



# WHAT ARE MEDICAL COUNTERMEASURES?

## 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.

## MCMs

PREVENT  
PROTECT AGAINST  
TREAT OR  
DIAGNOSE



DISEASES OR HEALTH EFFECTS CAUSED BY

# CBRN

THREAT AGENTS

CHEMICAL  
BIOLOGICAL  
RADIOLOGICAL  
NUCLEAR



EMERGING  
INFECTIOUS  
DISEASES

## EXAMPLES of MCMs

### BIOLOGIC PRODUCTS

- Vaccines
- Blood products
- Antibodies



### DEVICES

- Diagnostic tests
- Personal protective equipment (PPE)



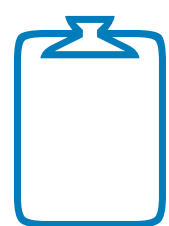
### DRUGS

- Antimicrobials
- Chemical threat antidotes
- Treatments for radiation injury



- Gloves
- Respirators/masks
- Gowns

## FDA's MCM ROLES [some examples]



FDA IS RESPONSIBLE FOR ASSESSING **SAFETY & EFFECTIVENESS** OF MCMs FOR FDA APPROVAL



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



FDA WORKS WITH PARTNERS TO ADVANCE **DEVELOPMENT & AVAILABILITY** OF MCMs

- Governments (state, local, territorial, tribal, national, international)
- Domestic & international organizations
- Medical & scientific community
- Industry

### + PHEMCE

Public Health Emergency  
Medical Countermeasures  
Enterprise (Federal agencies)

## TO PREPARE FOR & RESPOND TO EMERGING THREATS

# 121

**MCMs APPROVED**  
SINCE 2012\*

# 60+

**EUAs**  
SINCE 2005

FDA CAN ISSUE **EMERGENCY USE AUTHORIZATIONS** TO ENABLE **ACCESS** TO MCMs PRIOR TO APPROVAL (OR FOR UNAPPROVED USES)



FDA ALSO HAS OTHER LEGAL AUTHORITIES TO FACILITATE EMERGENCY ACCESS TO 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](http://www.fda.gov/medicalcountermeasures)

[AskMCMi@fda.hhs.gov](mailto:AskMCMi@fda.hhs.gov)



**U.S. FOOD & DRUG**  
ADMINISTRATION

\*Number includes approved MCMs listed in the MCMi annual program update in fiscal years 2012-2017