

Compliance Update

ICPHSO Annual Meeting

Orlando February 27, 2007



This presentation has not been reviewed or approved by the Commission and may not reflect its views

Status of the Commission

- Hal Stratton resigned in July 2006
- As of January 15, 2007, the Commission lacks a quorum for official action
- Vice Chairman Nancy A. Nord is Acting Chair until a new Chair is appointed by the President and confirmed by the Senate
- Senate Commerce Committee has reported out a bill that would allow the Commission to operate with only two Commissioners for a further six months

Delegated Authority

- Director of Compliance has long had authority to:
 - Accept or reject Corrective Action Plans
 - Open or close civil penalty investigations
 - Settle civil penalty cases or recommend referral of such cases to Justice Department
- General Counsel has had authority to
 - Refer criminal cases to Department of Justice

New “Interim” Delegations

- Before quorum expired, Commission adopted several new delegations
- Allow Compliance to accept civil penalty settlements in three specific cases with concurrence of General Counsel
- Give Compliance authority to accept penalty settlements below \$50,000, subject to approval of each Commissioner
- Give General Counsel authority to refer civil penalty cases to Dept of Justice

“You can rely on the integrity of most companies, but there are situations where the commission has to compel a recall by filing a lawsuit.”

Alan Schoem, former Director of
Compliance (1997-2004)

New Oversight

- Appropriations Subcommittee Chairs
 - Senate = Sen. Durbin
 - House = Rep. Serrano
- Authorizing Committee & Subcommittee
 - Senate = Sen. Inouye, Sen. Pryor
 - House = Rep. Dingell, Rep. Rush

Lighthearted Banter

PART Review

- Performance Assessment and Rating Tool (PART) is method for systematic review of agency programs
- In 2006, CPSC underwent PART review by Office of Management and Budget
- CPSC **rated “effective”** rating – best score possible (only one other independent agency has overall “effective” rating)

New FY 2007 Compliance Goals

- Discarded all goals relating to the absolute numbers of corrective actions or recalls obtained in different hazard areas
- Instead, focus on *efficiency* of operations at “front end” and “back end” of process
- “front end” is investigatory stage, deciding whether corrective action is necessary
- “back end” is negotiation stage, obtaining corrective action when needed

Preliminary Determination (“PD”)

- Each Section 15 report launches a staff investigation as to whether a defect exists and if so whether it creates a “substantial product hazard”
- Usually involves a “**product safety assessment**” by the Engineering staff and collection of injury data from the firm and from Epidemiology staff
- The process culminates in a “**preliminary determination**” by a senior Compliance official
- Staff will request a recall if and only if it determines there is a substantial product hazard

“Front End” Goal

- Concept: expedite investigations in an area of *strategic* importance (**fire** hazards)
- Clock starts when a report is filed or corrective action (CA) case is launched and stops when staff makes preliminary determination (PD)
- 2007 Target = make PD **within 120 days** in 66% of cases involving fire hazards

“Back End” Goal – Defect Cases

- Concept: obtain corrective action quickly where staff determines it is appropriate
- Clock starts when PD letter (recall request) is issued and stops when Corrective Action Plan is accepted
- 2007 Target = obtain corrective action in 80% of cases **within 75 days** after staff Preliminary Determination (PD)

“Back End” Goals

Regulated Products Cases

- Clock starts when Letter of Advice (LoA) is issued and stops when firm agrees to take action
- 2007 Target = obtain corrective action for 85% of cases **within 50 days** after Letter of Advice
- 2007 Target = for fire cases, 80% within 50 days after Letter of Advice

“Fast Track” or “No PD” Option

- If firm does not contest the need for a recall, it can request “Fast Track” handling
- This approach avoids any need for a staff “preliminary determination” of defect and “substantial product hazard”
- Staff focuses instead on assessment of remedy and methods for notifying consumers
- Firm must be prepared to move quickly, stop sale usually within days

“Fast Track” Goal

- Concept: expedite process so that firms can launch corrective action as soon as possible after initial report
- Target = 90% of cases **within 20 days**
- FY 2006 performance = 98% in 20 days
- 2007 Survey will assess satisfaction with Fast Track program – gives firms an opportunity to provide valuable feedback anonymously

New Goals for Field Operations

- Increase number of establishment inspections to **at least 400** in FY 2007
- Establish efficiency goal for in-depth investigations, particularly in areas of strategic importance (fire and carbon monoxide)

Will the New Goals Affect You?

- **Consumers benefit** from quicker resolution of many reports to CPSC (fire hazards accounted for > 25 percent of all recalls in FY 2004-06)
- **Firms benefit** from shorter “limbo” period faced by firms after reporting
- Firms and their counsel can expect staff to insist on **stricter adherence to deadlines** for submitting information, samples, etc.

Revised Section 15 Reporting Rule

Published in July 2006

- Adds factors to be considered in determining whether a *defect* exists
- Inserts new subsection discussing *significance of safety standards* for reporting
- Discusses how the *number of products in use* may be relevant to the existence of a substantial product hazard

Is Your Product Defective?

- Not all products that pose a risk of injury are defective (classic example = sharp knife)
- Reporting rule identifies factors to be considered in determining whether a risk of injury signals a product defect
- Revision makes explicit several factors that were only implicit before:
 - The *obviousness* of the risk at issue
 - The *adequacy of warnings and instructions* to mitigate the risk
 - The *role and foreseeability of consumer misuse*

Does Your Product Comply with Applicable Standards?

- Section 15 expressly requires firms to report if they obtain information that a product does not comply with a *mandatory standard* adopted under the Consumer Product Safety Act (CPSA) or a voluntary standard *relied upon by the Commission* under the CPSA
- Revision explains that either compliance or non-compliance with safety standards may be relevant to preliminary determinations made by CPSC staff

Significance of Other Standards

- Failure to comply with applicable standards (FHSA/FFA/PPPA/voluntary) may be indicative of a defect – should always lead firms to consider reporting
- Compliance with standards does not automatically preclude defect finding
 - Standards rarely cover all aspects of performance
 - Standard may be out of date or otherwise inadequate

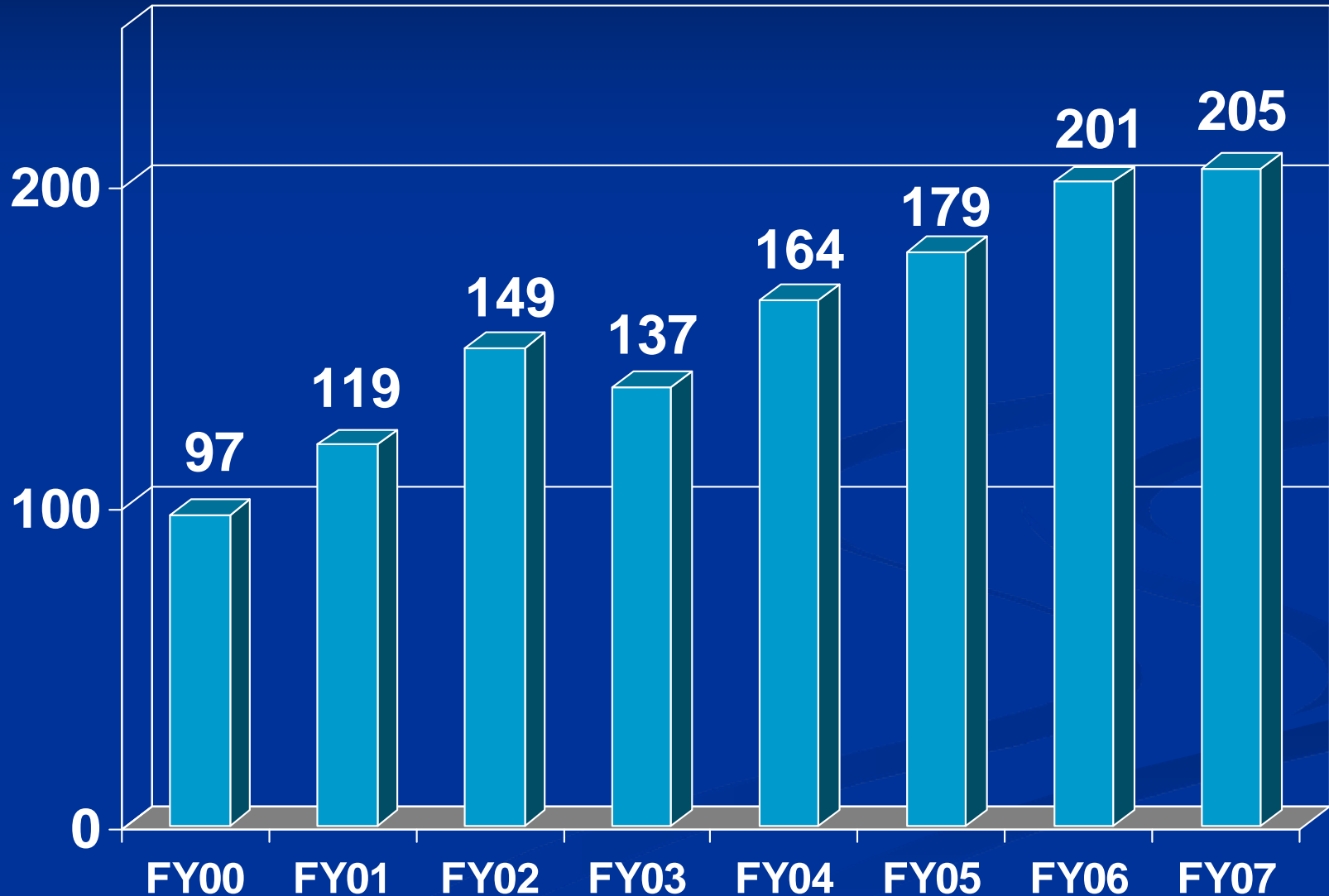
How Many Products Remain in Use?

- Reporting rule sets forth factors to be considered in evaluating whether a “substantial risk of injury” exists
- One factor is the number of products *distributed* in commerce
- Revised rule expressly recognizes that the risk of injury to be considered depends on the **number of products *in use***
- *Do not wait* until number of products declines if report is appropriate earlier

ATLA Commentary

- Lewis S. (“Mike”) Edson, president of the Association of Trial Lawyers of America, addressed the revised rule in BNA Product Safety and Liability Reporter (Nov. 6, 2006)
- Two related criticisms:
 - Claims firms will submit **fewer reports** as a result of the revised rule
 - Cites **five specific recalls** that might never have occurred if revised rule had been in place

No Apparent Decline in Section 15 Reports to Date (FY 2007 Compared to Recent Years)



Response to Specific Examples of Recalls Deemed Unlikely

- Three of the five highlighted cases involve hazards that were *never reported* to CPSC – the staff found these problems and obtained recalls. Nothing in the revised rule would change that outcome.
- The other two cases were **Fast Track** recalls – i.e., cases that the firms reported *with the intention of doing a recall*. There is no basis for assuming that the revised rule would change a firm's incentive in such cases.

Civil Penalty Factors

- CPSA section 20 specifies five factors that the Commission *must* consider in assessing and compromising civil penalties
- Office of Compliance has often evaluated other factors in deciding whether penalty is appropriate and if so, what size
- Proposed new part would identify additional factors for consideration by staff and the Commission

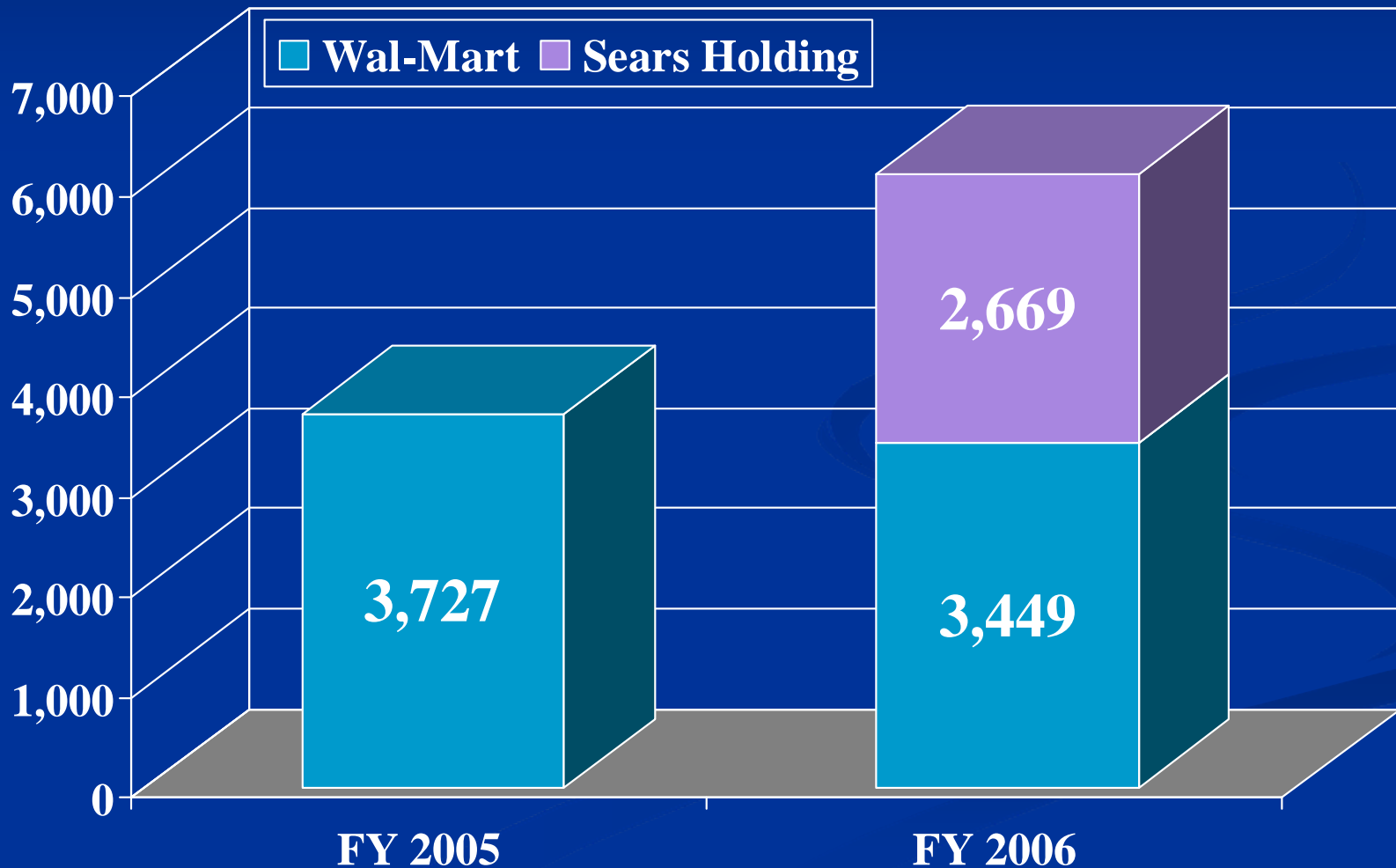
Proposed Civil Penalty Factors

- Firm's previous record of compliance
- Timeliness of reporting
- Firm's surveillance efforts
- Firm's cooperation and good faith
- Economic gain from non-compliance
- Expected rate of failure for given product

Retailer Reporting Update

- After an experimental period, Wal-Mart formally began reporting at start of FY 2005
- Sears Holding began weekly reporting in FY 2006 (formally announced in September 2006)
- 3rd major retailer recently began reporting trial
- 4th major retailer has committed to program
- Session on retailer reporting at ICPHSO tomorrow morning during ABA program

Retailer Reporting Volume



7,176 Incidents Reported
by Wal-Mart in FY 2005-06

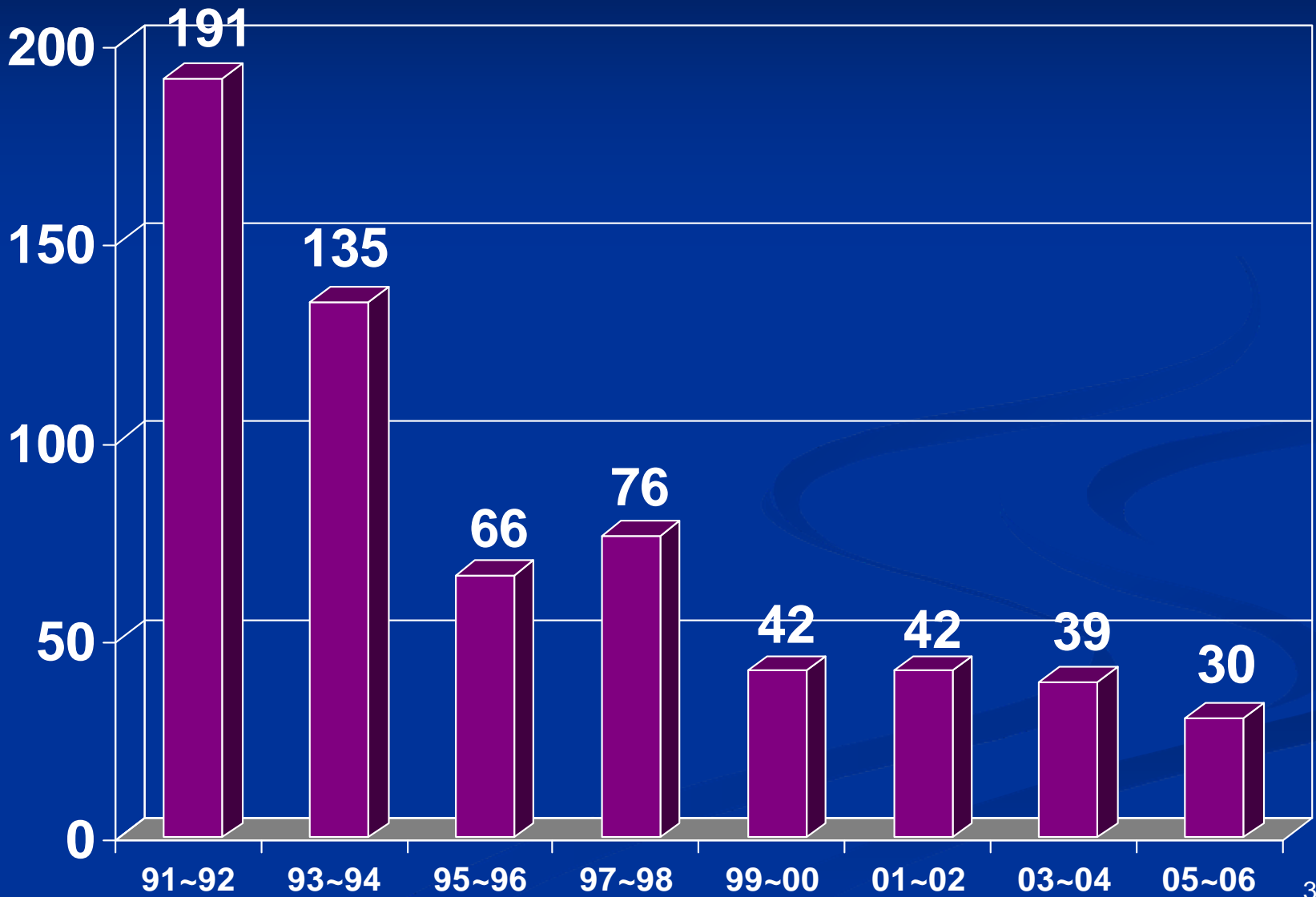
3,392 Incidents “Triggered”

534 In-Depth
Investigations
Assigned

New Section 37 Reporting Period

- CPSA Section 37 requires manufacturers (including importers) to report if they settle or lose three cases involving death or grievous injury caused by a particular model of a consumer product within specified two-year periods
- New reporting period began January 1, 2007

Is Product Liability Waning?



Mattress Standards

- New open-flame mattress standard (16 CFR 1633) will take effect on **July 1, 2007**
- New website materials, including Q & A
- Free workshops in Bethesda on March 28-29 and San Diego on April 11 (registration is required)
- Retailers must avoid “mismatching” foundations and mattresses
- Interim enforcement policy allows fewer tests under 1632 standard while firms are qualifying prototypes

Fireworks Program Initiatives

- Advance Notice of Proposed Rulemaking published July 2007
- Considering various approaches to strengthen program:
 - Certification of compliance (FHSA section 10)
 - Reliance on voluntary standards
- Many thoughtful comments received
- Next steps: status report to Commission, Notice of Proposed Rulemaking

Lighter Program Initiatives

- Rulemaking pending on adoption of ASTM 400 voluntary standard
- FY 2006 Rule Review identified possible modifications to 16 CFR part 1210 and 1212
- New application format – will streamline processing and simplify data sharing with EU
- Cross-qualification guidelines – will help firms determine need for testing

Lead (Pb) Jewelry Update

- In 2005, CPSC issued an Interim Enforcement Policy on lead in children's metal jewelry
- More than two dozen firms have conducted voluntary recalls since policy was issued
- CPSC has received no report of lead poisoning caused by jewelry that meets the safe harbor levels of the policy
- CPSC granted petition from Sierra Club to consider ban on lead in children's jewelry

Improving Recall Effectiveness

- Staff is developing a document to identify “effective recall techniques”
- Staff is evaluating data from prior recalls to identify success stories and to consider how best to measure effectiveness
- Staff planning to make use of consumer focus groups and new Consumer Opinion Forum

Focus on Incidents & Injuries

- The number of products returned or corrected often underestimates recall effectiveness
- Whether incidents and injuries occur after a recall (and if so, how many) is an important measure of effectiveness
- Need to distinguish between injuries **occurring after** the recall and those **reported after** the recall but occurring before
- Staff developing a new form for Recall Progress Reports

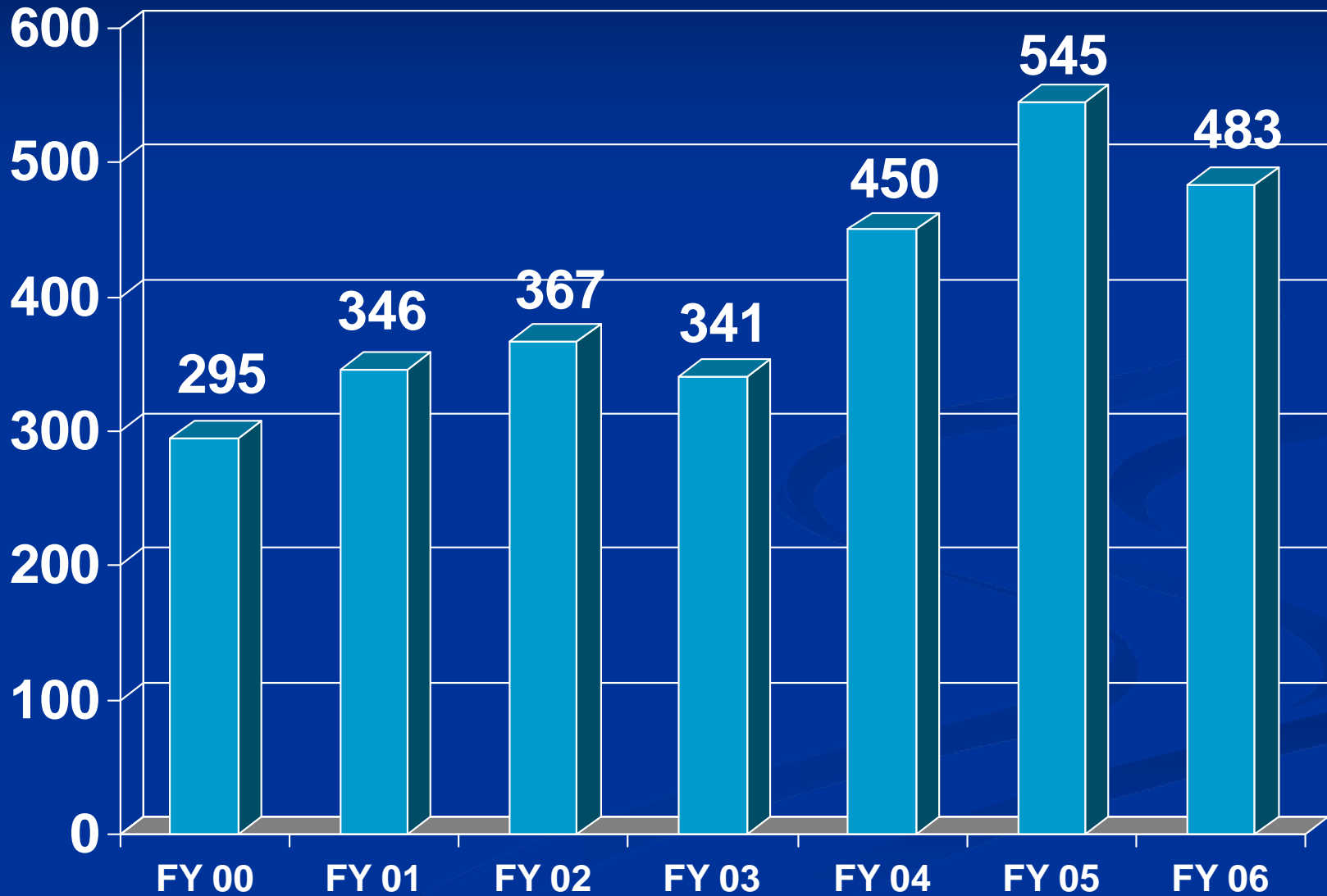
Strengthen CPSC Recall Monitoring

- Conduct Recall Verification Inspection at recalling firms
- Notify retailers of all CPSC recalls
- Execute Recall Checks at retail points of sale
- Notify retailer headquarters as well as recalling firm when recall check discloses problems
- Search internet for sales of recalled products
- State partners, private organizations

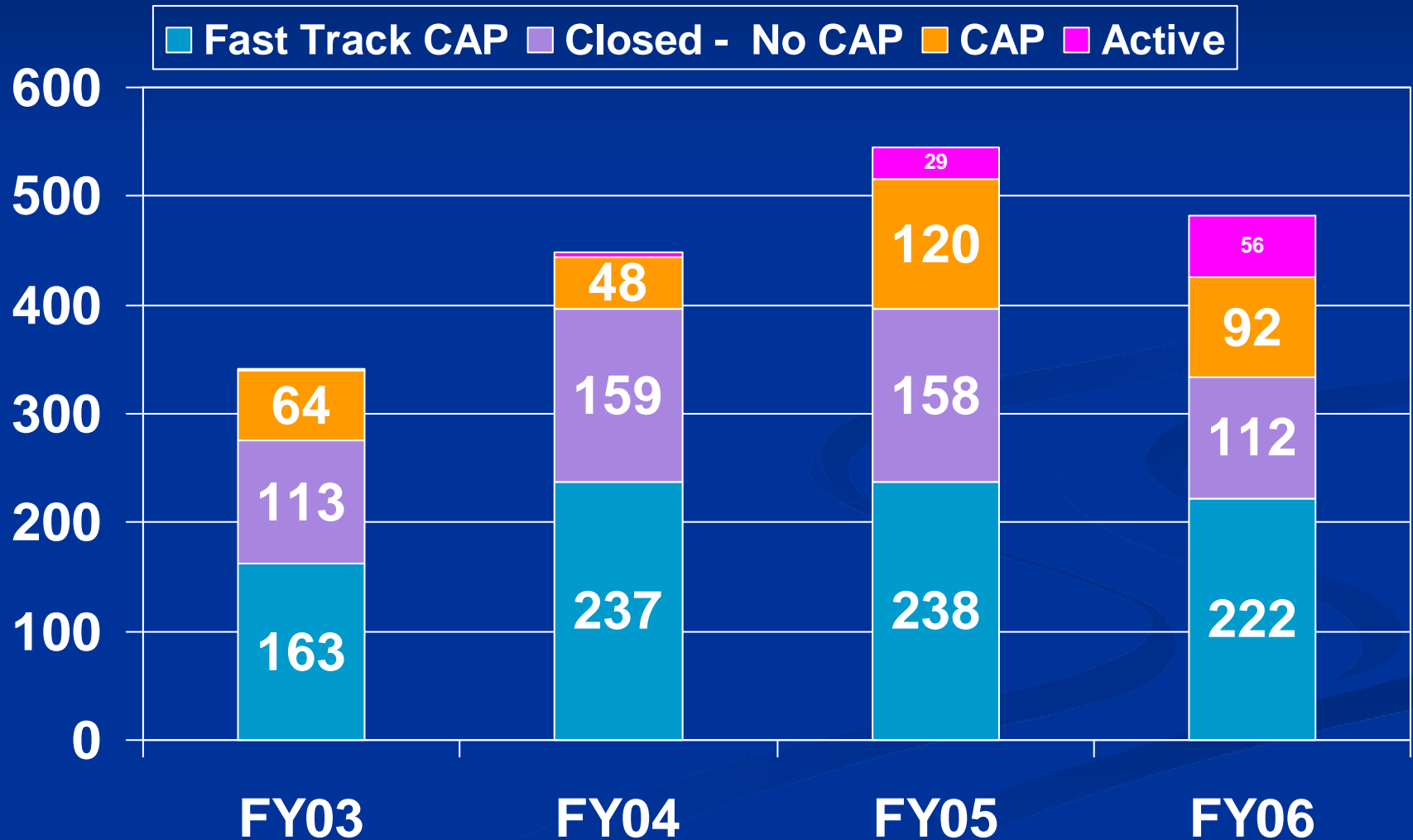
Sale of Recalled Products

- Recalling firm - Black Dog penalty
- Third-party sales of recalled products
 - Consumers using internet auction sites
 - Firms dealing in remainders
- Interim Delegation for civil penalties below \$50,000
- Contractor implementing recall – criminal penalty situation

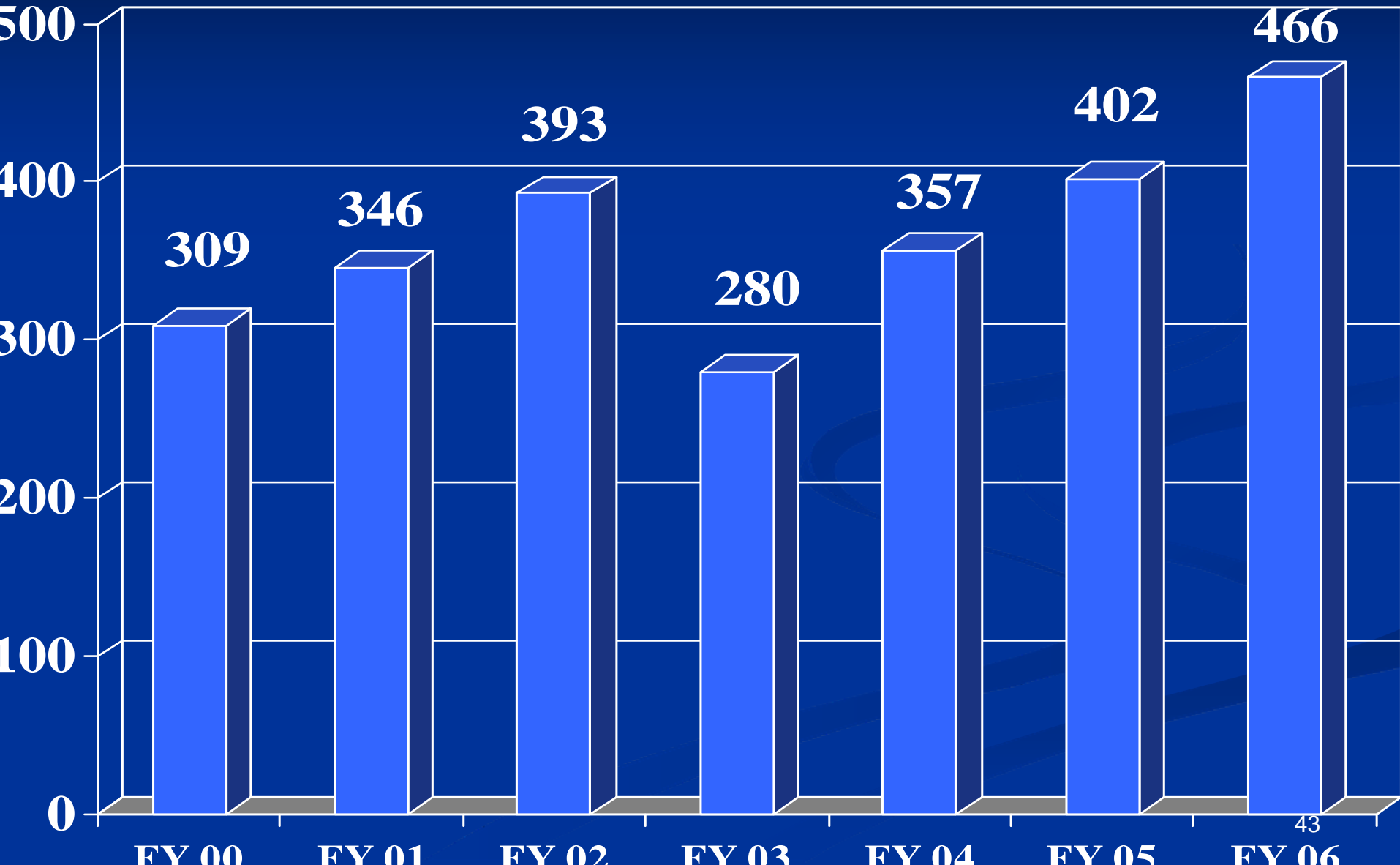
Section 15 Reporting Trend



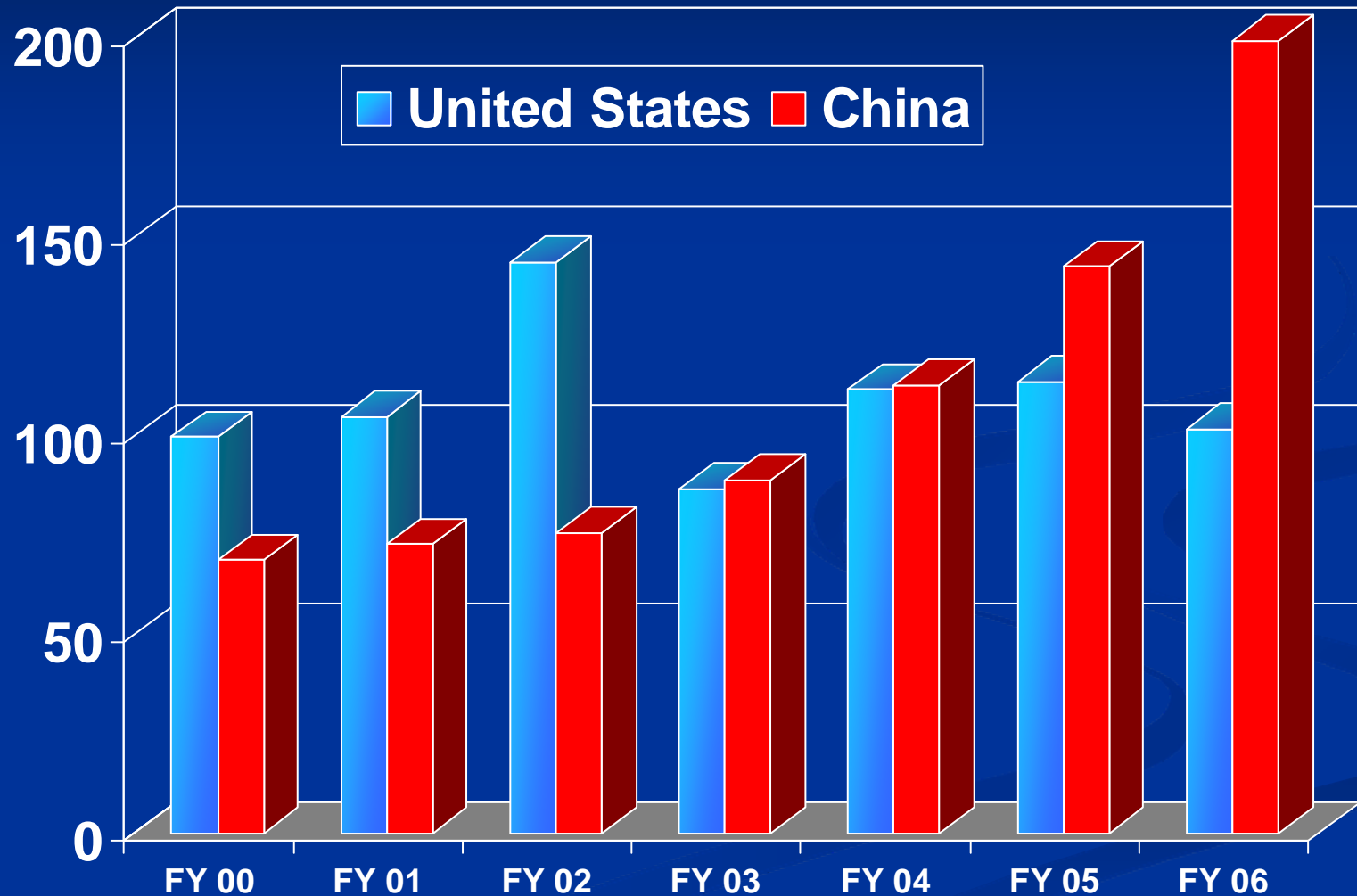
Disposition of Section 15 Reports



Voluntary Recalls by Fiscal Year



Sec. 15 Recalls by Country of Origin



Technical Teams

- Four interdisciplinary teams addressing cigarette lighters, electrical products, fireworks and toys
- Teams identifying issues to be addressed at next U.S.-Sino Safety Summit, Bethesda 2007
- Working Groups will convene in Beijing May 2007 shortly before ICPHSO

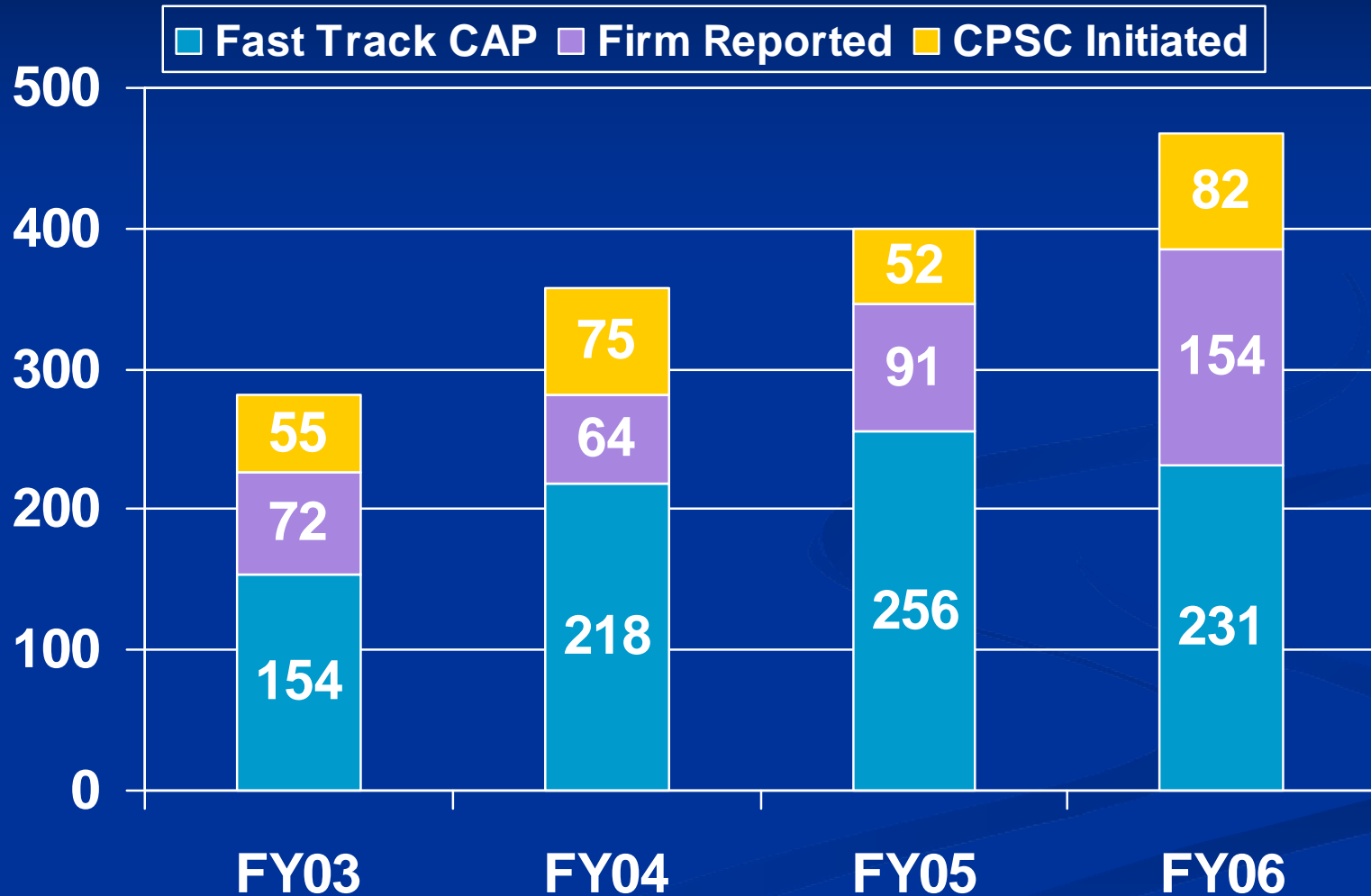
Recall Notice to Foreign Manufacturers

- Pilot program to give Chinese manufacturers direct notice of U.S. recalls involving their products
- CPSC will use the press release announcing the recall in the U.S. as the vehicle for notice to foreign manufacturer
- Following notice to the manufacturer, CPSC staff will provide the same recall information to the Chinese government.

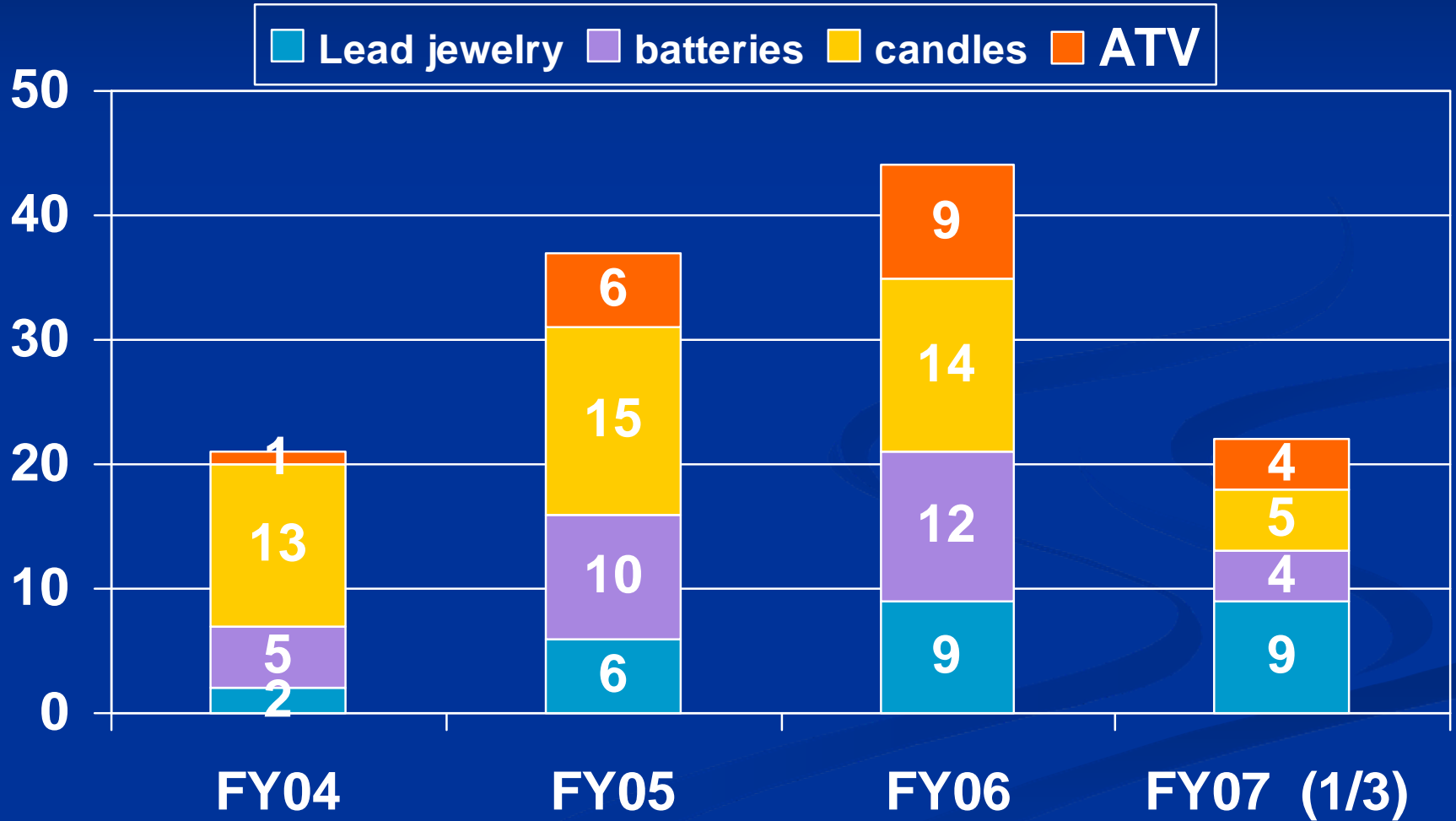
Recall Notice to Other Governments

- CPSC encourages firms to notify the governments of other nations promptly when an unsafe product was sold in their territory
- After a recall has been announced, CPSC is attempting to notify other nations for whom we have contact information when we know the recalled product was also sold there in significant numbers

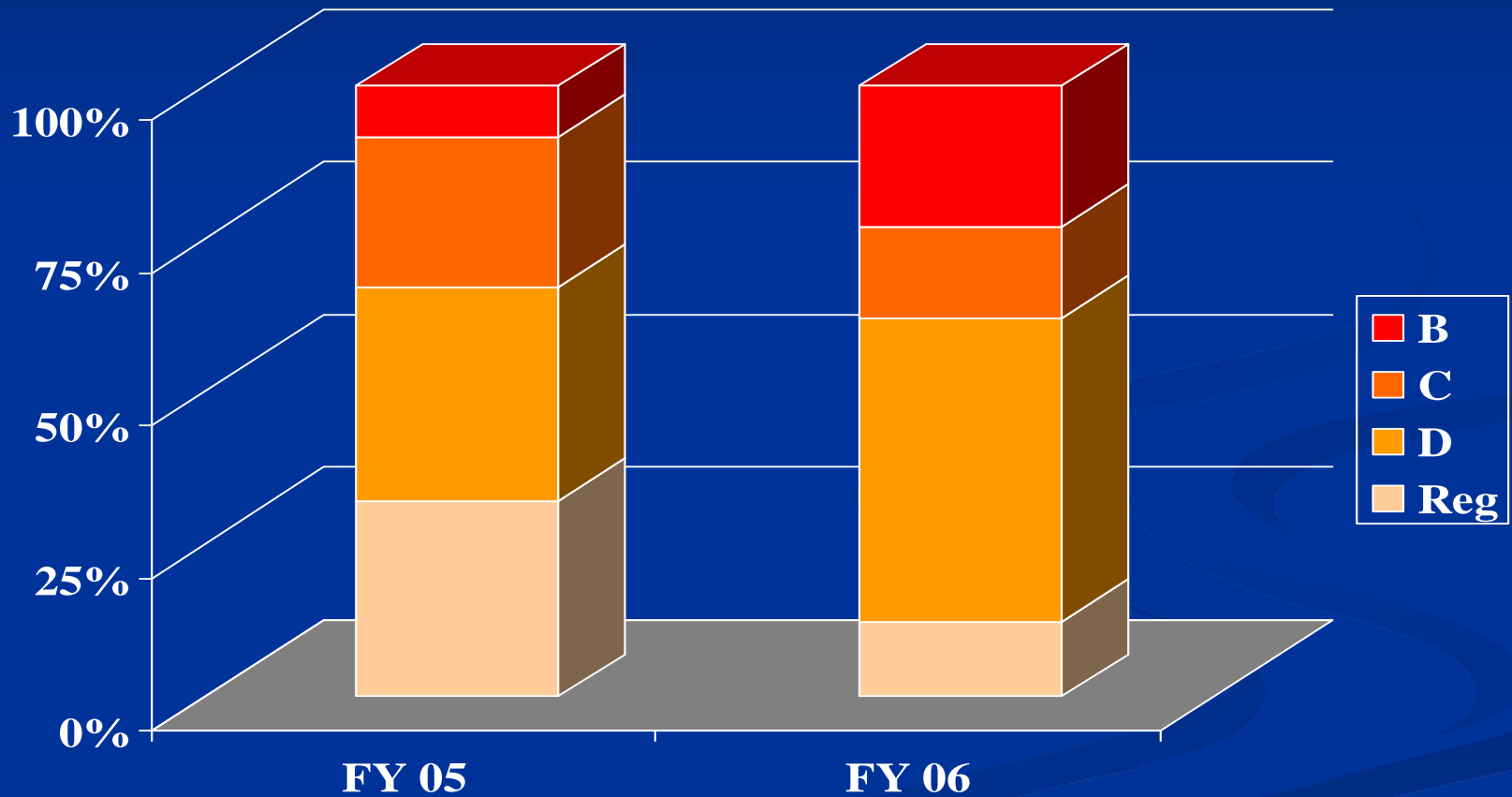
Recalls by Source



Hot Recall Areas



Recall Hazard Classification



Hazard Classification of Recalls

FY 2005—2006

	A	B	C	D	Reg
Firm reported	0	0	45	157	39
Staff initiated	0	34	29	22	39

Industry Guidance

www.cpsc.gov

- Business Section
- **Monitor CPSC Activities through:**
 - Recall Announcement Subscriptions
 - Public Calendar Subscriptions
 - CPSC Electronic Reading Room Inquiries
 - Seminar Attendance (e.g., ICPHSO)

Questions?

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