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Overview

- **Drug counterfeiting**
  - **Definition**
  - **Prevalence**

- **FDA Combating Counterfeit Drugs Initiative**

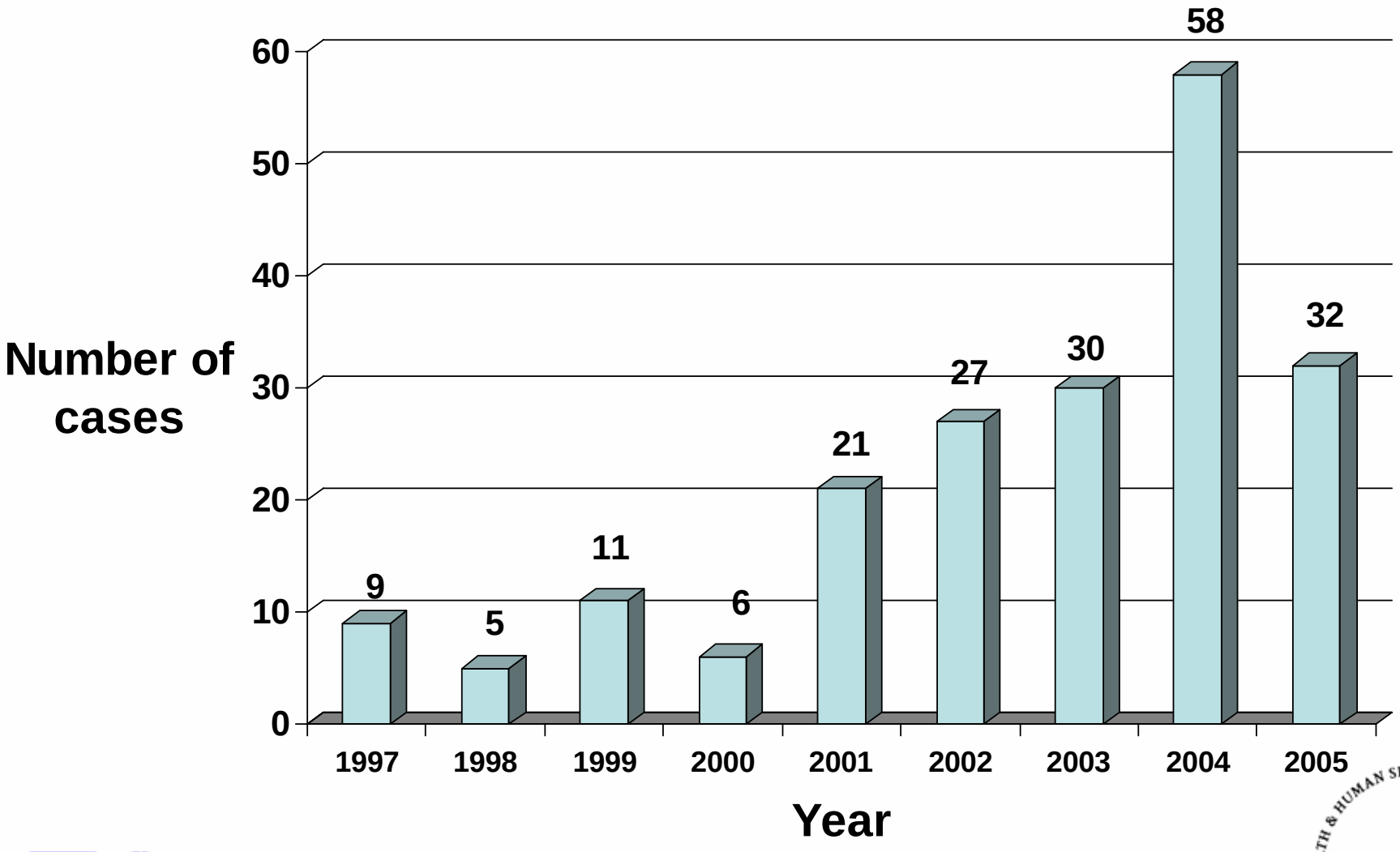
What is a Counterfeit Drug?

- U.S. law defines counterfeit drugs as those sold under a product name *without proper authorization*, where the identity of the *source is knowingly and intentionally mislabeled* in a way that *suggests* that it is the *authentic* approved product.

- Can apply to both brand name, generic products, or the bulk ingredients used to make the product.

- May include products without the active ingredient, with an insufficient quantity of the active ingredient, with the wrong active ingredient, or with fake packaging.

Counterfeit drug cases opened by FDA per fiscal year



Framework -- U.S. Action Plan

"Anti-counterfeiting strategy must be a multi-layered approach"

--FDA's 2004 Counterfeit Drug Task Force Report

- Secure:
  - ***product and packaging***
  - ***movement of drugs*** through the supply chain
  - ***business transactions***
- Ensure appropriate ***regulatory oversight and enforcement***
- Increase ***penalties***
- Heighten ***vigilance and awareness***
- International ***cooperation***

Secure the Product

Technology Based Approach

- **Implement track/trace technologies**
  - Relies on unique serial number on *each* drug package
  - RFID (radio frequency identification)
  - Barcodes
- **Use authentication/anti-counterfeiting technologies**
  - *Overt* - *e.g.,* holograms, color shifting ink, watermarks
  - *Covert – e.g.,* inks and dyes that fluoresce or absorb UV light, invisible bar codes, some watermarks
  - *Forensic – e.g.,* chemical markers, taggants, other unique chemical features of a substance

Secure the Movement of the Product

- **2004 FDA Task Force Report calls for adoption of electronic track and trace technology to produce an electronic pedigree**

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

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 approach using both paper and e-pedigree will be needed during a transition period.

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.

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.

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.

Electronic Track and Trace – Privacy Issues

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.**

- Privacy issues are a real concern
- Most statements made on labeling of prescription drugs are regulated by FDA and requires agency pre-approval. Therefore, manufacturers should work with FDA before choosing a statement or symbol to add to their product labeling.
- Appropriate disclosure of the presence of RFID tags
- Consumer education is necessary – application, true risks, benefits, vulnerabilities

Electronic Track and Trace – Privacy Issues

Privacy Issues – "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.**

- There are benefits to keeping the RFID tag "active" after sale and deactivating it before dispensing the product. An "active" tag can help to identify drug products that have found its way back into the drug supply chain and for recalls.
- It's unclear if technological methods to deactivate the tag are mature enough for use, and this area warrants further discussion.
- We respect the privacy concerns and do not believe that it is necessary for an "active" tag to go to the patient.

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 must remain vigilant in their responsibility to deliver safe/effective drugs to the patients**

For more information on FDA's Counterfeit Drug Initiative:

www.fda.gov/counterfeit/

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