Are you ready for a recall?

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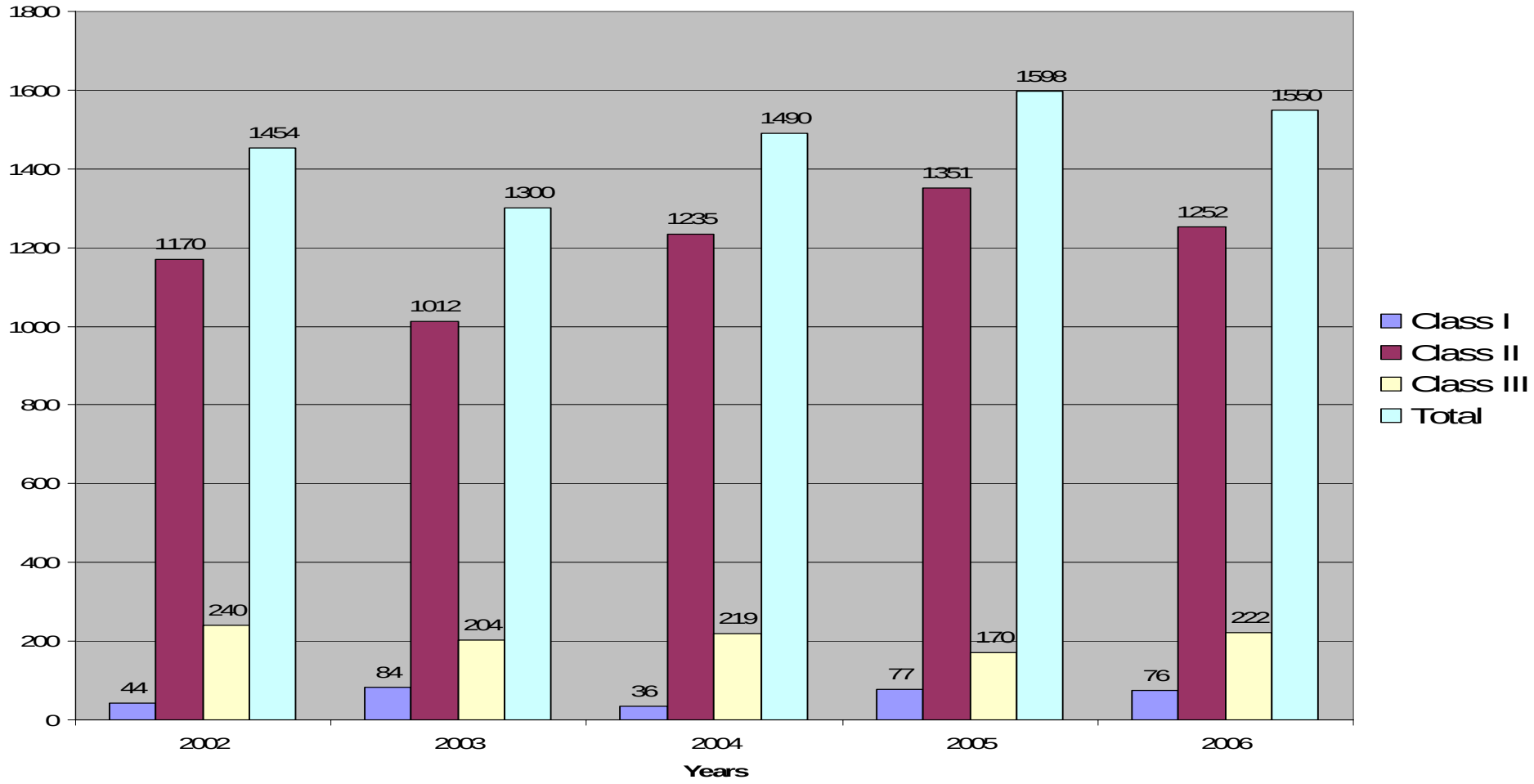
Willie R. Bryant, Jr.
Consultant Stericycle, Inc.

CDRH Recall Stats, FYs 2002-2006



Who Should Have a Recall Plan?

- Manufacturers
- Own-Label distributors
- Distributors of foreign manufactured products
- Repackers
- Wholesalers – Direct to consignees, e.g. institutions, hospitals, clinics, physician offices, & consumers.

What kind of plan is needed?

- **Comprehensive Plans**
  - Depend on the organization types
  - Address all aspects of a recall
  - Recognize the potential effects on the recalling entity

What should coverage include?

- **Domestic and Global Distribution**
- **Manufacturing Partners**

When should a recall be prepared for?

- Ideally – prior to first product approval
- Realistically – If a comprehensive plan is not in place, then “immediately”
- Annually – Review, assess, modify, update
- After each recall event – postmortem.

Why Should a recall plan be in place?

- **Quality System Regulations, Sections 820.100 - Corrective and Preventive Action, and 820.9 – Nonconforming Product**
- **21 CFR 7.59, General Industry Guidance**
- **Minimize risk to the public**
  - Speed of notification/correction/removal
- **Manage publicity**
  - Prevent as much negative publicity as possible
  - Speed, accuracy, honesty, thoroughness
- **Maintain Customer trust**
- **Minimize risk of litigation**

How does one develop a recall plan?

- **If not already in place, develop a SOP/Recall Manual**
- **Understand the recall landscape**
  - Definitions
  - FDA's Enforcement Mechanism
  - Work with FDA – District offices and occasionally, CDRH
- **Define the scope**
- **Define responsibilities**
  - Recall team/action committee
  - Recall coordinator
  - Management
  - Third parties
- **Develop a checklist to cover all operations**

Examples of operations for a check list!

- Health Hazard Evaluation – When, by whom, inside/outside?
- Classifications (FDA) and responsibilities for each.
- Distribution and tracking of recalled product.
- Trace back system for BRCs and returned product.
- External Notification – Who, to what level, how, method, press release, web site notice w/updates.
- Internal Notification – All employees, communication staff, marketing/sales force. Who handles it, how, and when?
- Investigation into “root cause” of the recall.
- Company official who is FDA contact and/or spokesperson for the company
- Insurance
- Counsel

“Recall Plan Assessment”

- Assess Current State –
- How does it compare with current firm infrastructure – Are all the correct and necessary departments included (Management, quality, safety/medical, communications, regulatory, legal, marketing, distribution, etc).
- Do you have the right people on the recall team
- Is each team member capable of representing his/her organization with knowledge of processes and procedures necessary.
- Review past events for situations that could be improved upon.
- Look for risk areas that may not be common to all products, such as the necessity of having recalling firm technicians making on-site field corrections. Do you have the staff to do it, and how long would it take? What happens with device use in the meantime?

Test the Plan
Analyzing and Processing the Results

- How - Conduct a “Mock Recall”!
- Test your decision making process – Find out if what you have on paper (SOP) will work and, how well it works, in actual practice.
- Duplicate the environment! Pick a product – Define a hazard – Consider it to be a Class I Recall, worst case scenario.
- Initiate the Mock Recall operation – document the operations. Who did what, when, how and why?
- At completion, conduct a post-mortem. Find out what went right, what went wrong.
- Look at the management process.
- Review internal communication processes.
- Review notification and correction or removal functions
- Draw conclusions, and make necessary adjustments to the plan.

Continuing Education

- Don’t create a recall plan and then set it aside until needed.
- Stay current with regulations.
- Review and update regularly. Personnel, in-house and out, change often.
- Develop an in-house training program. Review for older team, training for newer members.
- Attend conferences where recall topics are discussed. Compare other ideas with yours. Look for ways to improve your plan.
- Consider third party training for the team.

Available Recall Guidance Documents

- **"Methods for Conducting Recall Effectiveness Checks" (issued 6/16/78)**
  Internet: http://www.fda.gov/cdrh/ode/225.pdf
- **"510(k) Requirements During Firm-Initiated Recalls, K95-1" - Blue Book Memo (issued 11/21/95)**
  Internet: http://www.fda.gov/cdrh/k951.html
- **Regulatory Procedures Manual**
  Chapter 7 Recall and Emergency Procedures
  Internet:
  http://www.fda.gov/ora/compliance_ref/rpm_new2/ch7.html
- **Model Press Releases and FDA Enforcement Reports (includes recalls)**
  Internet:
  http://www.fda.gov/ora/compliance_ref/recalls/recallpg.html
- **Device Recalls: A Study of Quality Problems**
  Facts-On-Demand: #273

Thank You!

Willie Bryant
Consultant, Stericycle, Inc.
8209 James Street
Middletown, MD. 21769
301-371-8843 office
301-639-4991 cell
wrblmb@adelphia.net