



Private and Public Efforts to Combat Counterfeit Medicines: U.S. and WHO Initiatives

ILISA B.G. BERNSTEIN, Pharm.D., J.D.

Director of Pharmacy Affairs

U.S. Food and Drug Administration

AEI – The Global Impact of Fake Medicine

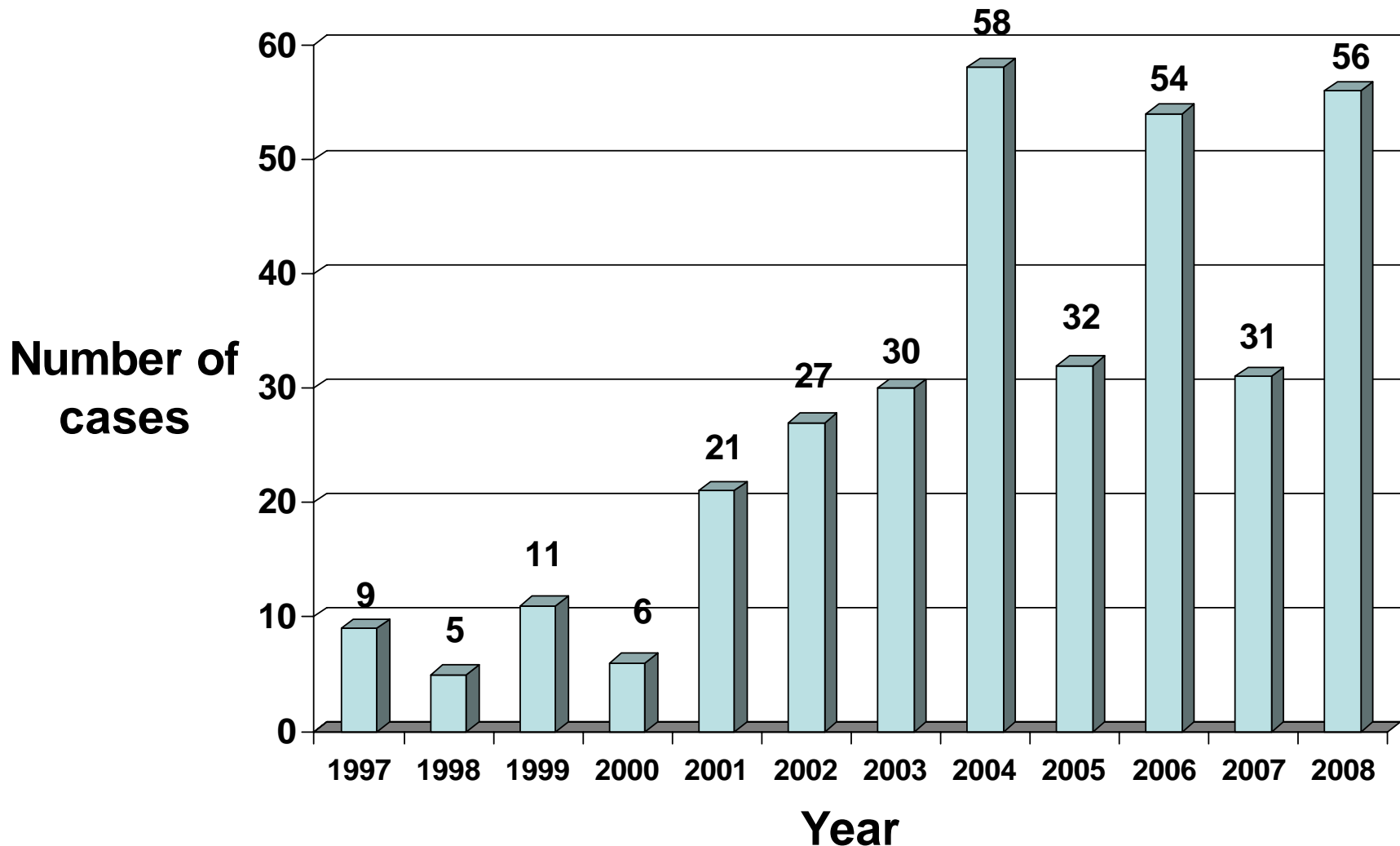
10 June 2009

Overview

- **U.S. Efforts**
 - Action Plan implementation
- **WHO International Medical Product Anti-Counterfeiting Task Force**



Counterfeit drug cases opened by FDA's Office of Criminal Investigations per fiscal year



Framework– U.S. Action Plan

“Anti-counterfeiting strategy must be a multi-layered approach”

- 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***
- Increase International ***collaboration***

Who is involved?

Supply Chain Stakeholders

- Manufacturers (legitimate)
- Wholesalers/Distributors
- Repackagers
- Dispenser
 - Pharmacy (retail/hospital)
 - Clinic
 - Doctor office
 - Long term care facility
 - Other outlets
- Others

Regulatory/Enforcement

- Drug regulatory authority (national/state)
- National/state/local police
- State/local health departments
- Other investigative authorities
- Dept of Justice
- CBP
- FBI
- ICE
- International components
- Judicial system

Securing the Product: What is the US supply chain doing?

- Anti-counterfeiting features
 - Manufacturers use for product packaging, labeling, product itself
 - Supply chain partnering on pilots
 - Manufacturers *exploring* mass serialization
 - RFID/2D barcodes
 - Standards development

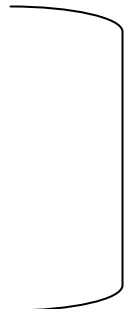
Secure the movement of drugs through the supply chain

- **Pedigree – documenting each sale or transaction of the product**
 - Knowledge of:
 - » Who had the product
 - » When they had the product
 - » How long they had the product
 - » Who they bought it from
 - » Who they sold it to
 - » Other information.....
- **Universal and Uniform Pedigree-- *ideal***
 - Identical format for all 50 states
 - Passed by all supply chain stakeholders
- **Electronic Pedigree -- *ideal***

Regulatory Tools

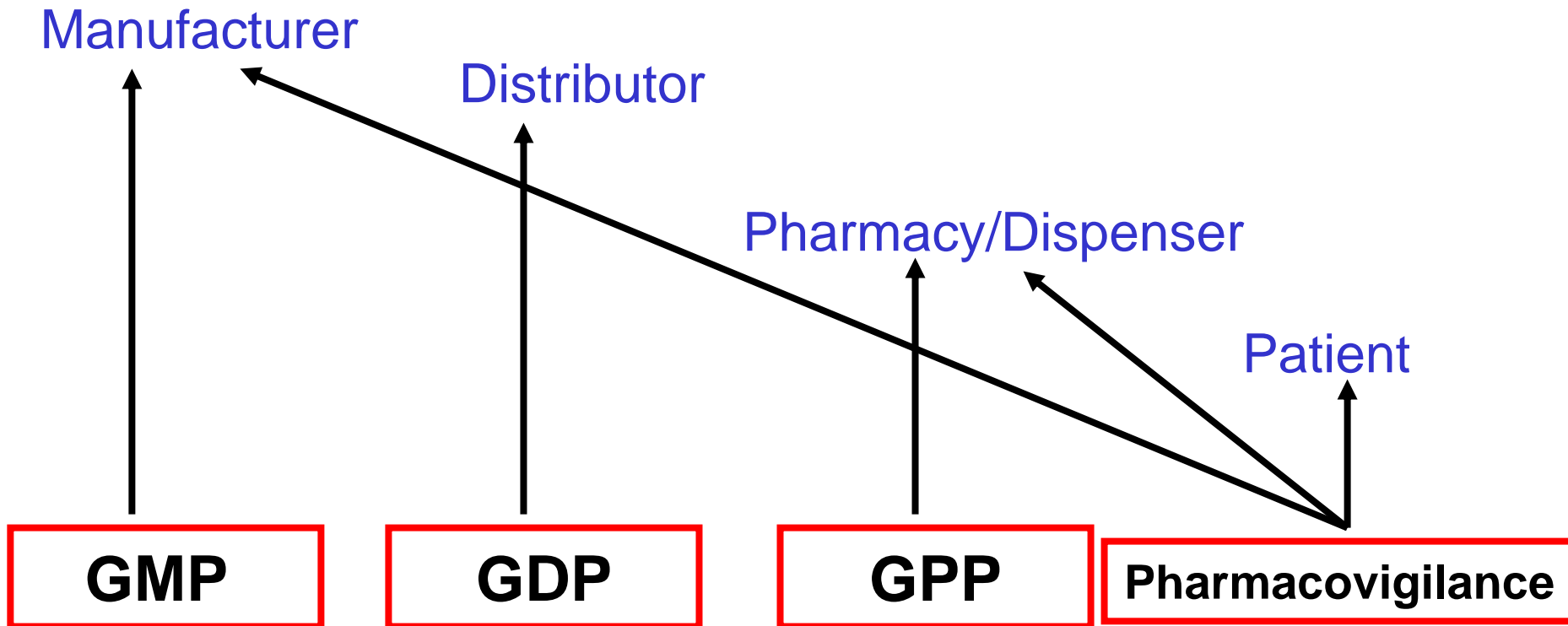
- **Pedigree laws**
 - Federal law – Prescription Drug Marketing Act
 - State laws
- **Food and Drug Administration Amendments Act of 2007 (FDAAA)**
 - Authority to develop standards for Drugs
 - Authority to develop standards for Unique Identifier for Devices
- **GxP's & Pharmacovigilance**
- **Supply Chain Security efforts**

FDA Standards Development (New section 505D of the Act)

- Secretary shall prioritize and develop standards for
 - Identification
 - Validation
 - Authentication
 - Tracking and Tracing
- 

Rx drugs
- Identification standard deadline: March 2010
 - FDA Draft Guidance on Standardized Numerical Identifier — published 1/2009
 - GS1 Standards
 - Consortiums

Building on GxP's & Pharmacovigilance





IMPACT

International **M**edical **P**roducts
Anti-**C**ounterfeiting **T**askforce



World Health Organization's (WHO) work in combating counterfeit medicines: Three-prong strategy

- **Providing tools, international norms, standards and guidelines** to assist in the assurance that drugs circulating in national and international commerce are safe, effective, and of good quality
- **Providing support to Member States** to build national regulatory capacity
- **Developing global activities** to combat counterfeit medicines

IMPACT Conceptual Framework

- **IMPACT** is a voluntary coalition of stakeholders that has the purpose of coordinating international activities aimed at combating counterfeit medical products;
- **IMPACT** stakeholders reflect the fact that combating counterfeiting of medical products cannot be successfully achieved by the health sector alone but requires coordinated effort and effective collaboration among health sector, enforcement, border control, justice (all at different administrative levels), as well as health professionals, manufacturers, importers, distributors, media, patients/consumers;
- **IMPACT** is led by WHO to keep focus on the public health implications of counterfeiting rather than on IPR-related aspects.
- **IMPACT** output include recommendations, policy advice, and reference and training materials that reflect consensus reached among IMPACT stakeholders.

How does IMPACT work?

- **Secretariat: WHO**
- **5 working groups, focusing on the areas where weaknesses have been identified and action needs to be taken at national and international level**
 - **Legislation and Regulatory Infrastructure Working Group**
 - **Regulatory Implementation Working Group**
 - **Enforcement Working Group**
 - **Communications Working Group**
 - **Technology Working Group**

Who are/should be IMPACT members?

All 193 WHO Member States and major international stakeholders, such as:



WHO IMPACT activities

- **Legislation Working Group**
 - Principles for Legislation for Medical Products.....Medical Devices
 - Definition
- **Regulatory Implementation Working Group**
 - GDP update
 - Develop regulatory toolkit
 - Rapid Response Guidance
 - more
- **Enforcement Working Group**
 - Training
 - Operations
- **Communications Working Group**
 - Communications Strategy
 - Video
- **Technology Working Group**
 - Survey of technology
 - Promote mobile technologies

IMPACT enforcement in action....

- In 2008, 3 operations... Asia, Africa, internet
- 350 agents from police, customs, regulatory bodies from over 51 countries received a training in : Cambodia, Italy, Kenya, Tanzania, Thailand, Uganda, Vietnam
- PFIPC Investigative Guide Manual translated into 4 languages and provided during IMPACT Enforcement trainings
- Coordinated effort between enforcement community and private sector representatives



IMPACT next steps

- World Health Assembly:
 - Counterfeit medical products was on the agenda for discussion at the 62nd WHA, but due to unforeseen circumstances, this issue, along with several others, were deferred to the next WHA.
- IMPACT continues to exist and is moving forward with it's agenda and work plan.



COMMENTS OR QUESTIONS???

THANK YOU!!!!

Ilisa Bernstein, PharmD, JD

ilisa.bernstein@fda.hhs.gov