of cases by recall volume, for a final population of 78 recall cases. From this population, we randomly selected 13 class B recall cases and 12 class C recall cases for our sample.[3] We determined that the risk-assessment component of internal control was significant to this objective, and we assessed CPSC's policies and practices for recall monitoring against the underlying principle that management should define objectives clearly to enable the identification of risks and define risk tolerances. Additionally, we determined that the information and communication component of internal control was significant to this objective, and we assessed CPSC's practices for collecting and monitoring information from firms against the underlying principle that management should use quality information to achieve the agency's objectives. We assessed whether CPSC's policies for recall monitoring

[3]The sample population only included one class-A recall case and was not randomly selected for analysis.

meet internal control standards and whether CPSC's oversight practices match its policies. Additionally, we assessed whether CPSC collects information on firms' recall progress in accordance with its policies and uses this information to make decisions about recalls.

To address the fourth objective, we reviewed key performance indicators used in CPSC's Annual Performance Reports, data collection methods CPSC uses to track recall effectiveness, and other documentation relevant to CPSC's assessment of recall effectiveness and use of best practices. We reviewed documentation related to CPSC's efforts to consider and incorporate best practices for implementing recalls, such as presentations by the National Highway Traffic Safety Administration, Federal Trade Commission, Department of Agriculture, and Food and Drug Administration from a 2017 workshop hosted by CPSC. Additionally, we interviewed CPSC officials to understand the indicators, measures, and evaluations CPSC uses to assess recall effectiveness and CPSC's methods for collecting data in this area. We compared CPSC's practices for collecting data on and assessing recall effectiveness with CPSC's goals. We assessed whether CPSC's efforts to measure recall effectiveness accurately capture recall effectiveness, and whether the information CPSC collects from firms on recall progress could be updated to improve CPSC's ability to measure recall effectiveness.

We conducted this performance audit from November 2019 to November 2020 in accordance with generally accepted government auditing standards. Those standards require that we plan and perform the audit to obtain sufficient, appropriate evidence to provide a reasonable basis for our findings and conclusions based on our audit objectives. We believe that the evidence obtained provides a reasonable basis for our findings and conclusions based on our audit objectives.

Appendix II: Overview of CPSC's Process for Addressing Hazards Associated with Regulated Products

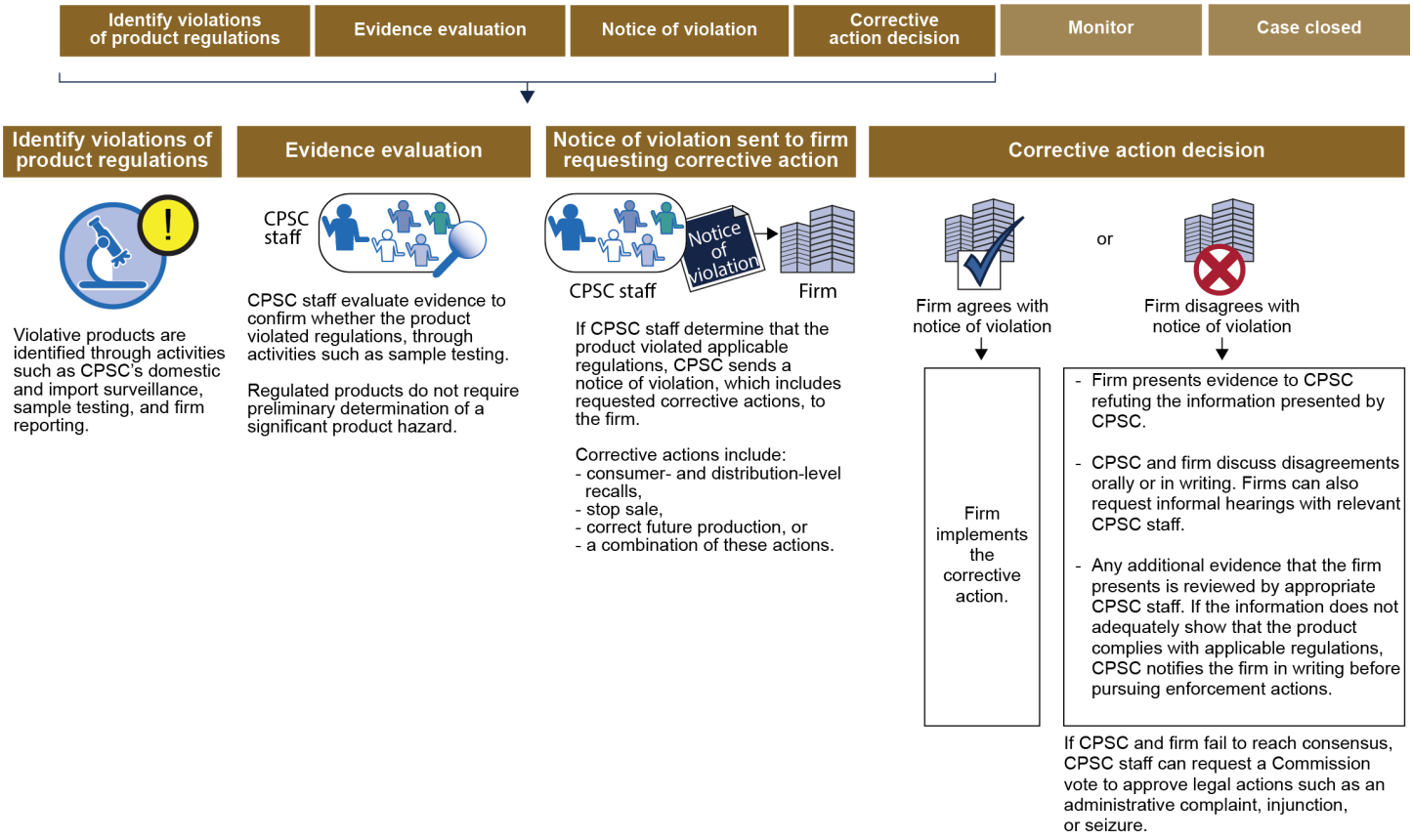
The Consumer Product Safety Commission (CPSC) has a six-stage process for addressing hazards associated with regulated product cases—which involve violations of statutes enforced by CPSC, such as the Consumer Product Safety Act, Federal Hazardous Substances Act, or the Flammable Fabrics Act. CPSC officials described these stages in a written response. CPSC's Regulated Products Handbook, which provides recall guidance to CPSC stakeholders such as manufacturers or distributors, also described some of these stages.[1] This process includes the following:

1. CPSC surveys the market for and firms report on violative products.
2. CPSC staff evaluate evidence, including conducting sample testing.
3. CPSC sends a notice of violation to the firm that includes a requested corrective action.
4. Firm agrees with or contests the notice of violation.
5. If the firm agrees, CPSC monitors implementation of the accepted corrective action.
6. CPSC closes the case when the firm adequately implements the corrective action.

See figure 8 for an overview of the first four stages of CPSC's regulated product process. CPSC officials told us that as of September 2020, they were developing new standard operating procedures for staff that detail steps they should take to manage regulated product cases.

[1]Consumer Product Safety Commission, Office of Compliance and Field Operations, *Regulated Products Handbook*, (Bethesda, Md.: May 2013).

Figure 8: First Four Stages of CPSC's Process for Addressing Hazards Associated with Regulated Products, as of September 2020



Source: GAO analysis of Consumer Product Safety Commission (CPSC) policies and procedures. | GAO-21-56

Appendix III: CPSC Participation in the Development of Voluntary Standards

Private sector standard-development organizations coordinate the process of developing most voluntary product safety standards.[1] The Consumer Product Safety Commission (CPSC) participates in the process and collaborates with standard-development organizations and other stakeholders—which can include industry representatives and consumer advocates—to develop consensus-based voluntary standards. Stakeholders volunteer to participate in the standard-development process, which is conducted in accordance with the relevant standard-development organization's own written policies and procedures. Such policies and procedures prescribe how the committees and subcommittees that develop voluntary standards operate, including rules on voting and how to maintain balance among participating stakeholder groups.

CPSC officials told us that technical staff, such as those with expertise in specific products or risks, carry out the agency's responsibilities for the voluntary standards in whose development CPSC chooses to participate. They said that because of the agency's limited resources, CPSC prioritizes participating in standard development for products with the highest consumer product safety risks or where they think it will produce the greatest benefit to the public. The officials added that if CPSC does not have in-house technical expertise on a particular product or risk, the agency may still participate if the risk warrants the resource commitment, though they might opt to monitor the situation to learn more about the product and associated risks before actively participating.

CPSC contributes to the development of voluntary standards primarily by engaging in the following activities:

- **Voluntary standards proposals**. CPSC submits to standard-development organizations proposals for products it believes warrant new voluntary standards or revisions to existing voluntary standards. Products for which CPSC has proposed the development of voluntary standards for include 3-D printers, portable fireplaces, and athletic helmets.
- **Committee leadership roles.** CPSC staff may hold leadership positions on voluntary standard-development committees and subcommittees with approval from the Executive Director. Responsibilities of a committee chair may include scheduling and

[1]Examples of such standard-development organizations include the American National Standards Institute, Underwriters Laboratories, and ASTM International.

presiding over meetings, ensuring due process, and establishing task groups to address specific topics related to the proposed standard.

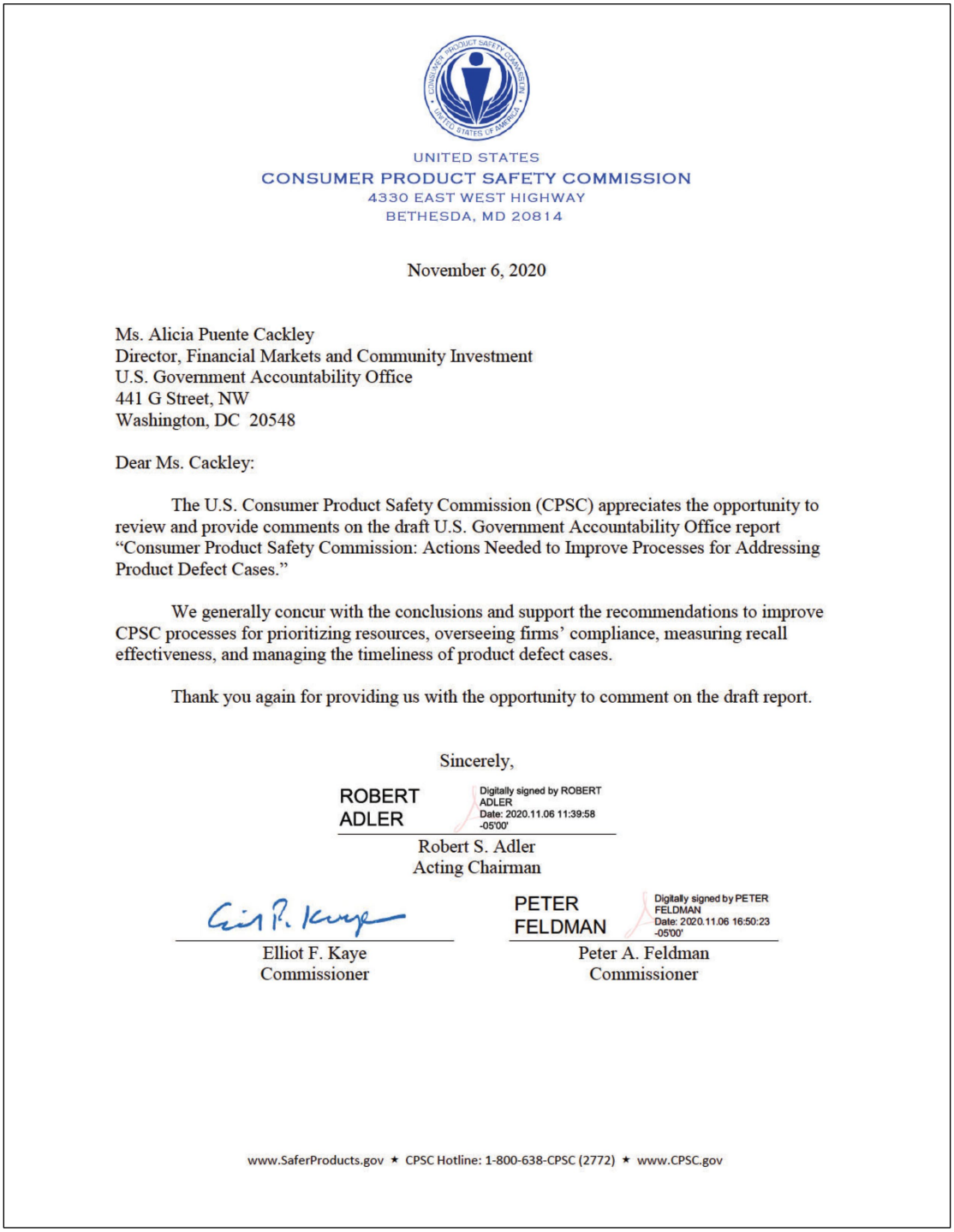
- **Technical comments and recommendations**. CPSC staff often provide standard-development committees with technical comments and recommendations on proposed standards. Recommendations may include those related to performance requirements, the scope of products covered by the standard, and language on warning labels, among other matters.
- **Data sharing.** CPSC may provide committees with hazard incident data, such as deaths or injuries associated with a product, to inform the development of the standards. For example, in February 2020, CPSC provided a committee developing a voluntary standard for electric-powered scooters with data on injuries associated with the scooters, including dates and severity of the injuries.
- **Voting on voluntary standards.** Since 2016, CPSC staff are allowed, with the approval of the Office of the Executive Director, to exercise voting powers in the development of voluntary standards. CPSC officials noted that CPSC staff usually do not vote on the standards because CPSC's vote would not affect the outcome. CPSC staff told us that providing comments on the development of standards has been a more effective way to influence decisions about the standards. CPSC officials told us that since 2016, 10 CPSC staff have been authorized to vote on 16 voluntary standards.

Although voluntary standards are not enforceable by law, CPSC officials and representatives from a standard-development organization said that the agency takes action to encourage manufacturer compliance. For example, CPSC officials said that in instances where CPSC identifies noncompliance with a standard, it may send letters to firms encouraging implementation of the voluntary standard because it is considered a best practice. They added that CPSC also conducts education campaigns for consumers and training for manufacturers and retailers to help encourage compliance. For example, officials from one standard-development organization told us that their organization and CPSC staff have conducted joint training sessions with manufacturers and exporters on voluntary standards. In addition, CPSC's Small Business Ombudsman provides firms with information and resources regarding voluntary standards on the CPSC website.

Stakeholders in the voluntary standard-development process generally told us that CPSC makes valuable contributions to the development of

voluntary standards. Officials from one standard-development organization said their organization has a close and collaborative relationship with CPSC and considers it a valuable partner in the standard-development process. In particular, they said CPSC technical staff provide valuable information and analysis for the committees in which they participate. Officials from another standard-development organization also said that they have a positive relationship with CPSC and that CPSC has been helpful at bringing consumer advocacy groups into the process. Legal experts with whom we spoke described CPSC's role in the voluntary standard development process as appropriate and positive, and one expert stated that the agency brings tremendous value when it comes prepared to contribute to the development of a particular product standard.

Appendix IV: Comments from the Consumer Product Safety Commission



UNITED STATES
CONSUMER PRODUCT SAFETY COMMISSION
4330 EAST WEST HIGHWAY
BETHESDA, MD 20814

November 6, 2020

Ms. Alicia Puente Cackley
Director, Financial Markets and Community Investment
U.S. Government Accountability Office
441 G Street, NW
Washington, DC 20548

Dear Ms. Cackley:

The U.S. Consumer Product Safety Commission (CPSC) appreciates the opportunity to review and provide comments on the draft U.S. Government Accountability Office report "Consumer Product Safety Commission: Actions Needed to Improve Processes for Addressing Product Defect Cases."

We generally concur with the conclusions and support the recommendations to improve CPSC processes for prioritizing resources, overseeing firms' compliance, measuring recall effectiveness, and managing the timeliness of product defect cases.

Thank you again for providing us with the opportunity to comment on the draft report.

Sincerely,

ROBERT ADLER
Digitally signed by ROBERT ADLER
Date: 2020.11.06 11:39:58 -05'00'

Robert S. Adler
Acting Chairman

Elliot F. Kaye
Commissioner

PETER FELDMAN
Digitally signed by PETER FELDMAN
Date: 2020.11.06 16:50:23 -05'00'

Peter A. Feldman
Commissioner

www.SaferProducts.gov ★ CPSC Hotline: 1-800-638-CPSC (2772) ★ www.CPSC.gov

Appendix V: GAO Contact and Staff Acknowledgments

GAO Contact

Alicia Puente Cackley, (202) 512-8678 or cackleya@gao.gov

Staff Acknowledgements

In addition to the contact above, John Fisher (Assistant Director), Jason Wildhagen (Analyst in Charge), Karl Antonsson, Aaron Colsher, John McGrail, Molly Miller, Marc Molino, Jennifer Schwartz, and Farrah Stone made key contributions to this report.

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Washington, DC 20548

Please Print on Recycled Paper.

Exhibit 7

From: Anand, Serena <SAnand@cpsc.gov>
Sent: Monday, August 08, 2022 6:06 PM
To: Wilson, Sarah <swilson@cov.com>; Anthony, Stephen <santhony@cov.com>; Brugato, Thomas <tbrugato@cov.com>; Mizerak, John <JMizerak@cov.com>; Fletcher, Michael <MFletcher@cov.com>; Korde, Rukesh <rkorde@cov.com>; Griepsma, Nick <NGriepsma@cov.com>
Cc: Eustice, John <JEustice@cpsc.gov>; Wolf, Liana <LWolf@cpsc.gov>; Mendel, Thomas <TMendel@cpsc.gov>
Subject: Amazon Deposition of Sharon White

[EXTERNAL]
Counsel,

Please find below Complaint Counsel's responses and objections to the requests listed at Attachment A to Respondent's Notice of Deposition of Sharon White.

1. Deponent's complete file concerning this matter, including, but not limited to, any and all academic records, office records, notices, correspondence, emails, memoranda, diagrams, documents, and reports relating to the subject matter of the June 30, 2022 Rebuttal Expert Report.
    a. Complaint Counsel objects to this request as vague, overly burdensome, disproportionate to the needs of the case, and for seeking privileged information. Complaint Counsel further objects that this seeks information already in Respondent's possession. Subject to and notwithstanding these objections, Complaint Counsel will produce non-privileged responsive documents.
2. Any and all documents, deposition testimony, photos, research, and other materials Deponent reviewed for this matter.
    a. Complaint Counsel objects to this request as vague, overly burdensome, and disproportionate to the needs of the case. Complaint Counsel further objects that this seeks information already in Respondent's possession. Subject to and notwithstanding these objections, Complaint Counsel will produce non-privileged responsive documents.
3. Any and all documents which the Deponent has reviewed in preparation for the deposition.
    a. Complaint Counsel objects to this request as vague, overly burdensome, and disproportionate to the needs of the case. Complaint Counsel further objects that this seeks information already in Respondent's possession. Subject to and notwithstanding these objections, Complaint Counsel will produce non-privileged responsive documents.
4. Any and all materials, treatises, articles, reports, or other data relied upon by the Deponent to support her opinion(s) in this matter.
    a. Complaint Counsel objects to this request as vague. Complaint Counsel further objects that this seeks information already in Respondent's possession. Subject to and notwithstanding these objections, Complaint Counsel will produce non-privileged responsive documents.
5. A recent copy of the Deponent's Curriculum Vitale (sic).
    a. Complaint Counsel objects that this seeks information already in the CPSC's possession. Subject to and notwithstanding this objection, Complaint Counsel states that the Curriculum Vitae provided by Ms. White with her Rebuttal Expert Report on June 30, 2022, is recent.
6. Copies of any and all demonstrative evidence and exhibits pertaining to the issues in this matter, and those which are relied upon by Deponent for any opinion Deponent expects to provide in this case.
    a. Complaint Counsel objects to this request as vague, overly burdensome, premature, and disproportionate to the needs of the case. Complaint Counsel is open to negotiating a reasonable schedule of exchange of demonstrative evidence and exhibits.

7. Copies of all agreements and/or contracts by and between Deponent and Complaint Counsel.
    a. Complaint Counsel objects to this request as vague and disproportionate to the needs of the case. Subject to and notwithstanding this objection, Complaint Counsel states that there are no agreements and/or contracts between Deponent and Complaint Counsel.
8. A list of cases that Deponent has provided deposition testimony or trial testimony in the last four years.
    a. Complaint Counsel states that Deponent has not provided deposition testimony or trial testimony in the last four years.
9. Copies of the deposition transcripts which Deponent has given in the last five years.
    a. Complaint Counsel refers Respondent to the response to Request No. 8.
10. Any and all correspondence between Deponent and Complaint Counsel relating to the transmission of facts or data that Deponent considered in forming her opinion(s).
    a. Complaint Counsel objects to this request as vague, overly burdensome, and disproportionate to the needs of the case. Subject to and notwithstanding these objections, Complaint Counsel will produce non-privileged responsive documents.
11. Any and all correspondence between Deponent and Complaint Counsel relating to any assumptions provided by Complaint Counsel that Deponent relied upon in forming her opinion(s).
    a. Complaint Counsel objects to this request as vague, overly burdensome, and disproportionate to the needs of the case. Subject to and notwithstanding these objections, Complaint Counsel will produce non-privileged responsive documents.
12. Copies of any notes Deponent created pertaining to this matter whether they were created in paper format, on a computer, or other electronic device.
    a. Complaint Counsel objects to this request as vague, overly burdensome, disproportionate to the needs of the case, and for seeking privileged information.
13. Copies of any articles and any other publication, whether for agency staff, or an external audience, which were authored or co-authored by Deponent which relate, in any way, to the issues raised in the Deponent's June 30, 2022 Rebuttal Expert Report.
    a. Complaint Counsel objects to this request as vague, overly burdensome, and disproportionate to the needs of the case. Complaint Counsel further objects that this seeks information already accessible to Respondent or in Respondent's possession.

Respondent can access the non-privileged documents responsive to the foregoing requests via the following link: https://cpsc.watchdox.com/ngdox/workspaces/196ce0b0-eaad-4824-b4ca-6866b5ff7d4b/7731264b-28f2-4fc7-b222-133d29bd1727

Kind regards,
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Exhibit 8

Analysis of Terms Comprising Potential Names for a Recall Notification Campaign

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Recall notices are vital in promulgating warnings about defective products to consumers. The present study examined potential names/titles of recall notifications that might be used in campaigns requesting the return of defective items such as foods, drugs, medical devices, etc. Sixty-one potential names were evaluated showing that some combinations of particular words forming potential names produced higher ratings, such as the terms *Recall* and *Urgent.* The term *Recall* is viewed as appropriate for campaigns involving many kinds of products, however, participants indicated that a different term should be used when the defective product is a surgically implanted medical device. Further analyses indicated that inclusion of *FDA* in the name produces higher ratings of appropriateness than a generic company name. Also, evaluations of individual words comprising the names showed similar patterns when combined with other words. Implications of these results are discussed.

INTRODUCTION

Each year, numerous products are discovered to have defects after leaving the manufacturer that pose risks to consumers' safety. When safety problems (or suspected safety problems) are discovered following the distribution or sale of the product, the product is sometimes recalled for credit, repair or replacement. The intention of a recall campaign is to alert the public to actual or potential product hazards or defects. Gibson (1998) points out that in the U.S. in 1996 there were over 1,885 recalls, or 5.16 per day. In theory, defective products are supposed to be recalled by the manufacturer. A manufacturer-based recall is frequently called a "voluntary" recall. When a manufacturer fails to perform a satisfactory voluntary recall, the government may step in to strongly recommend or require a recall to protect public safety and health.

How to effectively notify consumers in recall campaigns has not received much attention in research. However, there has been considerable research on the broad topic of warnings (e.g., Wogalter, 2006). Warnings and recall notices are both safety communications. Warnings generally accompany the product when purchased such as labels, inserts and manuals. However, recall notices are produced after the product has already left the manufacturer. Thus, with recall notices there is a temporal and spatial separation from the product that is larger than for most kinds of product warnings. For certain products, manufacturers have information on where to send the recall notices (e.g., registration or invoice information) but in many cases, a list of specific owners does not exist (Heiden, 2003). Therefore, in order to get the recall message publicized, press releases and other mass media methods are often used; and now more frequently, recalls are disseminated via the web. However, people may not see or hear about these press releases or have any awareness that they should search the web for recalls. Furthermore, in reaching target product users, consideration needs to be given to different literacy rates, social classes, native languages and age groups.

A potential way to benefit or facilitate the recall process is to title the notification so that it effectively alerts people to recognize that the communication concerns a defective product. The title or name of the recall notification might, in fact, use the term "recall" as it is highly descriptive of the purpose of the communication. Whatever name is chosen should probably serve to alert and convey a sense of urgency so as to provide some impetus to read (or listen to) the notification and to encourage people to return, repair or replace the product. Thus, the name ought to be both informative and motivating.

Research on components of warning messages has taken a similar tact of examining specific terminology to perform similar functions as desired for a recall campaign name. Warnings research has shown that there are differences in the way signal words (e.g., DANGER, CAUTION) differ in hazard connotation, attitudes/beliefs, and motivation (e.g., Edworthy & Hellier, 2006). Other descriptive terms in warnings can affect hazard judgments and compliance intentions (e.g., Kreifeldt, 1993; Lehto, House, & Papastavrou, 2000). Another important example of terminology in warnings is explicitness, in which specific messages (not general ones) increase measures of warning effectiveness (Laughery & Paige-Smith, 2006). Recently, Kim, Cowley and Wogalter (2007) examined the effects of textual semantics within warning instructional statements on intent-to-comply judgments. Kim et al.

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(2007) examined the effect of adding certain terms (e.g., critical, important, extremely) to warning directives to determine whether they increase compliance intentions. In general, the results indicated that some terms added emphasis to root or core instructional statements. Similar methodology is used in the present study to examine various names for recall notices.

The source of the message may also be important for credibility and urgency of the message. Research by Wogalter, Kalsher, and Rashid (1999) indicates that including relevant names of professional/scientific organizations or U.S. government agencies in warnings increases its rated credibility and people's compliance intent judgments. Wogalter et al.'s (1999) findings suggest the possibility that including the name of a U.S. government agency as part of the name of the recall notice might add value compared to the use of a non-government entity such as a product manufacturer. This issue is examined in the present research.

It is generally desired that research uncover principles that are applicable beyond the specific circumstances of the research. Thus it would be desirable to come up names of recall campaigns that are applicable to all products. However, there may be appropriate exceptions to the general "rules" for naming recall campaigns. Consider a special type of product, such as a surgically-implanted medical device (e.g., pacemakers). Indeed, 21% of all medical device recalls involve cardiac medical devices (Wallace & Kuhn, 2001). Moreover, medical device recalls have been increasing in number (Maisel, Sweeney, Stevenson, Ellison, & Epstein, 2001). The problem is that surgically-implanted medical devices cannot be "recalled" like other products. Return to the manufacturer cannot be easily accomplished if the device is already implanted. Moreover, the promulgation of a surgically implanted device recall may cause heightened anxiety and fear in affected persons. These negative emotions may not be justified, as the device might not actually be defective (e.g., it simply needs to be monitored more closely). In addition, these emotions might negatively influence whether some people will use this form of treatment in the future. Given that surgically implanted medical devices are different than most other products with respect to return or disposal, should it have the same or different name than other defective product recall campaigns? It is possible that consumers believe that *all* defective product notifications should have the same consistent name or do they believe an exception should be made exclusively for surgically-implanted devices? These questions are among those addressed in the present research.

METHOD

Participants

Data was collected from two different groups of participants. For the first group, data was collected (n= 94, M_{age} = 37.8, SD_{age} = 13.9) from undergraduates at two U.S. universities (n = 31, M_{age} = 24.5, SD_{age} = 6.0) and from a sample of non-student adults (n = 63, M_{age} = 44.4, SD_{age} = 11.7) in the Raleigh-Durham area of North Carolina. The university student group was composed of 22.6% males and 77.4% females, and they reported themselves to be in the following race/ethnic categories: 38.7% Hispanics and Latinos, 32.3% Caucasians, 12.9% African Americans, and 9.7% Asian and 6.4% other ethnicities. The nonstudent adult group was composed of 69.8% males and 30.2% females with self-reported race/ethnic classifications of 79.4% Caucasian, 17.5% African American and 3.1% Hispanic or Latino.

For the second group of participants collected (n = 143), the mean age was 25.7 years (SD_{age} = 11.4). There were 71 males and 72 females and the self-reported ethnic classifications were 69.9% Caucasian, 15.4% African American, 3.5% Asian and 11.2% other.

Materials and Procedure

Each participant completed a consent form followed by a demographics form and then were given the main study questionnaire with 3 parts.

In **Part 1**, participants were given a page of background information to read explaining the processes of recalls involving private companies and the FDA.

> *Imagine you are in charge of notifying the public about a potentially hazardous product, which after having left the manufacturer, is discovered to be potentially unsafe. Assume it could be a food product, a medicine, or a medical device, such as contaminated canned meat, substandard antibiotics, or a defective blood-sugar meter.*

The participants were then asked to examine the provided list of 61 potential names/titles of recall notices, and then asked to rate the appropriateness of each using a 9-point scale with the following numerical anchors and associated text: (0) *not at all appropriate*, (2) *somewhat appropriate*, (4) *appropriate*, (6) *very appropriate* and (8) *extremely appropriate*.

Part 2 began with a printed description of how a recalled surgically implanted medical device might or might not be a problem if the term *recall* was used in the name. Specifically stated was the following:

> *Some medical devices are surgically implanted inside a human body, such as heart pacemakers. Sometimes after surgery, it is discovered that some of the implanted devices may have defects and they*

need to be recalled. These situations are different from most other kinds of recalls of defective products because the people who have these devices may need to visit a physician, and may need to have another surgery to remove the device. However, "recalled" implanted devices are not always defective and may not need to be removed, but rather monitored more frequently by the physician. Thus there is some concern that people with the recalled device may panic unnecessarily. Here is the issue: Because users cannot simply "return" their surgically implanted device and may become anxious, do you think the word 'recall' should be used in these notices?

After reading the above paragraph, participants were asked to rate their agreement for the three items listed in Table 3 on a 9-point scale using the following numerical textual anchors: (0) *do not agree at all,* (2) *somewhat agree,* (4) *agree,* (6) *very much agree* and (8) *completely agree*.

Part 3 asked participants to rate, using the same rating scale as in Part 1, a set of 14 individual terms that were components of phrases used in Part 1. The list of terms can be seen in Table 2.

RESULTS

Table 1 shows the mean ratings and standard deviations of the 61 names/titles of recall notices. The list is ordered from the highest to lowest means. Certain components in the names tended to appear in the higher rated items. These included the words *Urgent, Recall, Alert, Danger*, and *FDA.* Of these, names with *Urgent* tended to be rated consistently the highest. Also, *Danger* was present in only a few names which were also highly rated.

Table 1. *Mean Appropriateness Ratings (and SD) for Names/Titles of Recall Notices Ordered from Highest to Lowest (n=94)*

Name	***Mean***	***SD***
FDA Urgent Recall Notice	5.72	2.00
FDA Public Safety Warning	5.70	1.98
Urgent Product Recall Bulletin	5.57	2.14
Product Danger Alert	5.54	2.16
FDA Urgent Recall	5.51	2.18
Public Safety Warning	5.49	2.12
Urgent Recall Notice	5.46	2.08
Urgent Recall	5.46	2.32
Product Danger Notice	5.36	2.25
Urgent Product Recall	5.31	2.13
FDA Recall Warning	5.23	2.01
Unsafe Product Notice	5.22	2.12
FDA Safety Warning	5.18	1.92
Product Warning Alert	5.17	2.24
FDA Unsafe Product Notice	5.13	2.35
Urgent Recall Bulletin	5.12	2.18
FDA Health and Safety Alert	5.05	2.22
FDA Alert	5.04	2.20
FDA Unsafe Product Advisory	5.03	2.27
FDA Health and Safety Bulletin	5.03	1.98
Company-X Urgent Recall	5.02	2.36
Product Warning	5.00	2.16
Company-X Urgent Recall Notice	4.99	2.34
FDA Warning	4.95	2.16
FDA Recall	4.90	2.25
Recall Notice	4.82	2.44
Public Safety Notice	4.79	2.20
FDA Safety Alert	4.74	2.13
Safety Warning	4.72	2.15
Product Recall Notice	4.70	2.22
Unsafe Product Advisory	4.69	2.21
Public Safety Alert	4.66	1.99
Urgent Notice	4.63	2.34
Recall Warning	4.62	2.15
Health and Safety Alert	4.60	2.39
Product Alert	4.57	2.33
Product Recall Warning	4.56	2.22
Company-X Warning	4.47	2.30
Company-X Recall Notice	4.40	2.40
Health and Safety Bulletin	4.39	2.40
Product Warning Notice	4.39	1.99
Safety Notice	4.36	2.21
Company-X Recall	4.31	2.33
Safety Alert	4.30	2.37
Product Recall Bulletin	4.28	2.26
FDA Notice	4.28	2.30
Public Safety Bulletin	4.21	2.36
Recall Bulletin	4.18	2.52
Safety Advisory	4.12	2.18
Safety Alert Bulletin	4.10	2.15
Safety Bulletin	4.06	2.40
Safety Recall Bulletin	3.99	2.12
FDA Bulletin	3.99	2.38
FDA Advisory	3.95	2.32
Product Advisory	3.94	2.40
FDA Safety Bulletin	3.85	2.26
Company-X Advisory	3.26	2.35
Product Notice	3.14	2.36
Company-X Notice	2.98	2.49
Company-X Bulletin	2.60	2.31

Mean ratings and standard deviations for the individual words evaluated in Part 3 are shown in Table 2. Note that the highest rated single terms in Table 2 were components of the highest rated names given in Table 1.

Phrases extracted from Part 1 containing the source entity *FDA* or *Company-X*, were analyzed to determine whether they were rated differently. Both entities were paired with the root words (*Bulletin, Warning, Recall, Advisory*, and *Notice*) and the means are displayed in Figure 1 and Table 1. The standard deviations were fairly homogeneous ranging from 2.16 to 2.89. A 2 (Source entity: *FDA* vs. *Company-X*) X 5 (Paired root words: *Bulletin, Warning, Recall, Advisory, Notice*) repeated measures analysis of variance (ANOVA) showed a significant main effect for both entities, $F(1, 93) = 42.27$, $p < .0001$, and root words, $F(4, 372) = 22.88$, $p < .0001$.

FDA received significantly higher ratings than *Company-X*. The terms *Warning* and *Recall* were given the highest mean ratings among the root words. The ANOVA also showed a significant interaction between root words and entities, $F(4, 372) = 4.25$, $p < .01$. The interaction means are displayed in Figure 1. The graph shows a pattern of means reflecting the main effects described above with the exception that the difference between the two entities was larger for *Bulletin* and *Notice* than for other root words.

Table 2. *Single Word Mean Appropriateness Ratings in Recall Campaign Names (n=143)*

Single Words	***Mean***	***SD***
Urgent	6.37	1.61
Recall	6.26	1.83
FDA	6.00	2.13
Danger	5.97	2.06
Warning	5.87	1.68
Unsafe	5.80	1.93
Alert	5.71	1.77
Safety	5.34	2.09
Health	5.33	2.02
Product	4.71	2.35
Advisory	4.62	2.00
Notice	4.05	2.20
Public	3.99	2.28
Bulletin	2.87	2.06

In Part 2, participants were asked to rate three items pertaining to the use of the term *Recall* in the name of a product-defect notification involving a surgically-implanted medical device. The means and standard deviations are displayed in Table 3.

Figure 1. *Mean ratings of appropriateness for word pairs involving entities and root words*

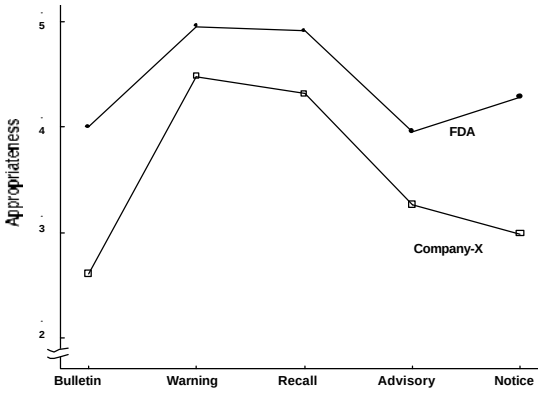

Table 3. *Means and Standard Deviations for Items Concerning the Use of the Term "Recall" with Respect to Medical Devices (n=94)*

	Mean	***SD***	***Item***
(a)	3.50	2.9	The word 'recall' should be used for *all* defective and potentially hazardous food, medicines and implanted medical devices.
(b)	5.09	2.7	A *different* word other than 'recall' should be used as part of the name for notices specifically concerning surgically implanted devices. The word 'recall' should only be used for all other instances of potentially hazardous food, medicines, and (non-implanted) medical devices.
(c)	2.55	2.8	The word 'recall' should *not* be used at all as part of the name of notices for potentially hazardous food, medicine and medical devices. Rather, another name should be used to fit *all* kinds of defective products (including surgically implanted ones).

A one-way repeated measures ANOVA applied to the data in Table 3 was significant, $F(2, 186) = 17.84$, $p < .0001$. Comparisons among the means using Tukey's HSD test (alpha = .05) showed that participants indicated the highest agreement to the second statement (Table 3, Item b), i.e., that the term *Recall* is appropriate for non-surgically implanted products but a different term other than *Recall* should be used for surgically implanted medical devices. The other two statements in Table 3 (Items a and c) were significantly lower and did not differ between themselves.

DISCUSSION

Although there has been research on terms used in warnings, this study provides insight into a somewhat different kind of safety communication: product-defect recall notifications. The results showed that in two separate assessments (one evaluating names of recall campaigns and the other evaluating individual component words), certain individual terms consistently produced high ratings of appropriateness for product-defect recall notification names. The top eight individual words from an independent group of participants were often components of the highly rated names: *Urgent, Recall, FDA, Danger, Warning, Unsafe, Alert,* and *Safety*. Similarly, the six highest rated names were: *FDA Urgent Recall Notice, FDA Public Safety Warning, Urgent Product Recall Bulletin, Product Danger Alert,*

Public Safety Warning, and FDA Urgent Recall. Given these results, consideration should be made to the use of the highest rated names and components of titles of actual product-defect notifications.

While the highest rated names tended to be 3 to 4 words, if greater brevity was desired then there were several 2-word phrases (e.g., *Urgent Recall*) that were rated nearly as high as longer names. Interestingly, both in this study on recall names and in Kim et al.' (2007) study with warning instruction statements, the word *Urgent* produced some of the highest ratings.

The results also showed that the inclusion of the source entity, *FDA*, produced higher ratings than a name with *Company-X*. This hierarchy was maintained across several root word pairings. Nevertheless, given the methodology employed, it is unclear whether the findings would generalize to an actual company name or to a different government agency (e.g., the U.S. Consumer Product Safety Commission). However, the direction of the findings is consistent with past research showing that the inclusion of the name of a government entity enhances warning credibility and compliance intent **(**Wogalter et al., 1999).

This research provides some insight with respect to consistent terminology for recalls and/or warnings. A common design strategy is to use standardized terminology and formats. However, the results of the present study suggest something somewhat different. The results showed that people believed it permissible not to use the term *Recall* for surgically-implanted medical devices, despite the fact that they believed that the term *Recall* should be used in other product defect campaigns. Thus, the "rules" should allow the use of different terminology for unique situations. This last finding further suggests that additional research is needed to determine the specific, appropriate wording for names of surgically implanted medical device "recall" campaigns as well as wording for other unique situations.

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