

# Biological and Chemical Threats: FDA's Public Health Challenge

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# FDA Mission

To ensure the safety and effectiveness of drugs, biological products, medical devices, the food supply, cosmetics, and products that emit radiation.



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# FDA Priorities

## Strong FDA

- Personnel, processes, infrastructure
- Enhance availability of new technologies

## Risk Management

## Decrease Medical Errors and AEs

## Better informed constituents

## Counterterrorism



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# Countering Terrorism

**Goal: To Strengthen FDA's Capability to Prepare for and Respond to Terrorist Threats and Incidents to Mitigate the Public Health Impact**



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# Program Strategies

**Facilitate development and availability of medical countermeasures**

**Ensure food safety and security**

**Ensure safety and security of medical products**

**Enhance the Agency's emergency preparedness and response capabilities**

**Ensure the safety and security of FDA personnel, physical assets, and sensitive information**



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# **Facilitate Product Development and Availability**

**Identify gaps in medical countermeasures and gaps in knowledge needed to develop these**

**Foster the development of novel and existing products for use as medical countermeasures**

**Work with partners to facilitate the availability of an adequate inventory of products for emergency situations**



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# Facilitate Product Development and Availability

**Encourage discussion with FDA before submitting an Investigational New Drug Application (IND) (so-called “pre-IND meeting”)**

**Frequent interaction during IND process helps assure that the data needed to evaluate the effectiveness, safety, and quality of manufacture are collected**

**“Streamlined INDs” for more wide-spread use of an investigational product in a public health emergency**

**Fast track designation**



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# Facilitate Development and Availability

Tools to facilitate the approval of a new drug (NDA) or biological license application (BLA)

- Accelerated Approval – effectiveness based on surrogate endpoints likely to predict clinical benefit, but not yet established (confirmatory post-marketing studies needed)
- The “Animal Rule”- animal efficacy data in lieu of human data, when human efficacy trials not feasible or ethical



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# Recent Product Approvals and Development Efforts

## Smallpox

- Approval of license supplements led to availability of millions of doses of smallpox vaccine
- Efforts to facilitate development of new smallpox vaccines
- Efforts to facilitate development of immune globulins and drugs to treat complications of smallpox vaccination and smallpox



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# Recent Product Approvals and Development Efforts (cont.)

## Anthrax

Approval of license supplements led to availability of millions of doses of anthrax vaccine

Efforts to facilitate development of new anthrax vaccines and immune globulins

Drugs for post-exposure prophylaxis

- Ciprofloxacin: approval of supplement based on information submitted by manufacturer and USAMRIID
- Doxycycline, procaine penicillin G: FDA published finding of safety and efficacy for this indication



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# Recent Product Approvals and Development Efforts (cont.)

**AtroPen Autoinjector (atropine):** new dosage form approved for children and adolescents exposed to certain nerve agents and insecticides

**Pyridostigmine Tablets:** 1<sup>st</sup> product approved under Animal Rule – for prophylaxis against Soman nerve gas

**Thyrosafe (KI):** Approved to protect thyroid gland against radio-iodine



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# Ensuring food safety and security

**The systems in place to reduce foodborne pathogens are the same systems that will assist in preventing or responding to a terrorist attack**

**Rely on science-based approaches to solving public health problems**



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# FDA Activities: Food Safety

## Anticipate

- Threat Assessments
- Intelligence Gathering

## Deter

- Guidance to Industry
- Increased Focus on Imports
- Research Agenda
- Developing “Shields”



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# FDA Activities: Food Safety

## Respond

- Emergency Response
- Lab Capacity/Surge Capacity
- Informing the Public



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# Conclusions

**Proactively Facilitating Development of Medical Products and Devices**

**Increasing Vigilance in Food Safety and Security**

**The goal is to prepare for what is reasonably foreseeable and have the flexibility to respond swiftly and effectively to any public health crisis**



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