Consumer Product Cases: The CPSC, Standards, Testing and Experts

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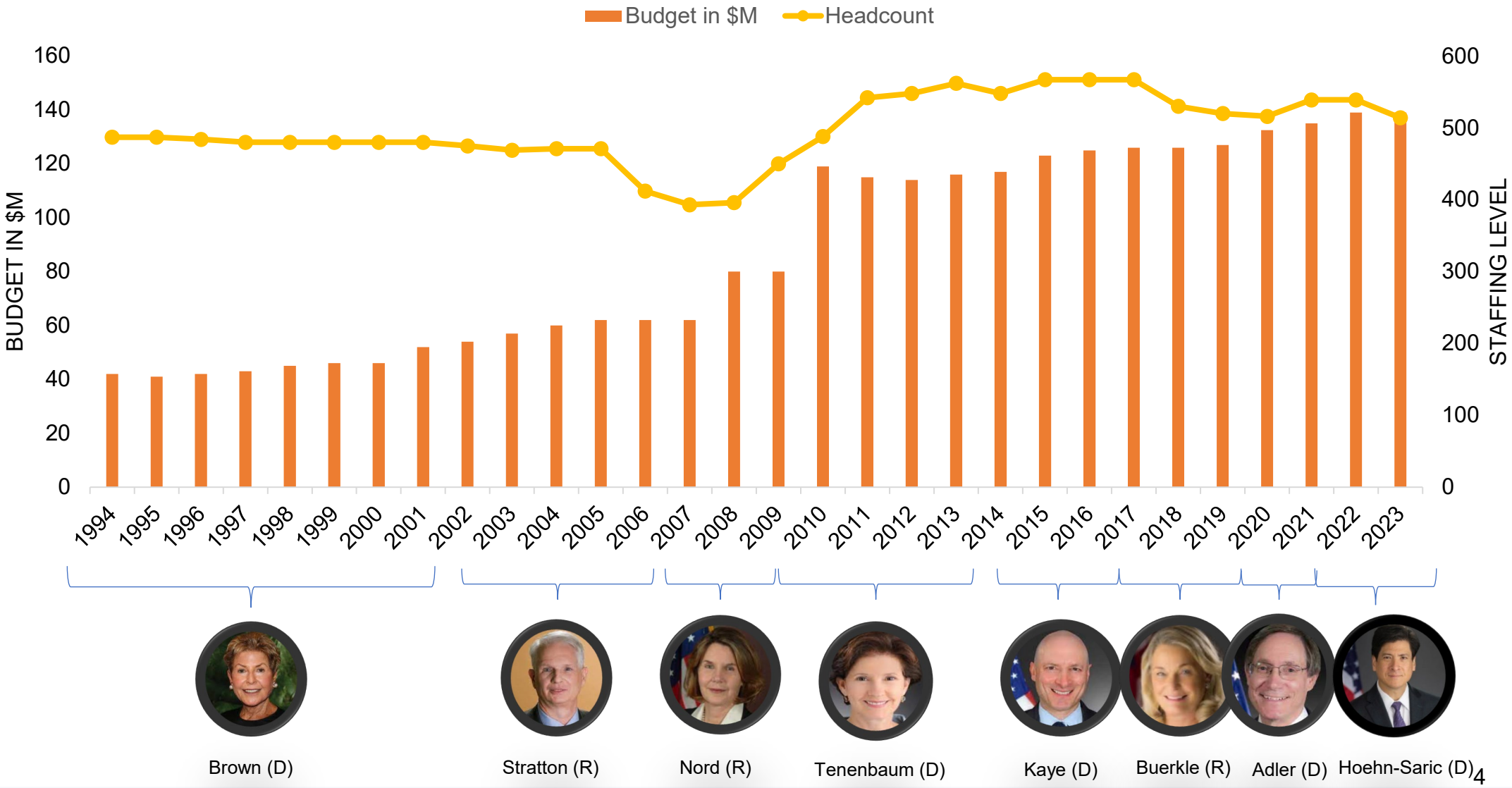
Introduction

- Board-Certified Product Safety Expert
- CPSC Commissioner (2014 – 2017)
- Testing Executive (2007 -2014)
- CPSC Senior Staff (2002 – 2007)
- NM State Representative (1999 – 2002)

Executive Summary

- “The new CPSC Administration will want to demonstrate a paradigm shift from the Trump Administration through bold compliance and enforcement prosecution.” (JPM September 2021)
- A more aggressive CPSC increases the likelihood that a record of agency interaction can become an issue in a product liability matter.
- Standards, official agency guidance and benchmark data can be introduced to inform the adherence or failure to comply with regulations and product safety management best practices.

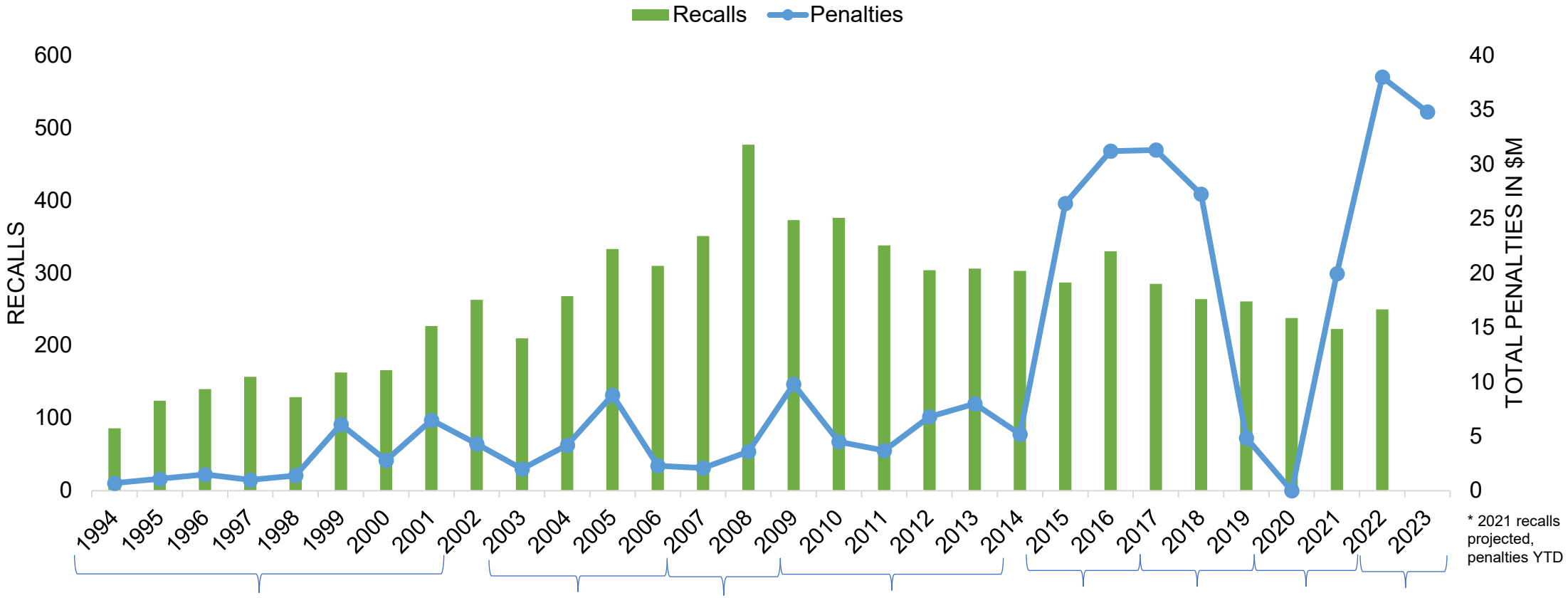
CPSC Budget and Headcount by Administration



CPSC Under President Biden

The new administration “clearly views product safety in different terms,” said Acting Chairman Bob Adler at ICPHSO February 24, 2021.

CPSC Compliance and Enforcement by Administration

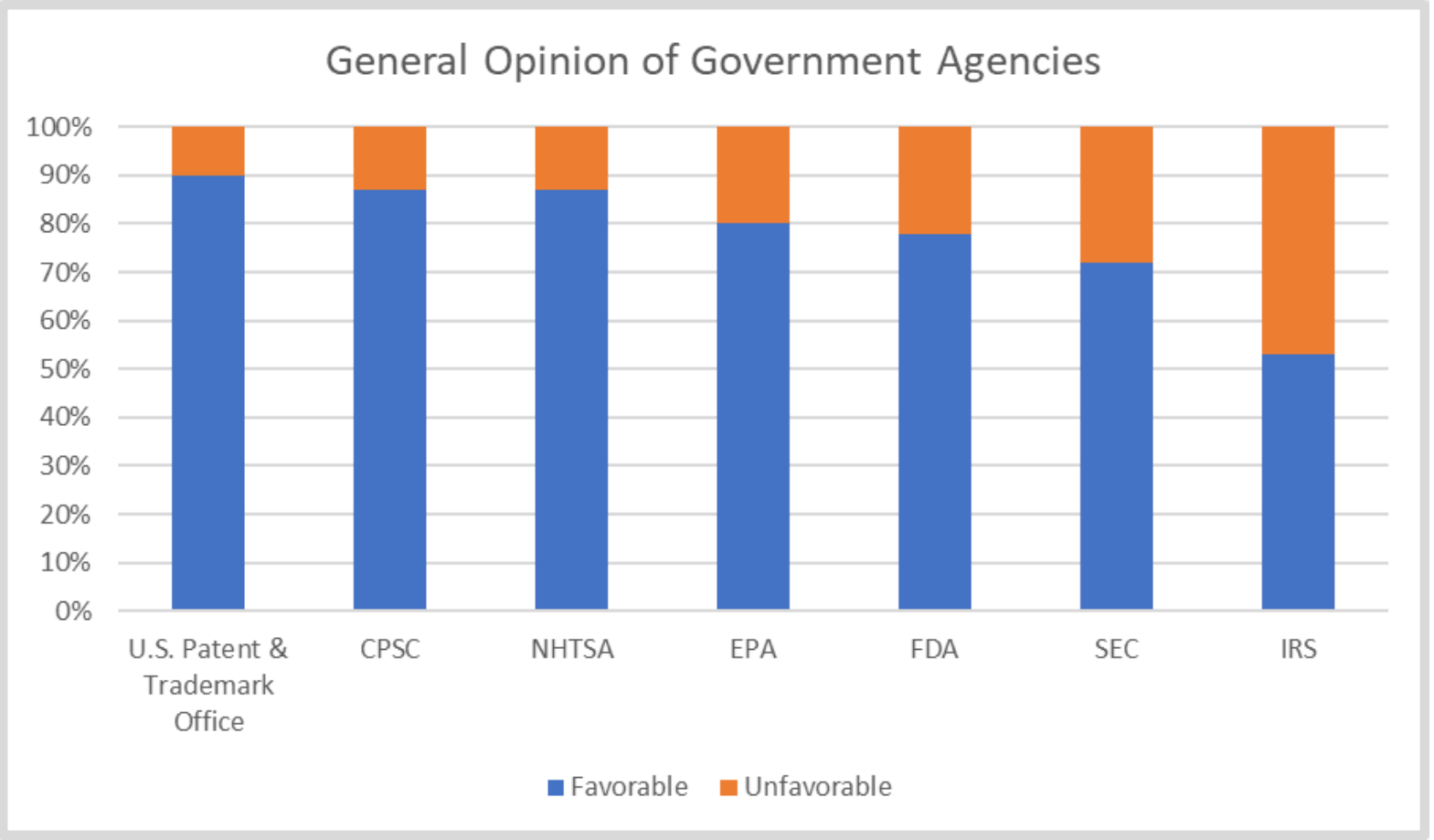


Brown (D) Stratton (R) Nord (R) Tenenbaum (D) Kaye (D) Buerkle (R) Adler (D) Hoehn-Saric (D)

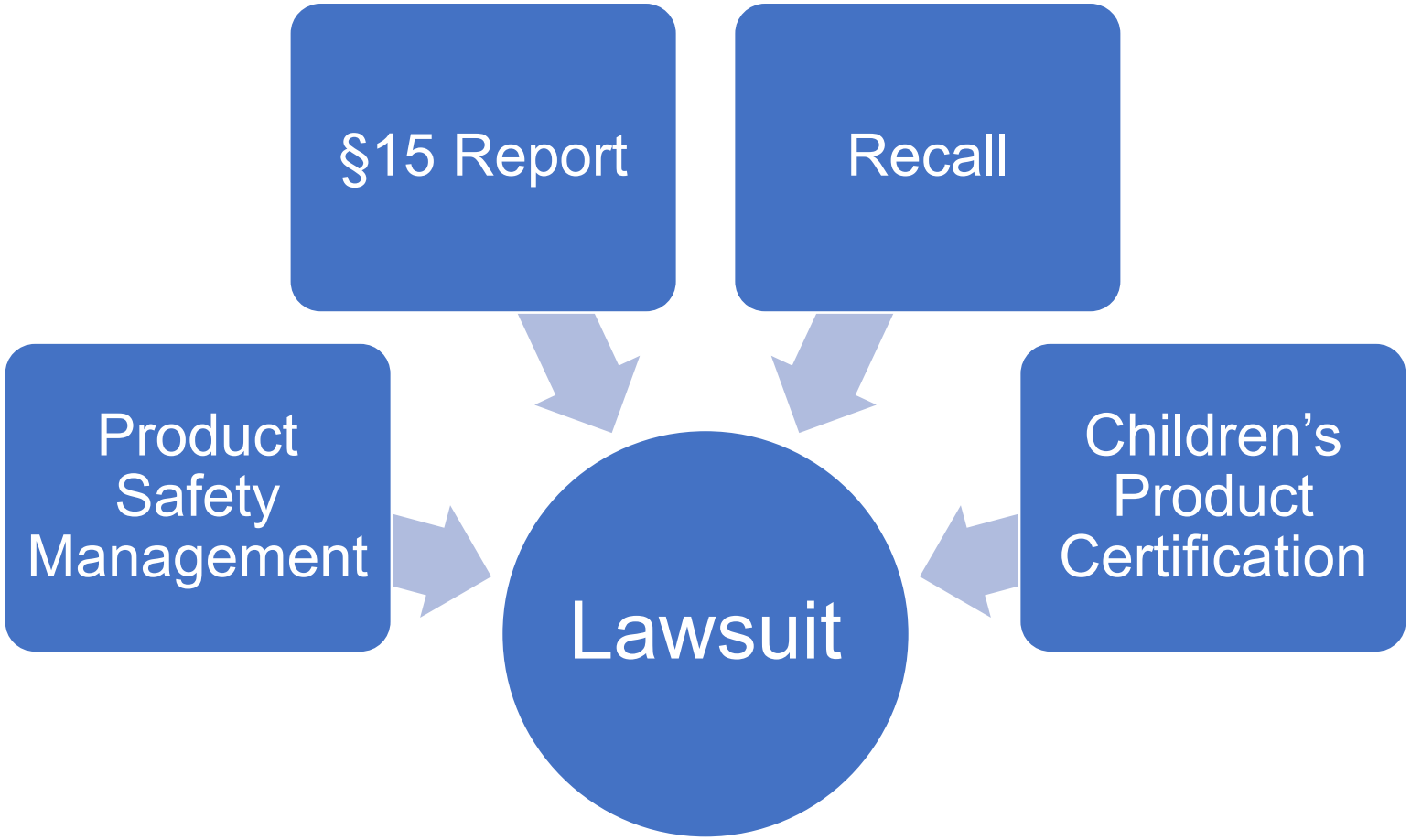
When CPSC Activity Spills Into the Courtroom

In many product liability lawsuits, there is a record of activity and engagement with the U.S. Consumer Product Safety Commission (CPSC).

CPSC is a Relatively Popular Agency



CPSC Issues Entering the Courtroom

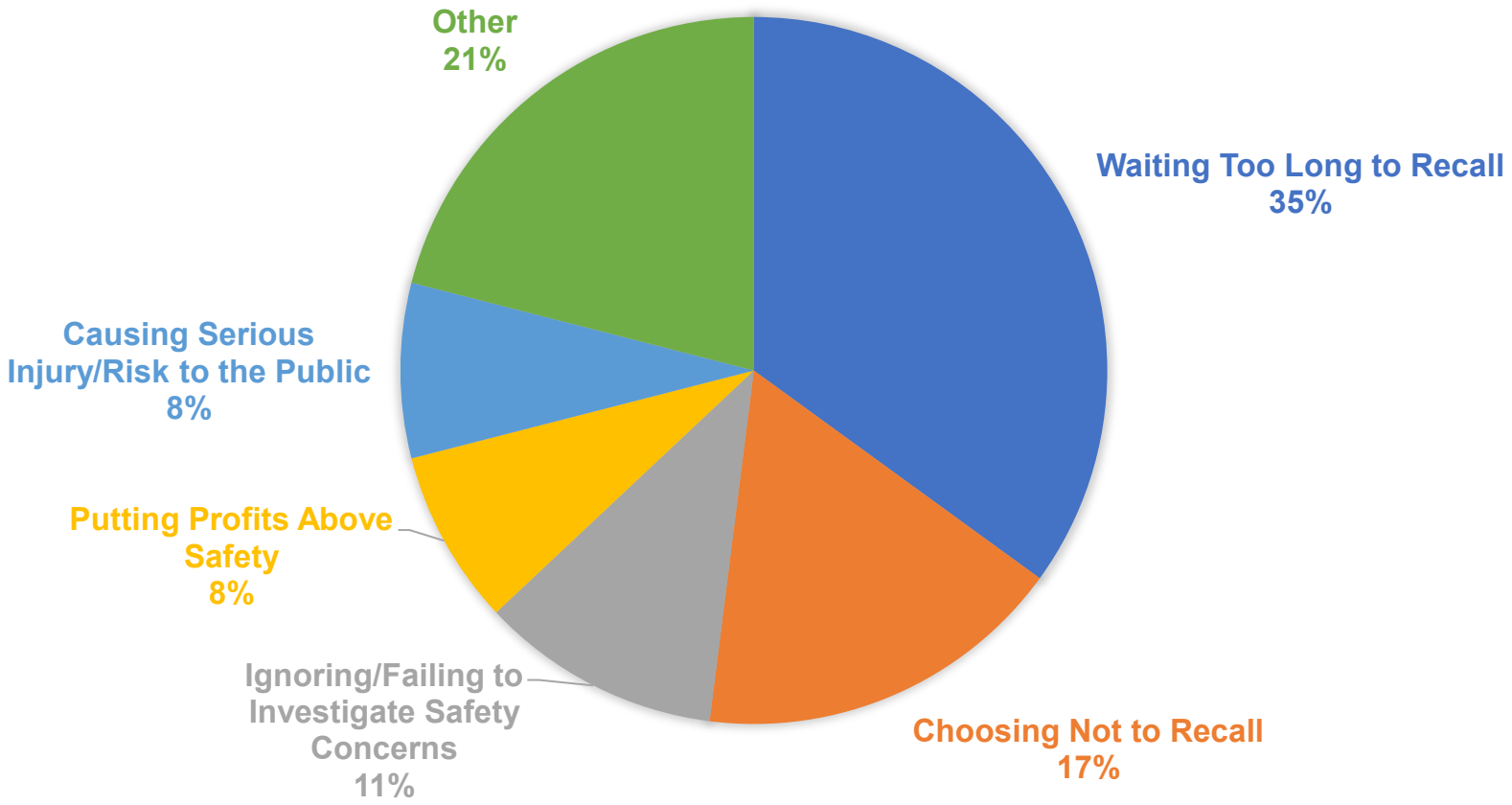


Product Safety Management

Effectively evaluating the standard of care.

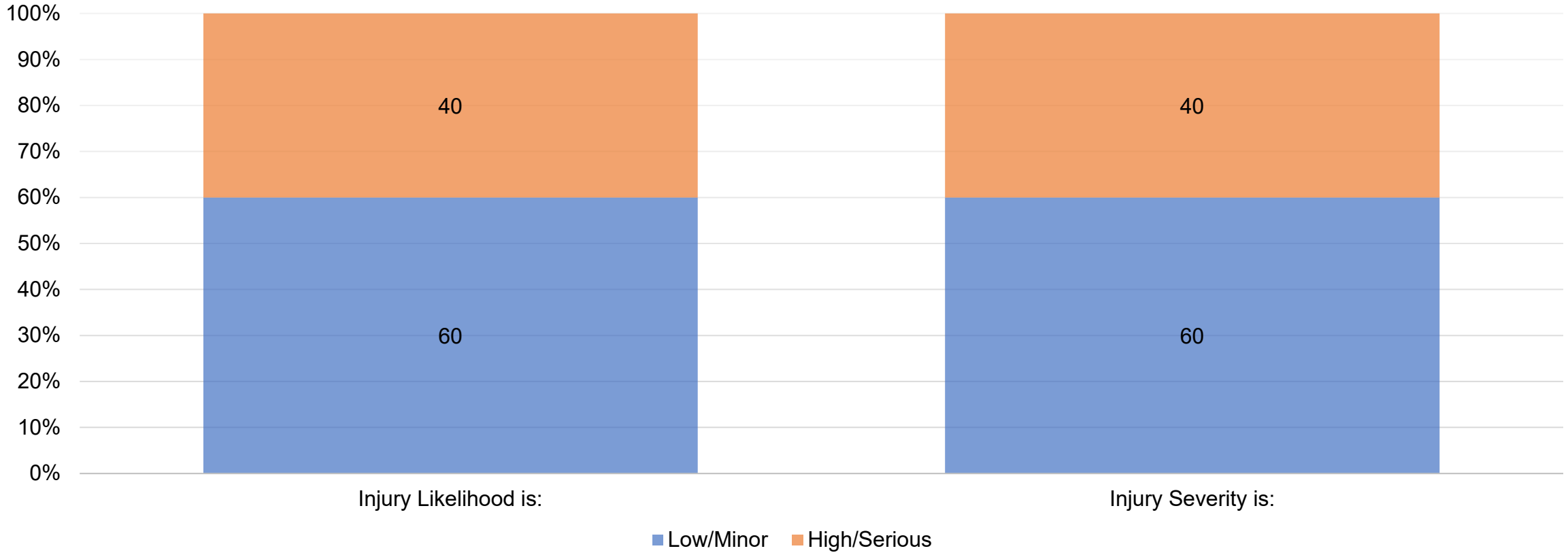
High Consumer Expectations

Manufacturer's Top Five Mistakes When Making a Recall Decision



Consumer Warning Expectation

A product manufacturer should first warn consumers about a possible health risk associated with a product when:



Scrutinizing the Standard of Care

1. What can you offer that is objective, from a reliable and authoritative source, to demonstrate that reasonable product safety management practices were followed?
2. What are the product safety management standards of duty/care in the industry?
3. Was reasonable care exercised and what is the foundation?
4. Would competent product safety management have elicited a different outcome?
5. Would a responsible company have supplied a post-sale warning?
6. Was a safety report to CPSC warranted?
7. How would CPSC have looked at this and would they have demanded a recall?

Product Safety Mgmt. Standards of Care

Agency Guidance

- CPSC Handbook for Manufacturing Safer Consumer Products
- "Best Practices" (www.cpsc.gov)
- Compliance program elements required in Consent Decrees
- CPSC YouTube Channel

Standards

- ISO 10377: Consumer Product Safety – Guidelines for Suppliers
- ANSI Guidelines for Organizing a Consumer Product Safety Organization
- ISO 10002 Quality Management -- Customer Satisfaction -- Guidelines for Complaints Handling in Organizations

Regulations

- "Reasonable Test Program" (non-children's products certification)
- "Due Care" (children's product certification)
- "High Degree of Assurance" (children's product certification)
- Recordkeeping requirements (children's product certification)

§15(b) Safety Reports Filed with CPSC

Products subject to liability suits have often been reported to the CPSC.

Mandatory Safety Reporting to CPSC [CPSA §15(b)]

(b) Every manufacturer, distributor and retailer who obtains information which reasonably supports the conclusion that such product:

(2) fails to comply with any rule, regulation, standard, or ban under this Act or any other Act enforced by the Commission;

(3) contains a defect which **could** create a substantial product hazard described in subsection (a)(2); or

(4) creates an unreasonable risk of serious injury or death,

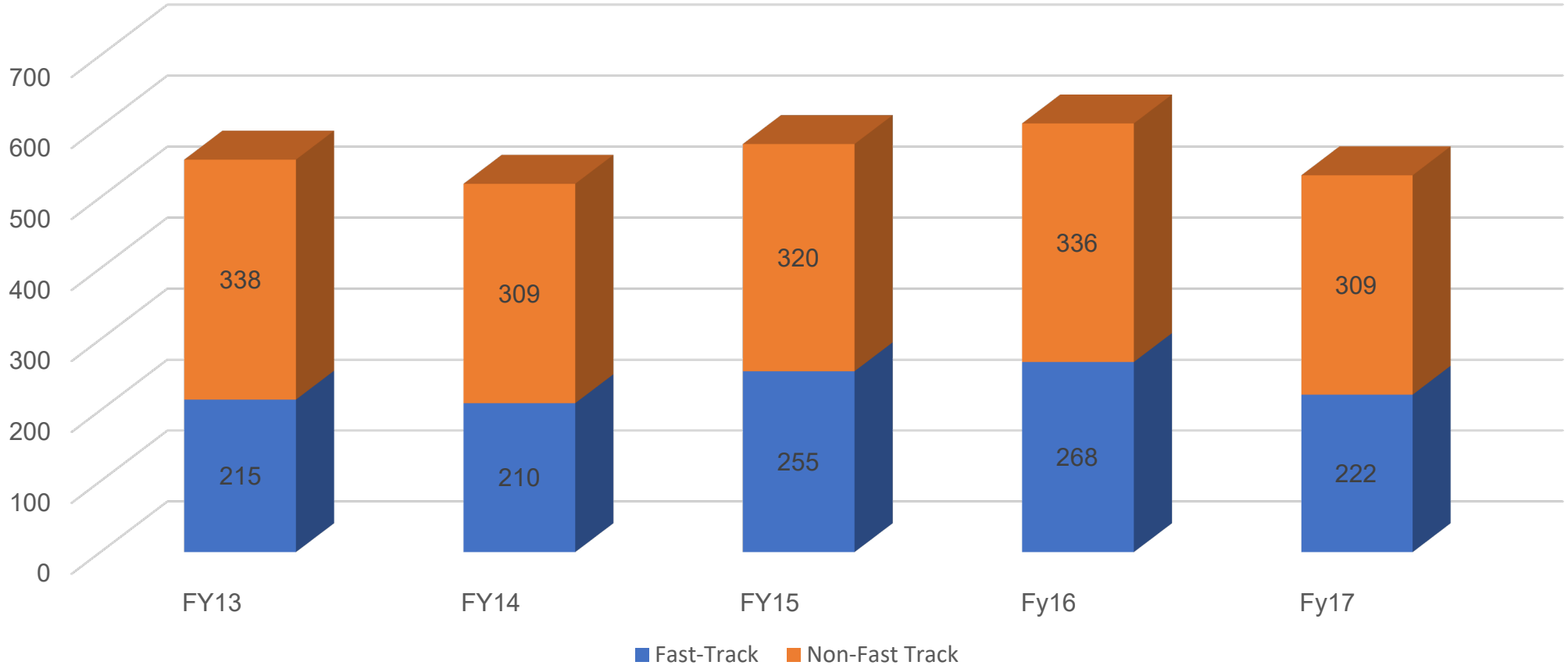
shall immediately inform the Commission..."

(a) For purposes of this section, the term 'substantial product hazard' means:

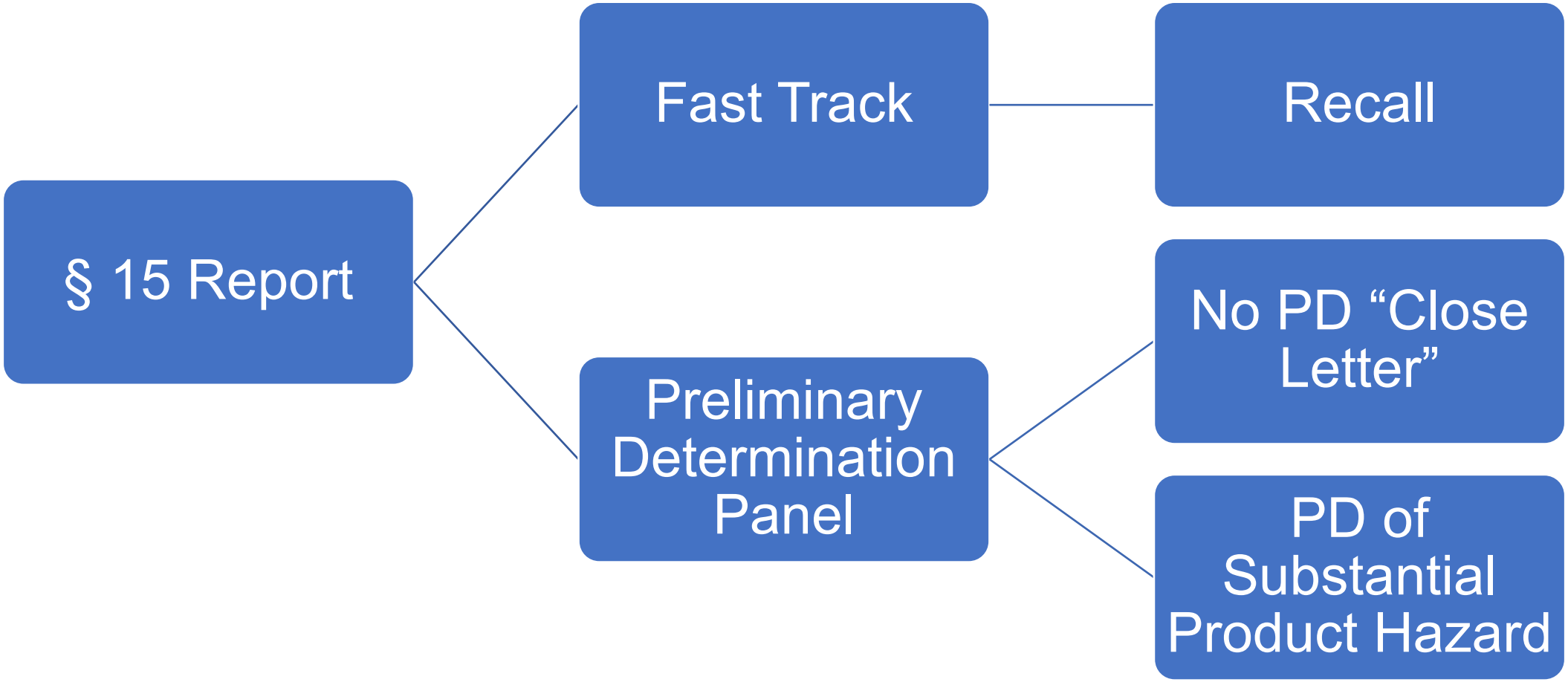
(1) a failure to comply with an applicable rule, regulation, standard or ban; or
(2) a product defect which (because of the pattern, number, severity of the risk, or otherwise) creates a substantial risk of injury to the public.

15 U.S.C. § 2064

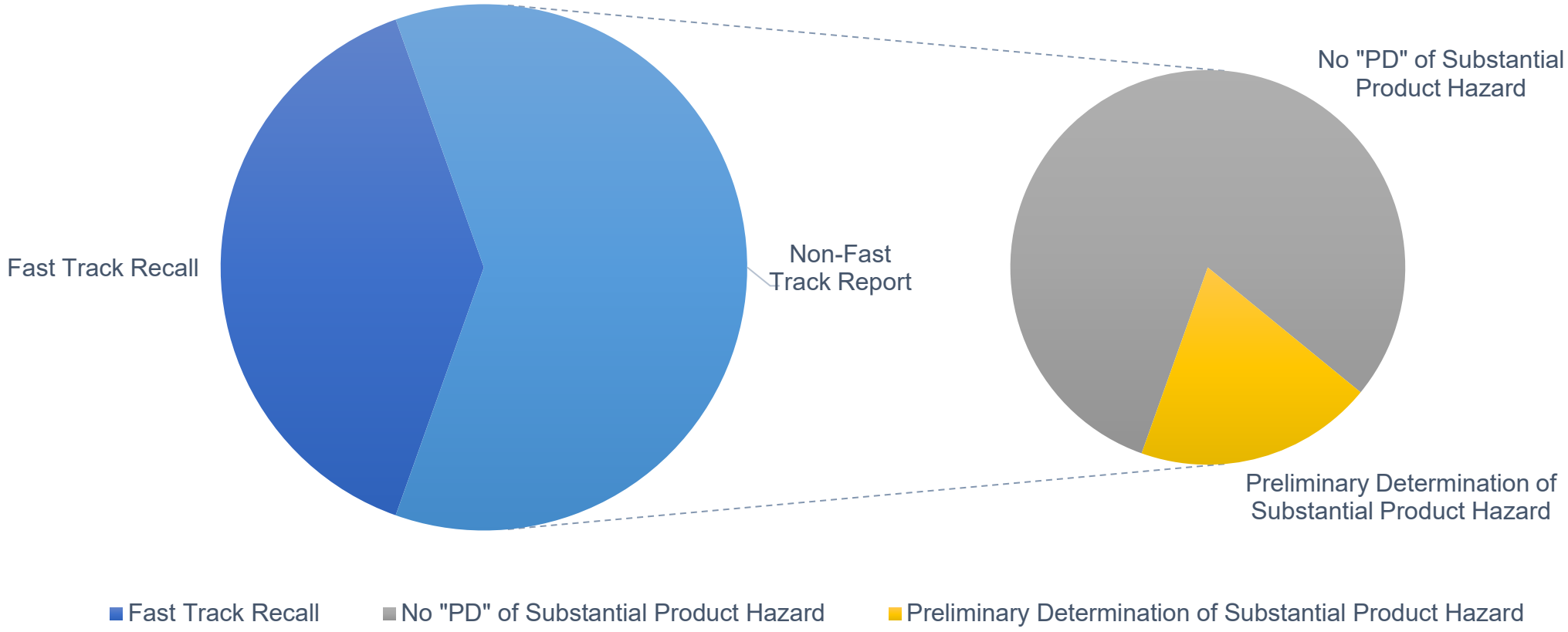
Section 15 Reports by CPSC Fiscal Year



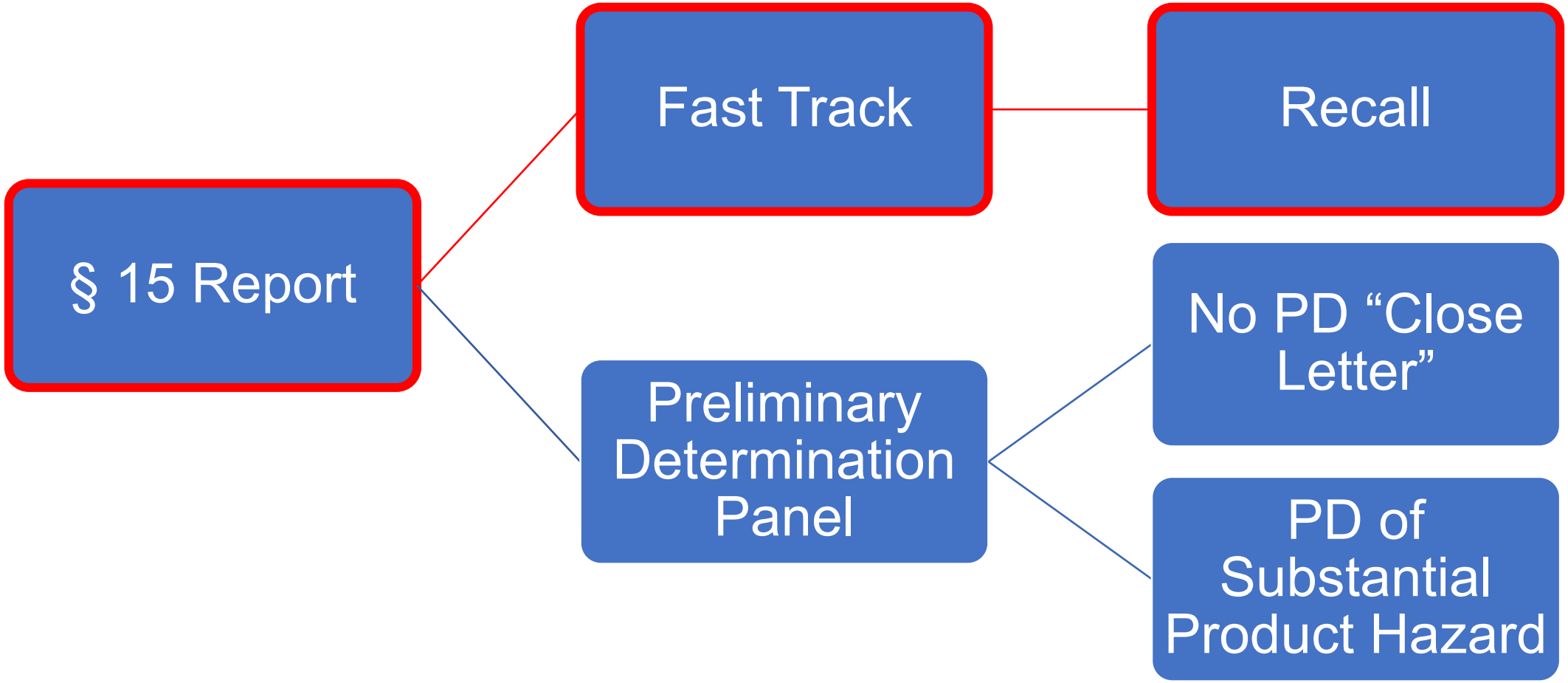
Typical CPSC Reporting Scenarios



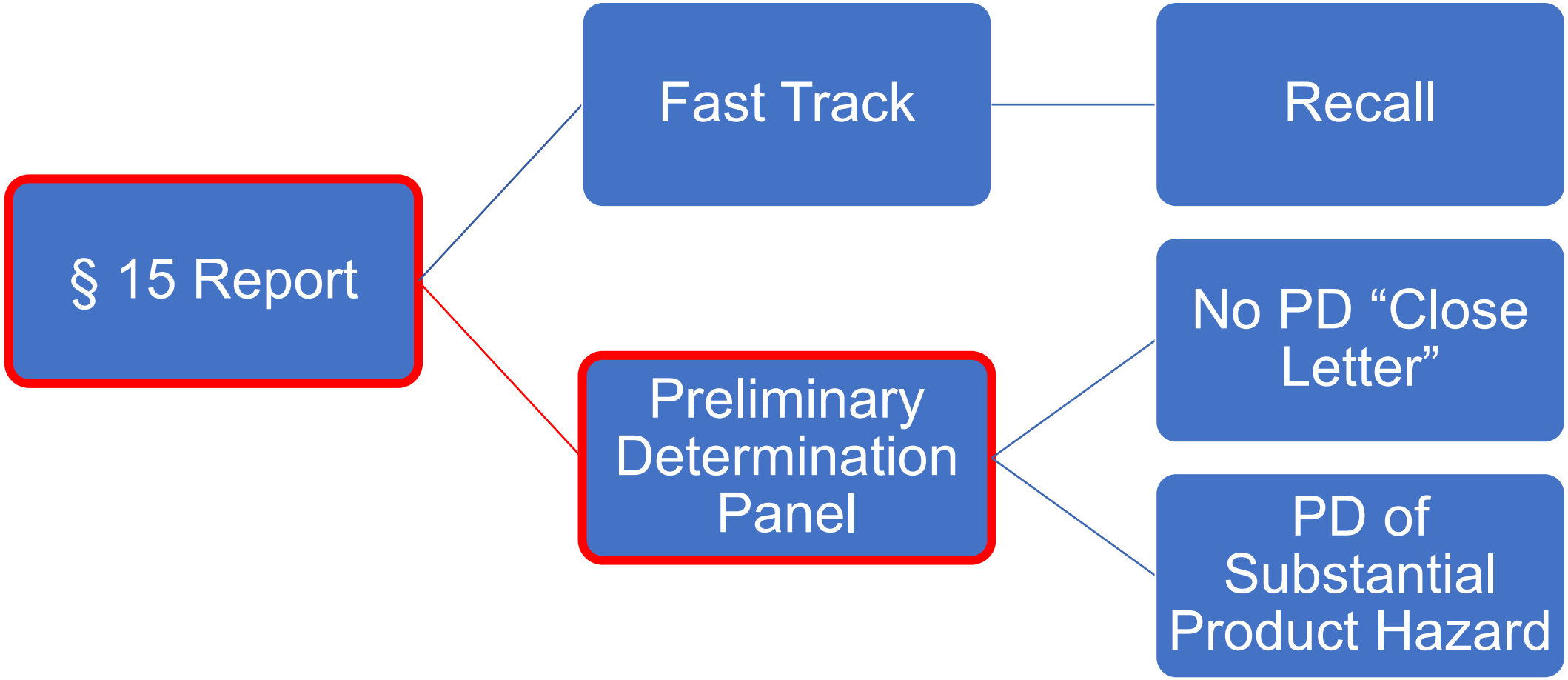
Disposition of §15 Reports to CPSC



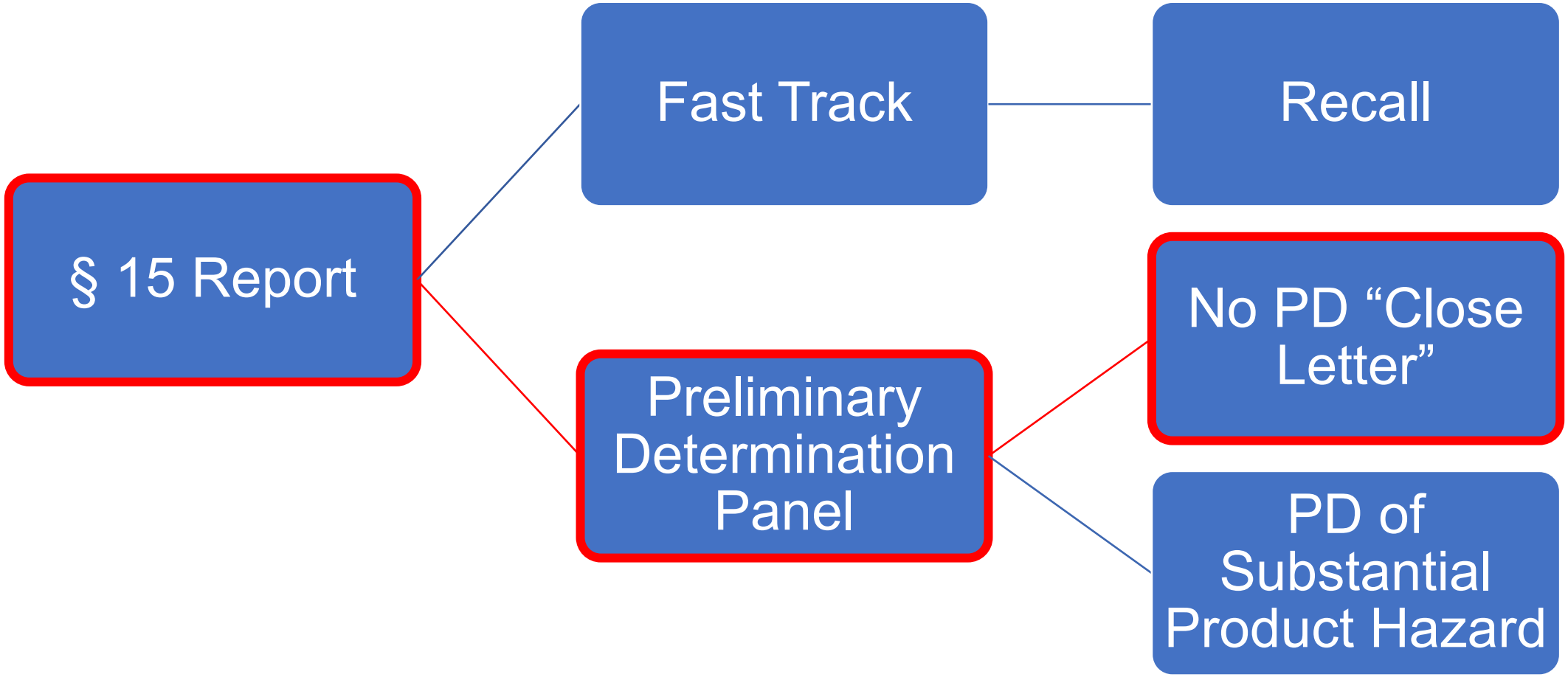
“Fast Track Recall” Report to CPSC



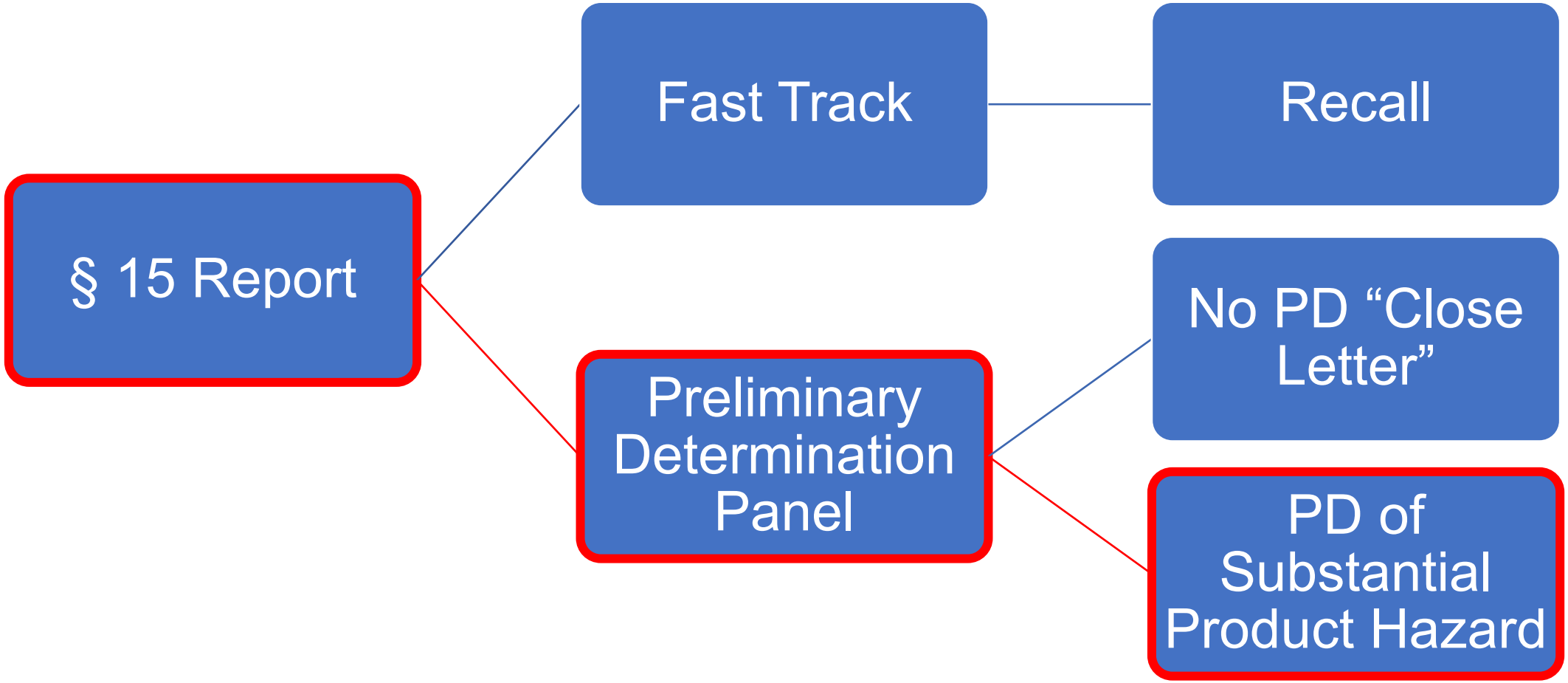
Standard §15 Report to CPSC



Standard §15 Report to CPSC: No “PD”



Standard §15 Report to CPSC: “PD”



Recalls

Was the recalling entity liable for failures in the design, execution and/or effectiveness of the recall?

Restatement (Third) of Torts: Prod. Liab. §11

§ 11 Liability of Commercial Product Seller or Distributor for Harm Caused by Post-Sale Failure to Recall Product

One engaged in the business of selling or otherwise distributing products is subject to liability for harm to persons or property cause by the seller's failure to recall a product after the time of sale or distribution if:

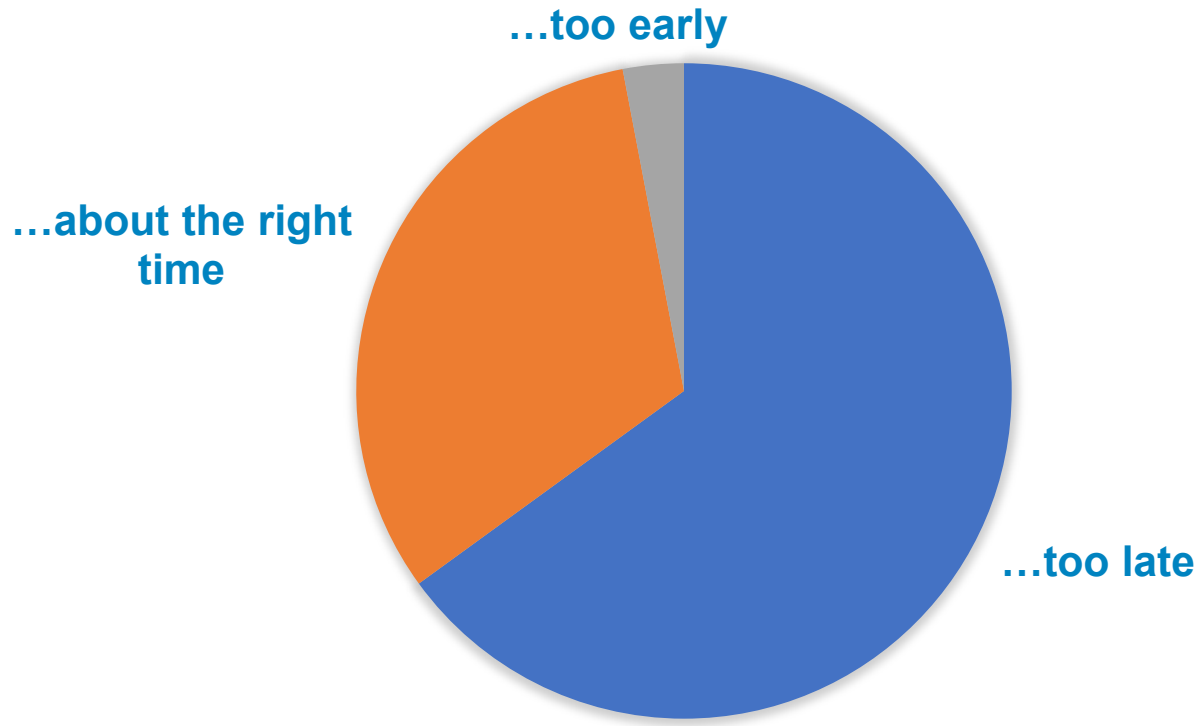
(a) (1) a governmental directive issued pursuant to a statute or administrative regulation specifically requires the seller or distributor to recall the product; or

(2) The seller or distributor, in the absence of a recall requirement under Subsection (a)(1), undertakes to recall the product; and

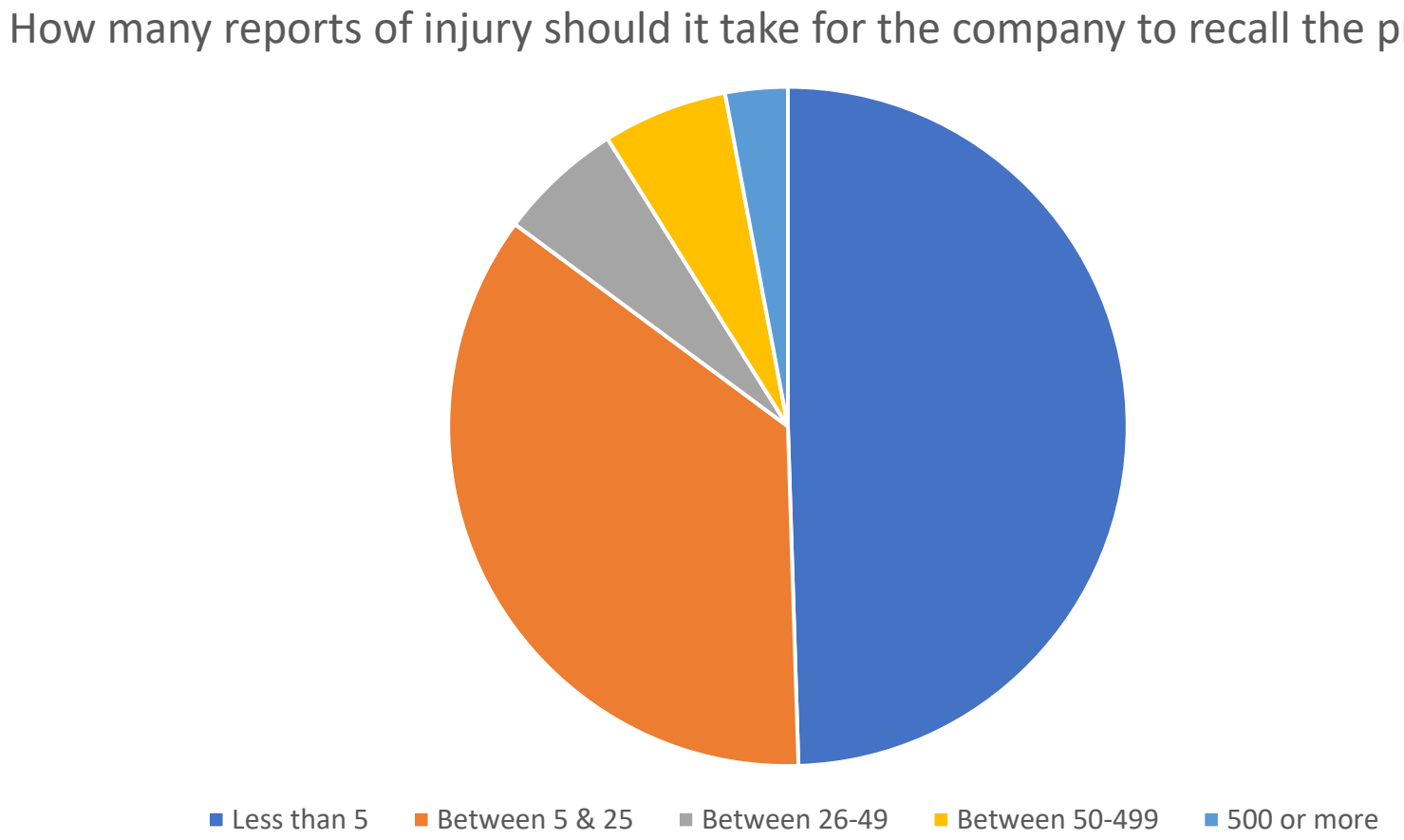
(b) The seller or distributor fails to act as a reasonable person in recalling the product.

Consumer Perceptions About Recalls

Product recalls typically happen…



A company that manufactures medical device products has sold 5,000 units of a particular product when it receives reports that consumers were injured by the product.



Negligent Recall Claim Questions

1. Can you present a credible and persuasive expert to examine the adequacy of the recall based on reliable sources?
2. Were additional efforts reasonable in the circumstances?
3. What were post-recall incidents, injuries and property damage?
4. How is a recall's effectiveness fairly measured?
5. Are there standards and authoritative sources defining the standard of care for a recall?
6. Did the CPSC want more in the recall?
7. What is the significance of a recall close-out letter from the CPSC?

Sources of Recall Standards of Care

Agency Guidance	▪ CPSC Recall Handbook ▪ "Best Practices" (www.cpsc.gov) ▪ FDA & NHTSA Guidance
Standards	▪ ISO 10393: Consumer Product Recall – Guidelines for Suppliers ▪ BSI: Code of Practice on Consumer Product Safety Recalls ▪ PROSAFE: Product Safety in Europe: A Guide to Recalls
Metrics	▪ CPSC recall effectiveness rates ▪ FDA Medical device correction results ▪ NHTSA Completion rates studied by GAO

Children's Product Certification

Detailed process regulations and recordkeeping requirements.

Certification Standards of Care

High Degree of Assurance

- “An evidence-based demonstration of consistent performance of a product regarding compliance based on knowledge of a product and its manufacture.”

Due Care

- “The degree of care that a prudent and competent person engaged in the same line of business or endeavor would exercise under similar circumstances. Due care does not permit willful ignorance.”

Five-Year Recordkeeping Requirements

Certificates	▪ Copy of the Children's Product Certificate ▪ Test Results from CPSC-listed laboratories authorized to perform mandatory third-party testing ▪ Test results to support certification must be provided for every manufacturing site
Periodic Testing	▪ Periodic or production test plan must be in writing in the file ▪ Periodic or production test results must be in the file ▪ Test plan must provide basis for ensuring continued product compliance after certification
Samples	▪ Documentation identifying the number of samples submitted for certification, periodic and production testing ▪ Documented procedure for selecting representative samples for testing ▪ Documentation must include the basis for inferring compliance
Material Changes	▪ Defined as any change in the product's design, manufacturing process, or sourcing of component parts that a manufacturer exercising due care knows, or should know, could affect the product's compliance. ▪ Records of design, manufacturing process or component material changes
Undue Influence	▪ Records of undue influence policy ▪ Training records including training material and employee participation ▪ Attestations of all employees to the undue influence policy

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