U.S. Food and Drug Administration
Before the California Board of Pharmacy
Enforcement Committee
June 20, 2006

FDA's News re: Pedigrees

- Federal pedigree regulations will be fully implemented.
- Vigilance and leadership by States, Federal govt, manufacturers, wholesalers, pharmacies, consumers, and others is essential.
- Further securing the U.S. drug supply continues to be a priority.

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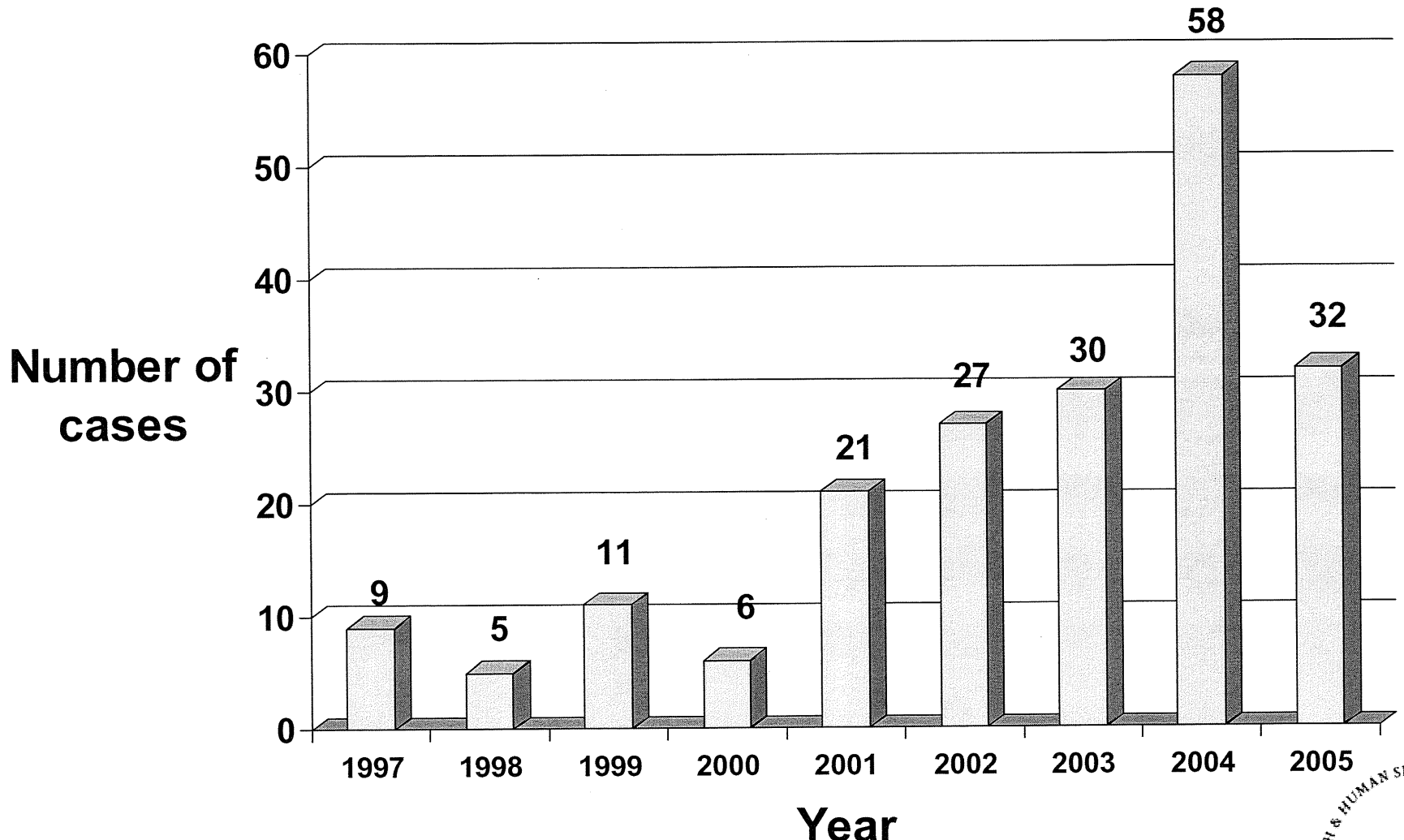
Overview

- Drug Counterfeiting in the U.S.
- Prescription Drug Marketing Act -- Background
- FDA Combating Counterfeit Drugs Initiative – 2006 Report Summary

Counterfeit drug cases opened by FDA per fiscal year



PDMA -- Background

- **Pedigree Requirement:**
  - Each person who is engaged in the wholesale distribution of Rx drugs and who is ***not*** the ***manufacturer*** or ***authorized distributor of record***, shall, prior to each wholesale distribution of such drug, provide a statement to the person who receives the drug identifying each prior sale, purchase or trade of such drug.
    - [21 USC 353(e)(2)(A)]

PDMA -- Background

- The Federal Food, Drug, and Cosmetic Act defines ***authorized distributor of record*** as a distributor with whom a manufacturer has established an "ongoing relationship."
  - [21 USC 353(e)(3)(A)]

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PDMA -- Background

- **1999 final rule provisions that were stayed:**
  - **203.3(u):** "Ongoing relationship" defined to include a *written* agreement between manufacturer and wholesaler
  - **203.50:** specifies the information to be included in the drug pedigree; information to be traceable back to 1st sale by manufacturer

FDA Counterfeit Drug Task Force Report – June 2006

- **Prescription Drug Marketing Act (PDMA)**
  - Pedigree regulations
- **Electronic track and trace**
  - E-pedigree
  - RFID
  - Technical issues
- **Report and recommendations fully endorsed by the Acting Commissioner**

PDMA Implementation

The Task Force recommends:

- **FDA not continue to delay the effective date of §§ 203.3(u) and 203.50 beyond December 1, 2006. (Let the stay expire)**
- **FDA issue a draft Compliance Policy Guide (CPG) for public comment that would focus FDA's pedigree-related enforcement efforts on those drugs most vulnerable to counterfeiting and diversion.**

- Will provide clarity in the drug supply chain regarding who is and is not required to pass a pedigree.
- The CPG will provide factors to consider for where FDA field personnel should target their enforcement efforts and prioritize resources.
- Risk-based focus
  - High value in US market
  - Prior history of counterfeiting or diversion
  - Reasonable probability for new drugs
  - Other violations of law

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Electronic Track and Trace -- E-Pedigree

The Task Force recommends that:

- **Stakeholders work cooperatively to continue to expeditiously implement widespread use of e-pedigree across the drug supply chain.**
- **FDA provide technical assistance if legislation related to e-pedigree is considered in Congress.**

- 2007 goal – will not be met
- FDA will not issue a new forecast or target date for adoption of e-pedigree
- The voluntary approach did not provide industry with enough incentives to meet FDA's deadline.
- Hybrid approaches during a transition period.

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Electronic Track and Trace --- RFID

The Task Force recommends that:

- **Stakeholders continue moving forward in implementing RFID across the drug supply chain.**
- **Stakeholders consider a phased-in approach, placing RFID tags on products most vulnerable to counterfeiting and diversion as a first step.**
- **FDA remain committed to facilitating RFID implementation and working with stakeholders, standards, organizations, and others.**
- **FDA work quickly to complete its RFID Impact Study examining drugs and biologics, and publicly share the results.**
- **Stakeholders explore the use of RFID for tracking medical countermeasures.**

- Continue to believe that RFID is the most promising technology
- Not mandating RFID – need a feasible, yet ambitious, timetable
- The CPG for conducting pilot studies for RFID tagging remain in effect as written until December 31, 2007.
- Urge manufacturers to take a risk-based approach
- RFID tracking could be useful for expeditious deployment and re-deployment of medical countermeasures in times of crisis.

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Electronic Track and Trace –Technical Issues

Mass Serialization ---The Task Force recommends that:

- **The NDC Number should continue to be closely associated with the product.**
- **For non-line-of-sight technology, such as RFID, the unique identifier for the product should either include an encrypted NDC number or an accessible link to the NDC number to protect privacy.**

- Mass serialization to identify individual drug product packages is a powerful tool.
- NDC is ubiquitous as a product identifier.
- Ideally, one numbering scheme in the drug supply chain.
- Inappropriate access to NDC # on individual products raises privacy and security issues.

Universal Pedigree/Uniform Pedigree Fields –The Task Force recommends that:

- **FDA provide technical assistance if legislation creating a universal and nationally uniform pedigree is considered in Congress.**

- Universal pedigree– passed by all, for all drugs.
- Uniform – same pedigree information requirements across country.
- To implement universal and nationally, uniform pedigree would require that PDMA be amended by Congress.

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Electronic Track and Trace – Technical Issues

Data Management/Data Security -- The Task Force recommends that:

- **We have no preference whether a distributed versus central database is used, as long as every entity in the chain of custody for the product has access to information about that product all the way back to the manufacturer.**

- It is important that specific event information in the e-pedigree be secure.
- It would be most efficient to let the market and technology dictate how best to capture and access data in e-pedigrees.
- It is essential for FDA and every entity in a drug product's chain of custody to have access to the product's pedigree data.

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Electronic Track and Trace – Privacy Issues

Labeling/Disclosure/Education

The Task Force recommends that:

- FDA work with manufacturers and other stakeholders in their efforts to develop appropriate messages, symbols, or statements for labeling of drug products and packaging that contains and RFID tag.
- FDA work with private and public sector organizations in their efforts to educate consumers about RFID.

"Turning Off" the RFID Tag

The Task Force finds that:

- We recognize that this is an important issue, but do not have sufficient information to make a recommendation at this time.

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Conclusion

- **Secure supply chain:**
  - Transparency and accountability
- **Widespread adoption of electronic track and trace holds tremendous promise**
- **FDA- more effective enforcement of the law**
- **Stakeholders (manufacturers, wholesalers, pharmacies, States, Federal govt, others) must remain vigilant in their responsibility to deliver safe/effective drugs to the patients**

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For more information on FDA's Counterfeit Drug Initiative:

www.fda.gov/counterfeit/

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