MEDICAL COUNTERMEASURES (MCMS)

FDA-REGULATED MEDICAL PRODUCTS

Medical countermeasures, or MCMs, are FDA-regulated products that may be used in a **PUBLIC HEALTH EMERGENCY** stemming from a terrorist attack with or accidental release of a biological, chemical, or radiological/nuclear agent, or a naturally occurring emerging infectious disease.

PREVENT, PROTECT AGAINST, TREAT OR **DIAGNOSE** DISEASES OR HEALTH EFFECTS CAUSED BY THREAT AGENTS

CHEMICAL
BIOLOGICAL
RADIOLOGICAL
NUCLEAR
& EMERGING INFECTIOUS DISEASES

EXAMPLES OF MCMS

BIOLOGIC PRODUCTS
- Vaccines
- Blood products
- Antibodies

DRUGS
- Antimicrobials
- Chemical threat antidotes
- Treatments for radiation injury

DEVICES
- Diagnostic tests
- Personal protective equipment (PPE)
  - Gloves
  - Respirators/certain masks
  - Gowns

EXAMPLES OF FDA'S MCM ROLES

1. **FDA assesses the safety & effectiveness of MCMs for FDA approval**

ACTIVITIES INCLUDE:
- Review evidence for approval
- Professional development
- Regulatory science
- Policy & legal support

- **GOVERNMENTS** (state, local, territorial, tribal, national, international)
- **DOMESTIC & INTERNATIONAL ORGANIZATIONS**
- **MEDICAL & SCIENTIFIC COMMUNITY**
- **INDUSTRY**

+ PHEMCE: Public Health Emergency Medical Countermeasures Enterprise (Federal agencies)

2. **FDA works with partners to advance development & availability of MCMs to prepare for & respond to emerging threats**

3. **FDA can issue Emergency Use Authorizations to enable to access MCMs prior to approval (or for unapproved uses)**

FDA also has other legal authorities to facilitate emergency access to MCMs

350+ MCMs
APPROVED SINCE 2012*

525+ EUAs
SINCE 2005
enabling access to **900+** MCMs

FDA MEDICAL COUNTERMEASURES INITIATIVE (MCMI)

MCMi is an FDA-wide initiative across FDA product centers (including CBER, CDER, and CDRH) and offices to coordinate MCM development, preparedness, and response, led by the Office of Counterterrorism and Emerging Threats, in the Office of the Chief Scientist.

LEARN MORE OR ASK US

www.fda.gov/medicalcountermeasures
AskMCMi@fda.hhs.gov

FDA U.S. FOOD & DRUG ADMINISTRATION

** Number includes approved MCMs listed in the MCMi annual program update in fiscal years 2012-2021*