



Medical Countermeasures Initiative Strategic Plan 2012 - 2016



**US Department of Health and Human Services
Food and Drug Administration**

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Message from the Commissioner

The US Food and Drug Administration plays a vital role in protecting our nation from chemical, biological, radiological, and nuclear threats, and from emerging infectious diseases. It is FDA's responsibility to ensure that medical countermeasures—such as drugs, vaccines, and diagnostic tests—to counter these threats are safe, effective, and secure. FDA works closely with our partners through the US Department of Health and Human Services' Public Health Emergency Medical Countermeasures Enterprise (Enterprise) to build and sustain the medical countermeasure programs necessary to respond to a public health emergency.

In August 2010, FDA rolled out its Medical Countermeasures Initiative (MCMi), which is intended to build on existing FDA medical countermeasure programs, with a goal of refocusing and strengthening FDA activities. We developed the MCMi as part of a comprehensive, yearlong review of the Enterprise, ordered by HHS Secretary Sebelius, to assess the United States' readiness to reduce the impact of a future public health emergency and improve our nation's capacity to respond quickly and effectively to these threats as mandated by President Obama.

The MCMi is designed to address key challenges in three areas: (1) enhancing the regulatory review process for the highest priority medical countermeasures and related technologies; (2) advancing regulatory science for medical countermeasure development; and (3) modernizing our regulatory and legal framework. This document describes FDA's strategic goals and key objectives for implementing the MCMi and addressing these challenges.

Achieving our medical countermeasures mission is critical for the health and security of our nation. At FDA, we recognize that our active engagement in the Enterprise is essential to developing the next generation of medical countermeasures that will be needed to protect the nation's health and security. We recognize that achieving our mission is a long-term proposition that will require a significant and continued investment of resources and a solid commitment of our leadership to what is a broadly shared responsibility.

The dedicated professionals at FDA, and those across the Enterprise, are deeply committed to succeeding. I believe FDA is uniquely equipped and positioned to contribute to the success of this effort to significantly strengthen national and global health and security.

Margaret A. Hamburg, M.D.
Commissioner of Food and Drugs
December 2011



Executive Summary

Developing medical countermeasures—including drugs and biological products, medical devices, and other medical equipment—that will be needed to protect the nation from public health emergencies involving chemical, biological, radiological, nuclear (CBRN) threats and emerging infectious diseases (EID), such as pandemic influenza, is critical to advancing the health, security, and well-being of the American people.

The US Food and Drug Administration’s Medical Countermeasures Initiative (MCMi), launched in August 2010, builds upon the substantial work ongoing at FDA to ensure that the nation has the necessary medical countermeasures to protect the nation from identified, high-priority CBRN and EID threats and to develop the capabilities necessary to produce medical countermeasures quickly in response to new or unanticipated threats.

The MCMi mission is to promote the development of medical countermeasures by enhancing FDA’s regulatory processes and fostering the establishment of clear regulatory pathways for medical countermeasures, and to facilitate the timely access to available medical countermeasures by establishing effective regulatory policies and mechanisms.

The MCMi is based on a three pillar strategy that integrates ongoing FDA medical countermeasure efforts with new initiatives as needed:

- **Pillar I** – enhancing the regulatory review processes for the highest priority medical countermeasures and related technologies
- **Pillar II** – advancing regulatory science for medical countermeasure development and evaluation
- **Pillar III** – modernizing the legal, regulatory, and policy framework for effective public health response

This document sets forth the strategic goals and key objectives that FDA will pursue through 2016 to build and sustain the programs needed to achieve the MCMi mission. FDA’s MCMi strategic goals include:

- **Goal 1:** Develop and maintain the highly qualified workforce with appropriate technical training, scientific skill, and subject-matter expertise, and improve infrastructure at FDA (e.g.,

information technology, laboratory equipment) so that the MCMi workforce has the tools required to succeed

- **Goal 2:** Build and sustain the integrated, coordinated programs necessary to ensure that the MCMi reflects medical countermeasure priorities and objectives and that MCMi programs are sufficiently resourced and aligned to fulfill MCMi program initiatives
- **Goal 3:** Engage MCMi stakeholders to foster effective collaboration, solicit input and feedback, improve program implementation, and maximize the transparency of programs and priorities
- **Goal 4:** Integrate MCMi programs to foster effective preparedness, planning, and response capabilities
- **Goal 5:** Establish and support Public Health and Security Action Teams to support development of high-priority candidate medical countermeasure products, product classes, and critical medical countermeasure technologies
- **Goal 6:** Establish and sustain a medical countermeasures regulatory science program to develop solutions to complex regulatory challenges and facilitate the incorporation of new, cutting edge science into the regulatory review process to speed product development
- **Goal 7:** Modernize the legal, regulatory, and policy environment to adequately support preparedness for and response to CBRN and EID threats with medical countermeasures.

FDA's MCMi is vital to our national security and will help protect the nation from potentially catastrophic CBRN and EID threats. Investments in the MCMi not only will create opportunities to improve overall public health, advance medical countermeasure development, and contribute to the development of products to treat other diseases and conditions, but also improve the safety, efficacy, and access to FDA-regulated medical products while reducing costs. The MCMi is clearly a timely and critical investment that will pay dividends far into the future of our nation.

CONTENTS

MESSAGE FROM THE COMMISSIONER	III
EXECUTIVE SUMMARY.....	VI
INTRODUCTION.....	1
CBRN AND EID THREATS	2
ROLE OF 21 ST -CENTURY REGULATORY SCIENCE IN ADDRESSING CBRN AND EID THREATS	6
MCMi ACTION PLAN	10
MCMi STRATEGIC GOALS AND KEY OBJECTIVES	12
IMPLEMENTATION	21
CONCLUSION	21
APPENDIX A: MEDICAL COUNTERMEASURES INITIATIVE ORGANIZATION.....	23
APPENDIX B: ALIGNMENTS AND LINKAGES	31
APPENDIX C: SUMMARY OF MCMi STRATEGIC GOALS AND KEY OBJECTIVES.....	34
APPENDIX D: CROSSWALK OF FDA STRATEGIC GOALS AND LONG-TERM OBJECTIVES WITH MCMi STRATEGIC GOALS AND KEY OBJECTIVES	35
APPENDIX E: ACRONYMS.....	37

Introduction

The world faces serious threats from chemical, biological, radiological, and nuclear (CBRN) threats and emerging infectious diseases (EIDs). These threats directly challenge national and international security, owing to the potential for massive loss of life as well as untold social, political, and economic disruption.

The US Department of Health and Human Services (HHS) has the mission to protect the US civilian population from CBRN threats and EIDs by providing leadership in the research, development, regulation, procurement, stockpiling, maintenance, deployment, and utilization of medical countermeasures.¹ HHS is pursuing a unified, integrated approach to its mission through the Public Health Emergency Medical Countermeasures Enterprise (PHEMCE or Enterprise), a coordinated, interagency partnership² that fosters the medical countermeasure programs necessary to improve public health emergency preparedness as well as to prevent and mitigate the adverse health consequences associated with CBRN threats and EIDs. The US Food and Drug Administration (FDA) is one of three primary HHS agencies included in the Enterprise. FDA supports the medical countermeasure mission by providing subject matter expertise in the areas of product development with a goal towards FDA approval³ as well as to other Enterprise activities, including ensuring timely access to medical countermeasures.

The HHS Secretary's 2010 *Enterprise Review* called on FDA to take an even more active role in fostering the development and facilitating the

¹ Medical countermeasures include qualified countermeasures as defined in section 319F-1(a)(2) of the Public Health Service Act (42 U.S.C. § 247d-6a(a)(2)); qualified pandemic or epidemic products as defined in section 319F-3(i)(7) of the Public Health Service Act (42 U.S.C. § 247d-6d(i)(7)), and security countermeasures as defined in section 319F-2(c)(1)(B) of the Public Health Service Act (42 U.S.C. § 247d-6b(c)(1)(B)).

² The Enterprise is led by the Office of the Assistant Secretary of Preparedness and Response and includes three primary HHS internal agencies: the Centers for Disease Control and Prevention (CDC), the Food and Drug Administration (FDA), and the National Institutes of Health (NIH). Key interagency partners are the Department of Homeland Security, the Department of Defense, the Department of Veterans Affairs, and the Department of Agriculture. See Public Health Emergency Medical Countermeasures Enterprise (PHEMCE) Management. Washington, DC: US Department of Health and Human Services. Available at <https://www.medicalcountermeasures.gov/BARDA/PHEMCE/phemce.aspx>. Accessed April 13, 2011.

³ For purposes of this document, the term "approval" refers to FDA-approval, licensure, or clearance under sections 505, 510(k), or 515 of the Federal Food, Drug, and Cosmetic Act or section 351 of the Public Health Service Act.

deployment of medical countermeasures.⁴ As a result, FDA launched its Medical Countermeasures Initiative (MCMi). This document presents FDA's *Medical Countermeasures Initiative Strategic Plan 2012 – 2016* and establishes the strategic goals and key objectives FDA will pursue to foster innovative, science-based regulatory oversight and to help build the critically needed scientific infrastructure and capacity to ensure that the nation has the ability to effectively develop, stockpile, deploy, use, and sustain the medical countermeasures required to protect the nation from CBRN and EID threats. The *MCMi Strategic Plan* is guided by and complements strategic- and operational-level planning for CBRN and EID threats across departments and agencies at the executive level, the White House, and the legislative branch (see Appendix B).

CBRN and EID Threats

“Over the coming years, [the United States] will continue to face a substantial threat...from terrorists attempting to acquire biological, chemical, and possibly nuclear weapons and use them to conduct large-scale attacks.”

The US intelligence community assesses that CBRN weapons and EIDs present real, substantial, and growing threats to the national security of the United States and will continue to do so for the foreseeable future.⁵

The United States faces CBRN threats from both state and non-state actors. The March 2011 unclassified annual threat assessment from the US intelligence community states that, “...many of the countries pursuing [weapons of mass destruction] programs will continue to try to improve their capabilities and level of self-sufficiency over the next decade. Nuclear, chemical, and/or biological weapons—or the production technologies and materials necessary to produce them—also may be acquired by states that do not now have such programs. Terrorist or insurgent organizations acting alone or through middlemen may acquire nuclear, chemical, and/or biological weapons and may seek opportunistic networks as service providers.”⁶ In 2009, the US intelligence community assessed that “[o]ver the coming years, [the United States] will continue to face a substantial threat, including in the US Homeland, from terrorists

⁴ *The Public Health Emergency Medical Countermeasures Enterprise Review – Transforming the Enterprise to Meet Long-Range National Needs*. Washington, DC: US Department of Health and Human Services. August 2010. Available at: <https://www.medicalcountermeasures.gov/media/1138/mcmreviewfinalcover-508.pdf>. Accessed April 5, 2011.

⁵ Clapper, J.R. Statement for the Record on the Worldwide Threat Assessment of the US Intelligence Community for the House Senate Committee on Armed Services. *Annual Hearing to Receive Testimony on the Current and Future Worldwide Threats to the National Security of the United States*, Hearing, March 10, 2011. Available at: http://www.dni.gov/testimonies/20110310_testimony_clapper.pdf; Accessed: March 31, 2011.

⁶ *Ibid.* 5, pg. 5.

attempting to acquire biological, chemical, and possibly nuclear weapons and use them to conduct large-scale attacks.”⁷

“Traditionally biological, chemical, or nuclear weapon use by most nation states has been constrained by deterrence and diplomacy, but these constraints may be of less utility in preventing the use of these weapons by terrorist groups. Moreover... Biological and chemical materials and technologies...move easily in our globalized economy, as do the personnel with scientific expertise designing and using them.”

The US intelligence community’s 2011 threat assessment notes that “[t]raditionally biological, chemical, or nuclear weapon use by most nation states has been constrained by deterrence and diplomacy, but these constraints may be of less utility in preventing the use of these weapons by terrorist groups. Moreover, the time when only a few states had access to the most dangerous technologies is well past. Biological and chemical materials and technologies, almost always dual-use, move easily in our globalized economy, as do the personnel with scientific expertise [in] designing and using them. The latest discoveries in the life sciences also diffuse globally with astonishing rapidity.”⁸ The 2009 US intelligence community assessment stressed that “[i]n particular...the terrorist use of biological agents represents a growing threat as the barriers to obtaining many suitable starter cultures are eroding and open source technical literature and basic laboratory equipment can facilitate production.”⁹

This assessment is in alignment with myriad strategic-level threat assessments including by the National Intelligence Council, which reported in November 2008 that “[f]or those terrorist groups that are active in 2025, the diffusion of technologies and scientific knowledge will place some of the world’s most dangerous capabilities within their reach. One of our greatest concerns continues to be that terrorist or other malevolent groups might acquire and employ biological agents, or less likely, a nuclear device, to create mass casualties”¹⁰; the Commission on the Prevention of Weapons of Mass Destruction Proliferation and Terrorism which reported in December 2008 that “terrorists are more likely to be able to obtain and use a biological weapon than a nuclear weapon”¹¹; and the National Security Council, which reported in November 2009 that “...(1) the risk [posed by biological threats] is evolving in unpredictable ways; (2) advances in the enabling technologies will continue to be globally available; and (3) the ability to exploit such

⁷ Blair, D. Testimony before the Armed Services Committee, United States Senate. *Annual Threat Assessment of the Intelligence Community*, Hearing, March 10, 2009. Available at: http://www.dni.gov/testimonies/20090310_testimony.pdf. Accessed March 31, 2011.

⁸ *Ibid.* 5, pg. 5.

⁹ *Ibid.* 7, pg. 21.

¹⁰ *Global Trends 2025: A Transformed World* (NIC 2008-003). Washington, DC: National Intelligence Council; November 2008. Available at: http://www.dni.gov/nic/PDF_2025/2025_Global_Trends_Final_Report.pdf. Accessed March 31, 2011.

¹¹ *World at Risk*. Washington, DC: Commission on the Prevention of Weapons of Mass Destruction Proliferation and Terrorism; December 2008. Available at: <http://documents.scribd.com/docs/15bq1nrl9aerfu0yu9qd.pdf>. Accessed March 31, 2011.

advances will become increasingly accessible to those with ill intent as the barriers of technical expertise and monetary costs decline.”¹²

“...for the foreseeable future [infectious diseases] will remain the top health-related threat to US national security...”

With respect to the threat posed by EIDs,¹³ in 2008 the National Intelligence Council assessed that although numerous infectious and noninfectious health conditions can potentially impact US strategic interests, “...for the foreseeable future [infectious diseases] will remain the top health-related threat to US national security...” and notes that the US population “...will continue to be vulnerable to [EIDs]—many of which will originate overseas (e.g., HIV/AIDS, West Nile, and dengue fever)—including a potential influenza pandemic or an outbreak of a “mystery” disease (e.g., SARS.)”¹⁴

Beyond the direct potential health effects to the US population, infectious diseases also threaten the health and well-being of the global population, can slow socioeconomic development, and disrupt domestic stability and security abroad, potentially challenging the legitimacy of governments and creating significant security risks on both regional and global levels.^{15, 16} These risks can ultimately affect the United States’ ability to protect the health of US forces and personnel, compromising our ability to deploy US assets abroad, impede our ability to coordinate US/international response efforts to global crises, and precipitate diplomatic frictions between the United States and other countries, ultimately impairing our ability to pursue US strategic objectives.^{17, 18}

“...health issues can suddenly emerge from anywhere in the globe and threaten American lives and US strategic objectives.”

Although the threats posed by CBRN agents and EIDs are significant and growing, there is considerable uncertainty associated with managing the risks posed by these threats. The 2010 annual threat assessment from the US Intelligence Community notes that the “... [2009 H1N1] influenza

¹²*National Strategy for Countering Biological Threats*. Washington, DC: White House, National Security Council. November, 2009. Available at: http://www.whitehouse.gov/sites/default/files/National_Strategy_for_Countering_BioThreats.pdf. Accessed March 31, 2009.

¹³ Emerging infectious diseases include “newly-emerging” infectious diseases (i.e., infectious diseases that newly appear in a population that heretofore had not been recognized in humans) and “re-emerging” infectious diseases (i.e., infectious diseases that have been recognized in humans but are increasing in incidence or geographic range). See: Morens DM, Folkers GK, Fauci AS. The challenge of emerging and re-emerging infectious diseases. *Nature*. 2004 Jul 8;430(6996):242-9.

¹⁴ *Strategic Implications of Global Health (ICA 2008-10D)*. Washington, DC: National Intelligence Council; December 2008. Available at: http://www.dni.gov/nic/PDF_GIF_otherprod/ICA_Global_Health_2008.pdf. Accessed March 31, 2011. Note: this study was “limited to examination of naturally occurring health phenomena, leaving the issues of bioterrorism and biowarfare for separate study”

¹⁵ *Ibid.* 5, pg. 31-32.

¹⁶ *Ibid.* 14, pg. 16.

¹⁷ *Ibid.* 5, pg. 31-32.

¹⁸ *Ibid.* 14. pg. 16.

“It is unlikely that any country will be able to detect cases early enough to prevent the spread of another new, highly transmissible virus should one emerge during the next five years...”

pandemic is the most visible reminder that health issues can suddenly emerge from anywhere in the globe and threaten American lives and US strategic objectives.”¹⁹ The emergence/re-emergence of infectious diseases is the outcome of a complex and dynamic interaction among multiple factors including biological, social, demographic, geographic, ecological, political, and economic factors (e.g., microbial adaptation, human susceptibility, urbanization, climate/weather, land use, travel, commerce, poverty, war, famine).²⁰ When and where the next infectious disease will emerge or re-emerge is extremely difficult to ascertain. In March 2011, the US intelligence community assessed that “[i]t is unlikely that any country will be able to detect cases early enough to prevent the spread of another new, highly transmissible virus should one emerge during the next five years...”²¹ And CBRN threats arguably pose greater uncertainty than EIDS, owing to the potential for their intentional use. Potential adversaries of the United States who are suspected of pursuing or possessing CBRN weapons are difficult to identify and gather information on, and CBRN weapons research, development, and production is difficult to detect or discern from legitimate research and development.²² It is difficult to gain insight into the specific intentions and capabilities of declared or potential aggressors who seek to maintain secrecy so as to prevent preemptive strikes and to achieve a tactical and strategic advantage. This makes it difficult to identify in advance when, where, and how a declared or potential adversary will make a CBRN weapons breakthrough or attack the United States with CBRN weapons. In addition, the CBRN threat is continually evolving in unpredictable ways as technology advances and intelligent adversaries adjust their strategies and tactics in response to US risk-reduction initiatives and perceived US vulnerabilities. Thus, predicting the likelihood of a CBRN attack based on estimating the specific intentions and capabilities of declared or potential aggressors in a way that is both accurate and actionable is extremely challenging, and advance warning of a CBRN attack is unlikely.

¹⁹ Blair, D. Testimony before the Senate Select Committee on Intelligence, United States Senate. Annual Threat Assessment of the Intelligence Community, Hearing, February 2, 2010. Available at: http://www.dni.gov/testimonies/20100202_testimony.pdf. Accessed April 1, 2011.

²⁰ Morens DM, Folkers GK, Fauci AS. The challenge of emerging and re-emerging infectious diseases. *Nature*. 2004 Jul 8;430(6996):242-9.

²¹ *Ibid.* 5, pg. 32.

²² *The Commission on the Intelligence Capabilities of the United States Regarding Weapons of Mass Destruction - Report to the President of the United States*. Washington, DC: Commission on the Intelligence Capabilities of the United States Regarding Weapons of Mass Destruction. March 31, 2005. Available at: http://govinfo.library.unt.edu/wmd/report/wmd_report.pdf. Accessed April 4, 2011.

Role of 21st-Century Regulatory Science in Addressing CBRN and EID Threats

HHS pursues an integrated, interagency, and multinational strategy to address the challenges presented by the diverse CBRN and EID threat spectrum as articulated in the 2009 *National Health Security Strategy* (NHSS).²³ This effort is part of the US government’s “whole of government” approach to protecting and improving the security of the United States, its citizens, and US allies/partners by integrating all elements of US power into addressing 21st century threats as described in the 2010 *National Security Strategy*.²⁴

The NHSS details 10 strategic objectives that “...describe what must be accomplished to address current gaps in national health security over the next four years and to sustain improvements in health security over the longer term.”²⁵ One of those strategic objectives is to promote an effective medical countermeasures enterprise. Medical countermeasure programs work in conjunction with efforts to prevent the development and deployment of CBRN weapons to serve as an overall deterrent to their development and use by making it more difficult to conduct a successful CBRN attack and reducing the anticipated rewards of such an attack.²⁶ In addition, should deterrence efforts fail and a CBRN attack occur, medical countermeasure programs will help mitigate the morbidity and mortality (and attendant economic consequences) of an attack, thus fostering resilience and recovery.²⁷

²³ *National Health Security Strategy of the United States of America*. Washington, DC: US Department of Health and Human Services. December 2009. Available at: <http://www.phe.gov/Preparedness/planning/authority/nhss/strategy/Documents/nhss-final.pdf>. Accessed April 4, 2011.

²⁴ *National Security Strategy*. Washington, DC: White House. May 2010. Available at: http://www.whitehouse.gov/sites/default/files/rss_viewer/national_security_strategy.pdf. Accessed April 4, 2011.

²⁵ *Ibid.* 23, pg. 4.

²⁶ For example, the National Strategy for Countering Biological Threats states that: “Ensuring that communities can quickly and effectively respond to large outbreaks of infectious disease in a manner that greatly reduces their impact is among the most effective ways to deter a deliberate attack...” *Ibid.* 12, pg. 6.

²⁷ “Mitigating illness and preventing death are the principal goals of [the United States’] medical countermeasure efforts” with respect to CBRN threats. See HSPD 18: Medical Countermeasures against Weapons of Mass Destruction. Washington, DC: White House. January 31, 2007. Available at: http://www.dhs.gov/xabout/laws/gc_1219175362551.shtm#1. Accessed April 4, 2011.

“...we are launching a new initiative that will give [the United States] the capacity to respond faster and more effectively to bioterrorism or an infectious disease – a plan that will counter threats at home, and strengthen public health abroad.”

“...we want to create a system that can respond to any threat at any time. The kind of system that is so dependable and comprehensive that it deters potential bioterrorism attacks...”

With EIDs, medical countermeasure programs have the potential to greatly limit the resultant morbidity and mortality (and attendant economic consequences) of these types of threats to the US population, fostering resilience and recovery. Furthermore, medical countermeasures can “...help advance economic development, foster diplomacy, and improve overall health worldwide...”, which can help strengthen US national security by improving the US ability to pursue strategic objectives abroad – for example by supporting humanitarian relief and medical diplomacy efforts and facilitating development among partner nations and regions.²⁸

Recognizing that CBRN and EID threats will continue to evolve in unpredictable ways and that the nation needs to continue to improve its ability to address these threats, President Obama announced in his 2010 State of the Union Address that the US government would be “...launching a new initiative that will give [the United States] the capacity to respond faster and more effectively to bioterrorism or an infectious disease—a plan that will counter threats at home, and strengthen public health abroad.”²⁹ The first step in this initiative was a comprehensive review of the Enterprise. In calling for the review, HHS Secretary Sebelius noted that “[t]he ultimate goal...is a modernized countermeasure production process where we have more promising discoveries, more advanced development, more robust manufacturing, better stockpiling, and more advanced distribution practices. In other words, we want to create a system that can respond to any threat at any time. The kind of system that is so dependable and comprehensive that it deters potential bioterrorism attacks and makes our enemies say, “It’s not worth the effort.””³⁰

The *Enterprise Review*—released in August 2010—laid out a vision for the Enterprise that shifts from a strategy focused largely on responding to known threats to one that pursues a “... flexible capacity to produce [medical countermeasures] rapidly in the face of any attack or threat, known or unknown, including a novel, previously unrecognized naturally occurring emerging infectious disease.”³¹ The *Enterprise Review* revealed that the current regulatory framework and the unmet need for regulatory science present real and perceived barriers for developers who are

²⁸ *Ibid.* 14, pg. 7.

²⁹ Obama, B. *Remarks by the President in State of the Union Address*. Washington, DC: White House. January 27, 2010. Available at <http://www.whitehouse.gov/the-press-office/remarks-president-state-union-address>. Accessed April 5, 2011.

³⁰ Sebelius, K. Speech before the American Medical Association Third National Congress on Health System Readiness. Washington, DC: US Department of Health and Human Services; December 1, 2009. <http://www.hhs.gov/secretary/speeches/sp20091201.html>. Accessed April 5, 2011.

³¹ *Ibid.* 4. pg. 6.

interested in developing medical countermeasures.^{32,33} Regulatory uncertainties associated with medical countermeasure development—largely driven by gaps in scientific knowledge—are among the most important challenges to medical countermeasure regulatory assessment and, thus, approval. This is especially so for novel medical countermeasures for which there may not be a clear development pathway, contributing to what developers perceive as a higher than typical risk environment for engaging in medical countermeasure development. Reducing regulatory uncertainty is one of the most important challenges that the US government must successfully address if it is to achieve the vision laid out in the *Enterprise Review*.

“FDA is critical to the success of the enterprise, as it oversees, from a regulatory standpoint, the entire evaluation process of [medical countermeasures]...”

The *Enterprise Review* recommends a series of new infrastructure initiatives and enhancements to the Enterprise that provide a strategy for transforming the medical countermeasure Enterprise.³⁴ Among the new infrastructure initiatives is “21st-Century Regulatory Science,” which the *Enterprise Review* deems “...a lynchpin to success of the enterprise.”³⁵ Indeed, the *Enterprise Review* notes that “...FDA is critical to the success of the [medical countermeasure] enterprise...” because FDA actions and guidance—from defining regulatory pathways to evaluating the safety, efficacy, quality, and manufacturing control of medical countermeasures—span the medical countermeasure lifecycle, from early development to deployment and use.³⁶ FDA evaluation of product safety and efficacy significantly affects the course of medical countermeasure development and approval. In addition, FDA involvement is crucial to developing medical countermeasures for inclusion in the Strategic National Stockpile and—should it be needed—moving quickly to authorize the circumscribed use of medical

³² *Ibid.* 4, pg. 8.

³³ The Enterprise Review was supported by the National Biodefense Science Board (NBSB) and the Institute of Medicine (IOM), both of whom held independent workshops to provide HHS with analyses of the challenges confronting the Enterprise and recommendations for addressing those challenges. Consistently at the forefront of the challenges identified by the NBSB and IOM was regulatory uncertainty and the NBSB and IOM both identified the need for increased involvement of the FDA in the Enterprise. See: (1) *Where are the Countermeasures? Protecting America's Health from CBRN Threats – A Report of the National Biodefense Science Board*. Washington, DC: National Biodefense Science Board. March 2010. Available at <http://www.phe.gov/Preparedness/legal/boards/nbsb/meetings/Documents/nbsb-mcmreport.pdf>. Accessed April 5, 2011; and (2) *The Public Health Emergency Medical Countermeasures Enterprise – Workshop Summary*. Washington, DC: Institute of Medicine. April 8, 2010. Available at <http://iom.edu/Reports/2010/The-Public-Health-Emergency-Medical-Countermeasures-Enterprise.aspx>. Accessed April 5, 2011.

³⁴ *Ibid.* 4, pg. 10-16. The recommended new infrastructure initiatives are 21st-Century Regulatory Science, Flexible Manufacturing and Advanced Development Core Services Partnerships, Expanding the Product Pipeline and Addressing Multiuse Potential, and an Independent Strategic Investment Firm for Innovation in Medical Countermeasures

³⁵ *Ibid.* 4, pg. 7.

³⁶ *Ibid.* 4, pg. 10.

countermeasures in an emergency—even if the product is not yet approved for that particular use.³⁷

The *21st-Century Regulatory Science* initiative as described in the *Enterprise Review* will help to accelerate medical countermeasure development and enhance the probability of approval by increasing resources at FDA to do a number of things, including: (1) step up FDA’s engagement in medical countermeasure development from the earliest steps in the process; (2) foster the establishment of clear, scientifically supported regulatory pathways for medical countermeasures; (3) identify and help to fill critical scientific gaps that often derail medical countermeasure development; and (4) facilitate the efficient use of available medical countermeasures by working to establish supportive legislative and regulatory policies and mechanisms. Advances in regulatory science will facilitate all of these efforts.

Advancing regulatory science and innovation—along with advancing medical countermeasures and emergency preparedness—is a cross-cutting strategic priority for FDA.³⁸ In 2010 FDA launched its Advancing Regulatory Science (ARS) Initiative, including enhanced collaboration and joint grant-making with the National Institutes of Health, to accelerate the translation of scientific breakthroughs into new, innovative medical therapies.³⁹ Regulatory science involves the focused development of new tools (or new uses for old tools), standards, and approaches to foster more efficient development of medical products and facilitate and ensure the evaluation of product safety, efficacy, quality, and performance.⁴⁰ Facilitating the development of medical countermeasures to protect against EID and CBRN threats is one of the major priorities of the FDA ARS Initiative. Anticipated outcomes of the ARS Initiative include strengthening advances in the biomedical sciences and more effectively translating cutting-edge developments in science and technology into

³⁷ Under the Project BioShield Act of 2004 [PL 108-276], the Secretary of HHS has the authority to authorize the “emergency use” of medical countermeasure in emergencies under certain terms and conditions [Section 564 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. § 360bbb-3)]

³⁸ *United States Food and Drug Administration Strategic Priorities 2011-2015 – Responding to the Public Health Challenges of the 21st Century*. Washington, DC: US Food and Drug Administration. April 20, 2011. Available at <http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Reports/UCM252092.pdf>. Accessed April 20, 2011.

³⁹ NIH and FDA Announce Collaborative Initiative to Fast-Track Innovations to the Public [FDA – NIH News Release]. Washington, DC: US Food and Drug Administration. Available at <http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/2010/ucm201706.htm>. Accessed April 6, 2011.

⁴⁰ Advancing Regulatory Science at FDA. Washington, DC: US Food and Drug Administration. August 2011. Available at: <http://www.fda.gov/downloads/ScienceResearch/SpecialTopics/RegulatoryScience/UCM268225.pdf>. Accessed August 19, 2011.

products; fostering prevention as well as response; and increasing the accuracy and efficiency of FDA regulatory review, which can reduce adverse events, improve access to FDA-regulated products, and reduce medical product development costs.⁴¹

MCMi Action Plan

The MCMi implements the Enterprise Review's call for a 21st-Century Regulatory Science initiative; it builds on the substantive medical countermeasures work ongoing at FDA.

FDA launched its Medical Countermeasures Initiative (MCMi) in August 2010.⁴² The MCMi implements the *Enterprise Review's* call for a 21st Century Regulatory Science initiative; it builds on the substantive medical countermeasures work ongoing at FDA and serves as a complementary, stand-alone component of FDA's overarching ARS Initiative.

The MCMi mission is to promote the development of medical countermeasures by enhancing FDA's regulatory processes and fostering the establishment of clear regulatory pathways for medical countermeasures, and to facilitate the timely access to available medical countermeasures by establishing effective regulatory policies and mechanisms.

FDA has organized the MCMi around an Action Plan built on a three pillar strategy that integrates ongoing FDA medical countermeasure efforts with new initiatives—as needed.

The Office of Counterterrorism and Emerging Threats (OCET), within FDA's Office of the Chief Scientist (OCS), provides overall strategic leadership and coordination for this agency-wide effort. OCET works in close partnership with FDA's three medical product centers— Center for Biologics Evaluation and Research (CBER), Center for Drug Evaluation and Research (CDER), and Center for Devices and Radiological Health (CDRH)—as well as the Office of Regulatory Affairs (ORA) to coordinate the MCMi. FDA has organized the MCMi around an Action Plan built on a three-pillar strategy that integrates ongoing FDA medical countermeasure efforts with new initiatives—as needed—based on the expected outcomes and elements of the 21st-Century Regulatory Science initiative as described in the *Enterprise Review* (see Appendix A).⁴³

- **Pillar I: Enhance the Medical Countermeasure Regulatory Review Process**—Goal: to advance the development of high-priority medical

⁴¹ Advancing Regulatory Science for Public Health. Washington, DC: US Food and Drug Administration. October 2010. Available at: <http://www.fda.gov/downloads/ScienceResearch/SpecialTopics/RegulatoryScience/UCM228444.pdf>. Accessed April 6, 2011

⁴² Hamburg, MA. *Remarks at the Medical Countermeasures Review Roll Out* [speech]. Washington, DC: US Food and Drug Administration. August 19, 2010. Available at <http://www.fda.gov/NewsEvents/Speeches/ucm226351.htm>. Accessed April 6, 2011.

⁴³ *Ibid.* 4, pg. 10-11.

countermeasures and related technologies. To do so FDA will: (1) increase regulatory review capacity and expertise in medical review divisions responsible for the evaluation of medical countermeasures and (2) establish multidisciplinary Public Health and Security Action Teams (Action Teams) that will help advance priority medical countermeasure development by working with internal and external entities—as appropriate—to identify and catalyze the resolution of challenges to navigating the medical countermeasure development pathway. The Action Teams will also foster medical countermeasure development more generally by helping to address a range of regulatory and policy issues facing medical countermeasure development and approval, including facilitating the use of consistent regulatory approaches, assisting in the identification and resolution of regulatory science gaps, and supporting the implementation of best regulatory review practices across FDA’s medical product centers.

- **Pillar II: Advance Regulatory Science for Medical Countermeasure Development and Evaluation** – Goal: to facilitate MCMi Pillar I and Pillar III activities by fostering regulatory science initiatives intended to help develop solutions to complex scientific regulatory problems and facilitate the incorporation of new, cutting edge science into the regulatory review process to simplify and speed development of medical countermeasures. This program will be implemented through both intramural and extramural collaborative research, as well as through partnerships with US government agencies, academia, non-government organizations, and industry. A critical component of Pillar II activities will be modernizing FDA’s infrastructure to support the medical countermeasure regulatory science program, including needed upgrades to laboratory equipment and information technology capabilities so that FDA researchers and reviewers have the tools they need to succeed.
- **Pillar III: Modernize the Legal, Regulatory, and Policy Framework for Effective Public Health Response** – Goal: to ensure that US laws, regulations, and policies enable and foster the application of advances in regulatory science to the regulatory review process and adequately support preparedness for and response to CBRN threats and EIDs with medical countermeasures. To do so, FDA will conduct a review of the strengths and weaknesses of the current legal, regulatory, and policy environment with respect to medical countermeasure development, distribution, administration, and use. When changes are needed to better protect public health, FDA will work with appropriate partners to develop and propose new approaches.

The three MCMi Pillars are interdependent and FDA will ensure cross-collaboration in their implementation.

MCMi Strategic Goals and Key Objectives

To achieve the MCMi mission, FDA will concentrate increased resources and management efforts on achieving the following strategic goals (figure 1) and underlying key objectives. In pursuing these strategic goals and objectives, FDA will adhere to its guiding principles: science-based decision making, innovation/collaboration, transparency, and accountability.



Figure 1.

Cross-Pillar Goals and Objectives

Goal 1: Strengthen the Workforce and Improve the Infrastructure Necessary to Support the MCMi

Standing up FDA's MCMi requires the development and maintenance of a highly qualified workforce with appropriate technical training, scientific skill, and subject-matter expertise. In addition, successful implementation of the MCMi will require improving infrastructure at FDA so that the MCMi workforce has the tools it needs to succeed. Establishing the infrastructure to support the MCMi will be pursued through the following three key objectives:

- **Objective 1.1— Build the Workforce Necessary to Implement the MCMi** – Increased staffing needs span the three MCMi Pillars and encompass a wide range of skills and expertise, from augmenting regulatory review capacity in the FDA review divisions responsible for the evaluation of medical countermeasures, to staffing Action Teams, to enhancing FDA regulatory science capacity, and expanding MCMi legal, regulatory, and policy capabilities. FDA will identify the staffing needs to fully support the implementation of the MCMi and establish and execute a prioritized plan to fill and support those needs.
- **Objective 1.2 – Develop and Sustain a Culture of Learning and Professional Development within FDA to Support the MCMi** – The MCMi spans a diverse set of issues, from national and homeland security to medicine and public health, and requires a multi-disciplinary staff with training and expertise in a diverse range of skills. FDA will develop programs to train MCMi personnel at all career stages to ensure that MCMi personnel have the requisite skills and abilities to implement and sustain the MCMi.
- **Objective 1.3 – Acquire the Infrastructure Necessary to Fully Support the MCMi** – The MCMi will require new and improved infrastructure within FDA to achieve its goals including, for example, improved or expanded information technologies and new laboratory equipment to support MCMi regulatory science. FDA will identify the infrastructure needs to fully support the MCMi and establish and execute a prioritized plan to fill those needs.

Goal 2: Build and Sustain Integrated and Coordinated MCMi Programs

FDA is committed to building and sustaining the integrated, coordinated agency programs necessary to achieve the MCMi mission. FDA is responsible not only for coordinating MCMi activities within and among its own offices and centers, but also for coordinating and aligning MCMi activities with federal partners and—where appropriate—external partners (e.g., industry, academia). MCMi program integration and coordination is essential to ensure that MCMi appropriately reflects Enterprise priorities and objectives and that MCMi programs are sufficiently resourced and aligned to facilitate the expeditious fulfillment of program goals and objectives. FDA is building and will sustain an integrated and coordinated MCMi through the following two key objectives:

- **Objective 2.1 – Coordinate MCMi Program Implementation and Activities** – To maximize the effectiveness of the MCMi, it is important to ensure that the efforts of the three MCMi Pillars are appropriately resourced and integrated and that the MCMi efforts across FDA centers and offices and across all levels of US government and—where appropriate—external partners (e.g., industry, academia) are appropriately targeted and integrated to facilitate fulfillment of MCMi program goals and objectives and minimize unnecessary redundancy. FDA will coordinate MCMi program implementation across the MCMi pillars and MCMi program activities across the Enterprise and among external partners to ensure that MCMi programs are effectively synchronized to maximize capital and capabilities.
- **Objective 2.2 – Evaluate MCMi Program Execution** – Building and sustaining a well-integrated, coordinated MCMi requires a planning and execution framework that is built on a foundation of continuous improvement supported by an evaluation of program execution. FDA will establish an evaluation framework to assess MCMi program execution based on defined metrics for success to ensure that MCMi priorities are reflected within program funding allocations and inform future strategy, planning, investments, and resourcing.

Goal 3: Actively Engage MCMi Stakeholders and Foster Transparency

Achieving the MCMi mission will require successful partnerships among all of the Enterprise stakeholders. FDA is committed to pursuing stakeholder engagement as a means of enabling effective collaboration with stakeholders to solicit input and feedback, improve MCMi program implementation, and maximize the transparency of MCMi programs and priorities. FDA will actively engage MCMi stakeholders and foster transparency through the following three key objectives:

- **Objective 3.1 – Engage MCMi Stakeholders in Developing MCMi Priorities** – To be maximally effective, the MCMi must deliver on the needs of its stakeholders. Accordingly, FDA is engaging its stakeholders in the US government and the private sector in developing MCMi program priorities and will create appropriate opportunities for stakeholder input into the MCMi.
- **Objective 3.2 – Strengthen Strategic Partnerships to Further MCMi Program Goals and Objectives** – The success of the MCMi depends on collaborations and partnerships with Enterprise and private sector partners in which FDA serves as a leader, facilitator, collaborator, and participant, as necessary and appropriate. FDA will continue to build and maintain a network of strategic partnerships that operate at multiple levels, across the public and private sectors, and are involved in and serve all aspects of the MCMi to maximize opportunities for collaboration and ensure that resources are appropriately prioritized.
- **Objective 3.3 – Clearly Articulate MCMi Program Priorities and Timelines** – Clear and timely communication of MCMi program priorities and associated timelines is critical to achieving the MCMi mission and maintaining effective engagement with stakeholders. FDA will continue to work to increase transparency and public visibility of its MCMi program, priorities, and timelines.

Goal 4: Integrate MCMi Program with Enterprise Public Health Preparedness Planning and Response Activities

The MCMi is part of a much larger US government initiative—coordinated through the Enterprise—to ensure that that the nation has the medical countermeasure programs, products, and systems necessary to be appropriately prepared for, protected from, and resilient in the face of the highest priority CBRN and EID threats. The Enterprise mission space

spans the full scope of medical countermeasure program activities from threat assessment to medical countermeasure research and development to acquisition, deployment, and use. As many of the complex challenges that face the Enterprise are inherently cross-cutting and multi-faceted, integration of component Enterprise programs is critical for fostering effective preparedness, planning, and response capabilities. Accordingly, FDA is dedicated to ensuring that the MCMi is fully integrated into Enterprise activities, and FDA will pursue this goal through the following two key objectives:

- **Objective 4.1 – Represent MCMi in Enterprise Strategic Planning and Policy Development** – FDA supports the Enterprise strategic planning and policy development through participation of FDA subject matter experts in various Enterprise partner committees and working groups. FDA will continue to collaborate with Enterprise partners on strategic planning and policy development related to medical countermeasures to ensure that the MCMi is fully integrated into Enterprise activities and that MCMi developments and issues inform and shape the evolution of Enterprise planning and policies.
- **Objective 4.2 – Coordinate MCMi Activities and Programs with Enterprise Response Activities** – Response to a CBRN or EID event with medical countermeasures requires active engagement of FDA to enable effective and timely response activities. For example, during a domestic or military emergency, potentially useful medical countermeasures may be available, but not yet FDA-approved for the particular use contemplated. In this situation, FDA has a variety of regulatory mechanisms that can allow for the use of these products, including as part of a clinical trial or as part of an expanded access program.⁴⁴ In addition, medical countermeasures can be made available under the emergency use authorization (EUA). FDA may issue an EUA authorizing the use of an unapproved medical countermeasure, or the unapproved use of an approved medical countermeasure, during a declared emergency if there are no adequate, approved, and available alternatives and if other statutory criteria are met.⁴⁵ FDA exercised the EUA authority extensively during the 2009 H1N1 pandemic to facilitate effective response. FDA will continue to work closely with Enterprise partners, medical

⁴⁴ Expanded access refers to FDA procedures that enable the distribution of investigational drugs and devices to a patient or patients who have a serious or immediately life-threatening condition, and lack therapeutic alternatives, when the primary purpose is to diagnose, monitor, or treat the patients' condition Section 561 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. § 360bbb). For more information see <http://edocket.access.gpo.gov/2009/pdf/E9-19005.pdf>

⁴⁵ Section 564 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. § 360bbb-3).

countermeasure developers, and first responders as appropriate to coordinate MCMi activities and programs with response activities to ensure that the nation is prepared to counter CBRN and EID threats.

Pillar I Goals and Objectives

Goal 5: Establish and Support Public Health and Security Action Teams

Action Teams will be established based on Enterprise partner priorities⁴⁶ and will support—as needed—the development of high-priority candidate medical countermeasure products, product classes, or critical medical countermeasure technologies. As FDA’s regulatory activities are governed by strict product confidentiality and non-disclosure rules, clear rules of engagement for Action Teams need to be defined so that they can function effectively and that relevant information can be shared between Action Team members and Enterprise partners. It is important that there is a common understanding of data, progress, and key challenges. Establishing and supporting Action Teams will be pursued through the following two key objectives:

- **Objective 5.1 – Establish Action Teams based on Near-, Mid-, and Long-Term Enterprise Priorities** – Given the large number of potential CBRN and EID threat agents, the inherent uncertainties associated with assessing the evolving threat space and the long timelines, risks, and high costs associated with developing medical countermeasures, it is not feasible to pursue medical countermeasure programs against every possible threat. Accordingly, HHS prioritizes both the threats for which medical countermeasure programs are pursued and the medical countermeasure programs that are pursued to counter those threats.⁴⁷ FDA will continually engage Enterprise partners to stay

⁴⁶ For more information on Enterprise partner medical countermeasure priorities see for example: *HHS Public Health Emergency Medical Countermeasure Enterprise Implementation Plan for Chemical, Biological, Radiological and Nuclear Threats* available at https://www.medicalcountermeasures.gov/BARDA/documents/phemce_implplan_041607final.pdf; *BARDA CBRN BAA- 11-100-SOL-00009* available at https://www.fbo.gov/index?s=opportunity&mode=form&tab=core&id=89ba389b4424e98020cb3de547001825&_cview=0; and *Report to the President on Reengineering the Influenza Vaccine Production Enterprise to Meet the Challenges of Pandemic Influenza* available at <http://www.whitehouse.gov/sites/default/files/microsites/ostp/PCAST-Influenza-Vaccinology-Report.pdf>.

⁴⁷ For example, as per HSPD-18, HHS is guided by 3 overarching principles in optimize investments in medical CBRN countermeasure programs : (1) Risk – focusing on countering current and anticipated CBRN threat agents that have the greatest potential for use by state and non-state actors to cause catastrophic public health consequences; (2) Medical Countermeasure

abreast of near-, mid-, and long-term medical countermeasure priorities and requirements and establish Action Teams—as needed—based on those priorities and in alignment with Enterprise partner investments in medical countermeasure programs.

- **Objective 5.2 – Establish the Infrastructure and Policies to Support and Guide Action Team Activities** – Success of the Action Team program will require extensive collaboration and coordination among FDA centers and other relevant offices, as well as with Enterprise partners. FDA will establish internal processes, tools, and structures to manage individual Action Teams, track progress, and facilitate coordination of the Action Team program both internally and externally. In addition, FDA will establish policies that will guide Action Team activities and develop any agreements necessary to support their functions (e.g., confidentiality agreements, memoranda of understanding).

Pillar II Goals and Objectives

Goal 6: Establish and Sustain a Medical Countermeasures Regulatory Science Program

The MCMi regulatory science program will focus on high-priority projects that are of value for public health and national security. Topic areas of special interest for medical countermeasure regulatory science include: (1) animal model development and qualification; (2) identification and qualification of biomarkers for safety and efficacy; (3) immune responses including identification of correlates of protection; (4) methods to assess product quality and related product release assays; (5) risk communication to improve public health outcomes; (7) validation of next-generation *in vitro* diagnostics platforms; (8) assessing performance of emergency medical equipment; and (9) real-time tracking and evaluation of MCM safety and efficacy during public health emergencies.

Impact - investing in medical countermeasure programs that have the greatest potential to prevent, treat, and mitigate the consequences of CBRN threats; and (3) Feasibility - linking the development and acquisition of medical countermeasures to the existence of effective deployment strategies that are supportable by present and foreseeable operational and logistic capabilities of federal, state, regional, territorial, tribal, and local assets/authorities. See HSPD 18: Medical Countermeasures against Weapons of Mass Destruction. Washington, DC: White House. January 31, 2007. Available at: http://www.dhs.gov/xabout/laws/gc_1219175362551.shtm#1. Accessed April 4, 2011.

The MCMi regulatory science agenda will be pursued through internal research, as well as through collaborations and partnerships with academia, US government agencies, non-governmental organizations, and industry. Establishing and sustaining the MCMi regulatory science program will be pursued through the following four key objectives:

- **Objective 6.1 – Assess and Prioritize Medical Countermeasure Regulatory Science Needs** – FDA will work both internally and with external partners to assess and prioritize on an ongoing basis medical countermeasure regulatory science needs, which will inform investments in MCMi regulatory science. This assessment and prioritization will be based on Enterprise priorities, including those that foster MCMi Pillar I and Pillar III activities.
- **Objective 6.2 – Strengthen and Sustain the Intramural FDA Medical Countermeasures Regulatory Science Program** – FDA maintains a strong intramural regulatory science program in its three medical product centers. The MCMi will expand and strengthen this program for center-specific research and for cross-center collaborative research.
- **Objective 6.3 - Establish and Sustain an Extramural Medical Countermeasures Regulatory Science Program** – FDA will establish an extramural component that is complementary to its intramural MCMi regulatory science program to engage entities outside of FDA (e.g., other US government agencies, academia, non-governmental organizations, and industry) in medical countermeasure regulatory science.
- **Objective 6.4 - Establish Processes to Maintain Effective Oversight of the Medical Countermeasures Regulatory Science Program** – FDA will establish processes and protocols to manage the MCMi regulatory science program, track progress, and facilitate coordination of research efforts to ensure that the MCMi regulatory science program is appropriately targeted and integrated to facilitate fulfillment of MCMi regulatory science needs and minimize unnecessary redundancy.

Pillar III Goals and Objectives

Goal 7: Modernize the Legal, Regulatory, and Policy Environment for Effective Public Health Response

It is essential that US laws, regulations, and policies continue to evolve to enable the application of advances in regulatory science to the regulatory review process for medical countermeasure development and to adequately support preparedness for and response to CBRN and EID threats with medical countermeasures. FDA is committed to expanding its work with Enterprise partners and external stakeholders to modernize its legal, regulatory, and policy environment and will pursue this goal through the following two key objectives:

- **Objective 7.1 – Identify Priorities for Modernizing the Legal, Regulatory, and Policy Framework for Effective Public Health Response** – FDA will assess on an ongoing basis the strengths and weaknesses of the legal, regulatory, and policy environment with respect to the development, distribution, administration and use of medical countermeasures and identify changes to the legal, regulatory, and policy framework that are necessary to foster medical countermeasure development and improve preparedness and response capabilities.
- **Objective 7.2 – Work with Enterprise Partners and External Stakeholders to Modernize the Legal, Regulatory, and Policy Environment for Effective Public Health Response** – FDA will launch collaborative projects with Enterprise partners and external stakeholders as necessary and appropriate to address high-priority needs for modernizing the legal, regulatory, and policy framework with respect to medical countermeasure development, distribution, administration, and use.

Implementation

FDA will implement the *MCMi Strategic Plan 2012 – 2016* with the full involvement of its leadership and an unwavering commitment to turning strategy into concrete actions. FDA will integrate MCMi priorities into its annual budget formulation and implementation planning.

The *MCMi Strategic Plan* maps out a broad strategic direction for the MCMi. To maximize effective MCMi implementation and promote course corrections when needed, FDA will assess all MCMi activities in detail on an ongoing basis—including performance measures and milestones—for their contribution toward MCMi goals and objectives. FDA will update the *MCMi Strategic Plan* as necessary to reflect evolving activities, progress toward MCMi goals and objectives, and to ensure continued alignment with US government goals and priorities. In addition, MCMi program performance will be reviewed on a quarterly basis through the FDA-TRACK Initiative and through periodic FDA and Enterprise senior leadership reviews. FDA will issue annual status reports on MCMi accomplishments.

Conclusion

Mitigating the threats posed by CBRN agents and EIDs is a critical national security priority for the nation. Medical countermeasures are critical tools needed to promote and protect the health of the US population and security of the United States. As such, they are a significant piece of our national strategy to counter CBRN and EID threats.

The *MCMi Strategic Plan 2012-2016* establishes the goals and key objectives FDA will pursue as part of its ongoing efforts to ensure that the nation has the medical countermeasures necessary to protect the population from the highest priority CBRN and EID threats and the systems to deliver them. The plan also reflects FDA's commitment to help foster the evolution of the Enterprise to a capabilities-based posture that can produce medical countermeasures quickly in response to "...any attack or threat, known or unknown..."⁴⁸ as envisioned in the *Enterprise Review*. FDA's active engagement is fundamental to achieving this vision and to the ultimate success of the Enterprise.

⁴⁸ *Ibid.* 4, pg. 6.

Success of the medical countermeasures Enterprise is in the vital national security interests of the United States as it helps protect the United States from potentially catastrophic CBRN and EID threats and can also help strengthen national security by offering opportunities to promote US interests and security abroad. Achieving the Enterprise vision also creates opportunities to improve the United States' health security beyond countering CBRN and EID threats and offers sound opportunities to promote global health security.

For example, FDA's investments in regulatory science to advance medical countermeasure development will contribute directly and indirectly to the development of products to treat other diseases and conditions and help improve the safety and efficacy of and access to FDA-regulated products while reducing costs. The MCMi is clearly a timely and critical investment that will pay dividends far into the future of our nation.

Appendix A: Medical Countermeasures Initiative Organization

MCMi MISSION

The mission of HHS is to enhance the health and well-being of Americans by providing for effective health and human services and by fostering strong, sustained advances in the sciences, underlying medicine, public health, and social services.⁴⁹ One of HHS's overarching strategic goals is to advance the health, safety, and well-being of the American people and one of the key strategies HHS is pursuing to achieve this goal is to "[m]odernize the medical countermeasure enterprise with more promising discoveries, advanced development, robust manufacturing, better stockpiling, and advanced distribution practices in the United States and abroad."⁵⁰ This strategy is in alignment with strategic objective #6 in the *National Health Security Strategy* to promote an effective medical countermeasures enterprise.⁵¹

HHS pursues a coordinated interagency approach to its medical countermeasures mission through the Public Health Emergency Medical Countermeasures Enterprise (PHEMCE or Enterprise). The mission of the Enterprise is to: (1) define and prioritize requirements for public health emergency medical countermeasures; (2) coordinate research, early - and late-stage product development and procurement activities addressing the requirements; and (3) set deployment and use strategies for medical countermeasures held by Enterprise partners.⁵²

The Enterprise is led by the Office of the Assistant Secretary for Preparedness and Response (ASPR) and includes three primary HHS internal agencies: (1) the Centers for Disease Control and Prevention (CDC); (2) the Food and Drug Administration (FDA); and (3) the National Institutes of Health (NIH). The Enterprise also includes key interagency partners: the Department of Homeland Security, the Department of Defense, the Department of Veterans Affairs, and the Department of Agriculture.

FDA's mission is to protect the public health by ensuring the safety, efficacy, and security of human and veterinary drugs, biological products, and medical devices; ensuring the safety of foods, cosmetics, and radiation-emitting products; and regulating tobacco products.⁵³ Specifically, FDA is responsible for advancing the public health by:

⁴⁹ *US Department of Health and Human Services Strategic Plan 2010-2015*. Washington, DC: US Department of Health and Human Services. Available at <http://www.hhs.gov/secretary/about/priorities/strategicplan2010-2015.pdf>. Accessed April 14, 2011.

⁵⁰ *Ibid* 49, pg. 67.

⁵¹ *Ibid* 23, pg. 13.

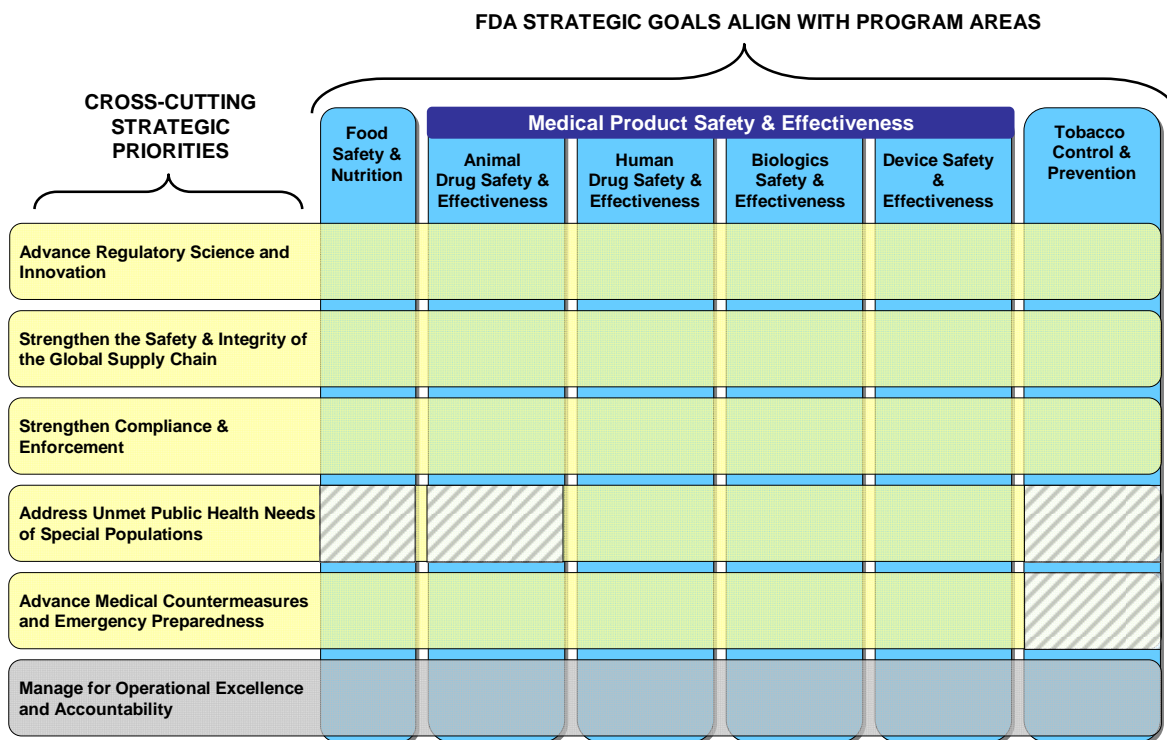
⁵² Parker, G. HHS Public Health Emergency Medical Countermeasures Enterprise Strategy for Chemical, Biological, Radiological and Nuclear Threats. *Federal Register*, 72 (53), 13109-13114. March 20, 2007, available at https://www.medicalcountermeasures.gov/BARDA/documents/federalreg_vol72no53_032007notices.pdf. Accessed April 14, 2011.

⁵³ *Ibid* 38, pg. 2.

- Helping to speed innovations that make medical products and foods safer and more effective
- Providing the public with the accurate, science-based information they need to use medical products and foods to improve their health
- Regulating the manufacture, marketing, and distribution of tobacco products to protect the public and reduce tobacco use by minors
- Addressing the Nation’s counterterrorism capability by ensuring the security of the supply of foods and medical products and by fostering development of medical products to respond to deliberate and naturally emerging public health threats

Advancing medical countermeasures and emergency preparedness is a cross-cutting strategic priority for FDA that aligns with program-specific strategic goals and long-term objectives across FDA (figure 2).⁵⁴

Alignment of FDA Cross-Cutting Strategic Priorities and Goals



Source: U.S. Food and Drug Administration Strategic Priorities 2011-2015, April 20, 2011, available at <http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Reports/UCM252092.pdf>

Figure 2.

With respect to the Enterprise, FDA plays a primary role in the medical countermeasure mission from discovery through development to deployment and use (figure 3).

⁵⁴ *Ibid.* 38, pgs. 15-16.

Enterprise Partner Roles

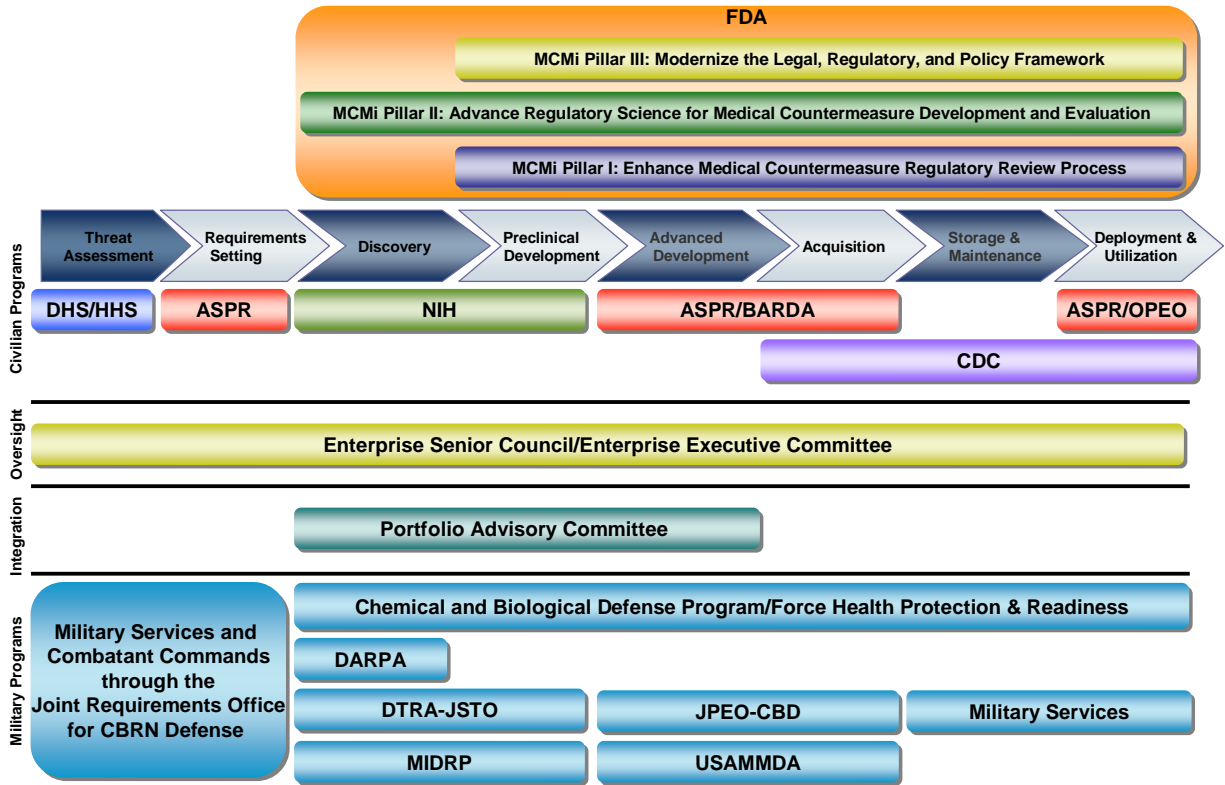


Figure 3

FDA ensures that the medical countermeasures it regulates are safe and effective for their intended use(s) and that they meet specified quality standards. FDA also facilitates the development and availability of medical countermeasure by providing regulatory guidance and scientific and technical expert review of medical countermeasure product applications, with the goal of approving medical countermeasures. In addition, FDA fosters effective and timely responses to domestic or military emergencies with medical countermeasures that are available but not yet FDA-approved for the particular use contemplated through employment of a variety of regulatory mechanisms that allow for emergency use of such products. Furthermore, FDA supports the medical countermeasure mission by providing FDA subject matter expertise in various Enterprise partner committees and working groups that develop requirements, plans, priorities, and policies and conduct program oversight and integration.⁵⁵

⁵⁵ Enterprise committees and working groups that FDA participates in include: the Enterprise Senior Council (ESC), which provides coordinated strategic direction and policy oversight for the Enterprise; the Enterprise Executive Committee (EEC), which coordinates end-to-end Enterprise activities; Requirements Working Groups that are responsible for developing scenario-based medical countermeasure analyses; Integrated Program Teams (IPTs) that are responsible for producing product-specific medical countermeasure requirements and providing policy support for cross-cutting medical countermeasure issues; and the Portfolio Advisory Committee (PAC) which manages the Integrated Portfolio for CBRN medical countermeasures that provides the EEC and DoD senior leadership with portfolio analysis of medical countermeasure pipelines and candidates to foster integration of medical countermeasure development activities.

The 2010 *Enterprise Review* called for greater investment in regulatory innovation and regulatory science and for FDA to take an even more active role in fostering the development and facilitating the deployment of medical countermeasures. In response, FDA launched its Medical Countermeasures Initiative (MCMi) to augment and better manage its ongoing medical countermeasure efforts. The mission of the MCMi is to promote the development of medical countermeasures by enhancing FDA’s regulatory processes and fostering the establishment of clear regulatory pathways for medical countermeasures and to facilitate the timely use of available medical countermeasures by establishing effective regulatory policies and mechanisms.

MCMi ORGANIZATION

The MCMi builds on the substantial, ongoing medical countermeasures work at FDA and integrates new initiatives—as needed—based on the expected outcomes and elements of the 21st-Century Regulatory Science initiative as described in the *Enterprise Review*. FDA has organized the MCMi around an Action Plan built on a three pillar strategy that integrates medical countermeasure activities across FDA into a cohesive framework that enables improved strategic leadership and coordination of FDA’s medical countermeasure activities (figure 4).

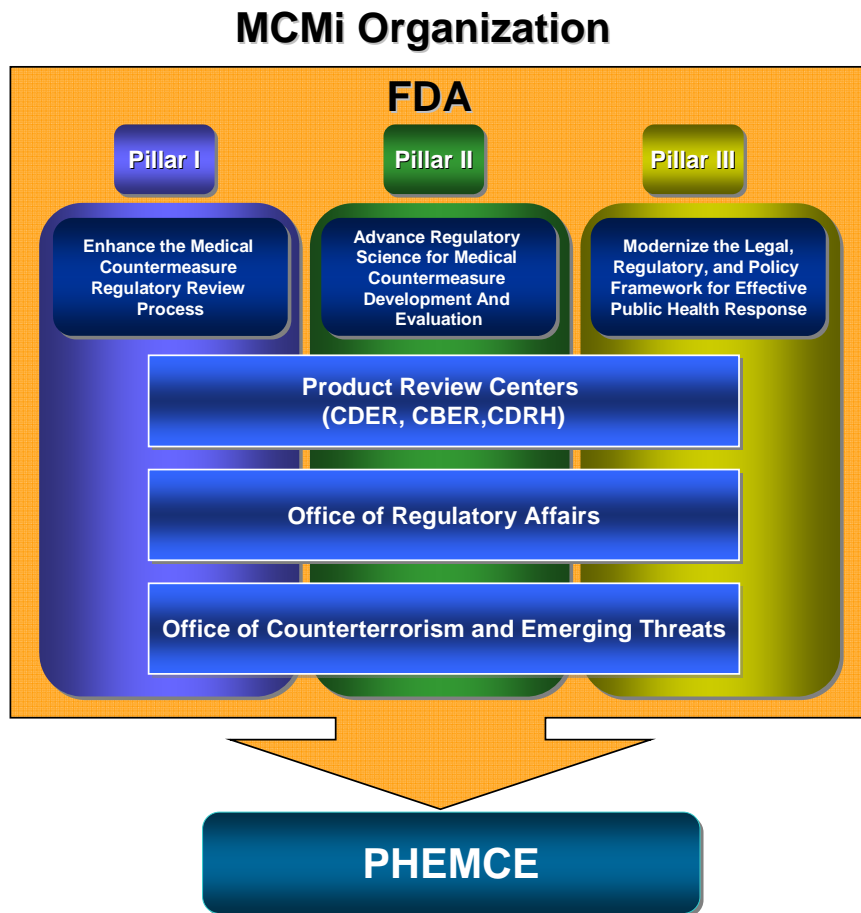


Figure 4

Pillar I: Enhance the Medical Countermeasure Regulatory Review Process

The goal of Pillar I is to advance the development of high-priority medical countermeasures and related technologies. FDA is pursuing this goal by increasing regulatory review capacity and expertise in the review divisions responsible for the evaluation of medical countermeasures and by establishing multidisciplinary Public Health and Security Action Teams. The Action Teams will work with sponsors, US government partners, and FDA review teams as appropriate to advance priority medical countermeasure development by tackling the range of regulatory, scientific and policy issues facing medical countermeasure development and approval.

Action Teams will be established as needed based on Enterprise priorities and may be charged with facilitating development of a *specific* medical countermeasure product, a *class or group* of medical countermeasure products, or to support the successful development of an important medical countermeasure technology. Action Teams will create collaborative environments within which to rapidly address both strategic and, as needed, special issues often associated with medical countermeasure development and approval. Action Teams will enhance the FDA review process by adding medical countermeasure-specific resources, such as scientists and other subject-matter experts, working collaboratively with the FDA review center Core Review Teams to help define and implement clear regulatory pathways, resolve regulatory science gaps that may currently impede medical countermeasure development, and align FDA's medical countermeasure regulatory strategy across products, programs, and Centers.

Pillar II: Advance Regulatory Science for Medical Countermeasure Development and Evaluation

The goal of Pillar II is to facilitate MCMi Pillar I and Pillar III activities by fostering medical countermeasure regulatory science intended to help develop solutions to complex scientific regulatory problems and facilitate the incorporation of new, cutting edge science into the regulatory review process to simplify and speed product development. Regulatory science is the applied research needed to develop and use new tools and standards to more efficiently develop and evaluate, through the regulatory review process, the safety, efficacy, and quality of medical products, including products suitable for at-risk populations (e.g., children, pregnant women, the elderly, and people with chronic health conditions).⁵⁶

The MCMi regulatory science program will focus on high-priority projects that are of value for public health and national security based on Enterprise partner priorities, including those that facilitate MCMi Pillar I and Pillar III activities. This program will have both internal and external research components. FDA maintains a strong intramural medical countermeasures regulatory science program in its three medical product centers and this program will be expanded and strengthened. FDA will also establish an extramural component to this program to engage

⁵⁶ *At-Risk Individuals*. Washington, DC: US Department of Health and Human Services. Available at <http://publichealthemergency.hhs.gov/Preparedness/planning/abc/Documents/AtRisk.pdf>. Accessed December 1, 2011.

entities outside of FDA (e.g., other US government agencies, academia, non-governmental organizations, and industry) in medical countermeasure regulatory science. Examples of scientific issues that this initiative will support include development and validation of novel manufacturing platforms; identification and qualification of animal models and surrogate measures of product efficacy; development of improved potency, sterility, and stability assays; development of standards for new point-of-care diagnostics; new approaches for statistical analyses of limited data sources; and new approaches for collecting and analyzing information about product use during emergencies.

Pillar III: Modernize the Legal, Regulatory, and Policy Framework for Effective Public Health Response

The goal of Pillar III is to ensure that US laws, regulations, and policies enable the application of advances in regulatory science to the regulatory review process and adequately support preparedness for and response to CBRN and EID threats. FDA will conduct a review of the strengths and weaknesses of the current legal, regulatory, and policy environment with respect to medical countermeasure development, distribution, administration, and use and, when changes are needed to better protect public health, FDA will work with appropriate partners to develop and propose new approaches.

Examples of the types of issues that this initiative will address—as identified in the *Enterprise Review*—include: (1) examining mechanisms for potential new or modified approaches for authorizing unapproved medical countermeasures that may be placed in the Strategic National Stockpile for use in emergencies; (2) examining approaches to minimize the need to issue emergency authorizations for unapproved uses of approved medical countermeasures; (3) identifying ways to collect product-related data during emergencies that may be useful in informing about the product’s safety and efficacy; and (4) assessing the current challenges posed by the Animal Efficacy Rule and identifying strategies to improve its implementation.

MCMi ROLES AND RESPONSIBILITIES

Office of Counterterrorism and Emerging Threats (OCET), Office of the Chief Scientist (OCS), Office of the Commissioner (OC)

OCET is responsible for providing strategic policy leadership and coordination for FDA’s counterterrorism and emerging threat portfolios and for working to identify and resolve complex scientific and regulatory challenges facing medical countermeasure development, approval, availability, and security.⁵⁷ The MCMi three pillar Action Plan is integrated into the existing OCET framework creating an OCET management structure that encompasses MCMi activities as well as OCET’s traditional strategic leadership and coordination functions within

⁵⁷ OCET’s mission is to facilitate the development and availability of safe and effective public health emergency medical countermeasures and establish policies to safeguard medical products from adulteration and prevent disruption of supplies as a result of terrorist activities.

FDA and in relation to the Enterprise, ensuring that the outputs of the MCMi inform updates to preparedness and response plans, address medical countermeasure needs not identified as Enterprise priorities (such as DoD specific medical countermeasure programs), and other liaison activities (such a coordinating Emergency Use Authorization activities).

Specific OCET roles and responsibilities within the MCMi include:

- Providing leadership, management, coordination, and accountability for the implementation of the MCMi
- Working in close partnership with FDA's three medical product centers—CDER, CBER, and CDRH—and the Office of Regulatory Affairs to manage and implement the MCMi
- Working with Enterprise partners to further medical countermeasure development and preparedness
- Facilitating relevant intra- and inter-agency communications

FDA Medical Product Centers

FDA's medical product centers are responsible for protecting the public health by ensuring the safety, effectiveness, and security of medical countermeasures including human and veterinary drugs, vaccines and other biological products, and medical devices under applicable federal laws.

- **Center for Drug Evaluation and Research (CDER)** - performs an essential public health task by making sure that safe and effective drugs are available to improve the health of people in the United States. CDER regulates over-the-counter and prescription drugs, including biological therapeutics and generic drugs.
- **Center for Biologics Evaluation & Research (CBER)** - regulates biological products for human use under applicable federal laws, including the Public Health Service Act and the Federal Food, Drug, and Cosmetic Act. CBER protects and advances the public health by ensuring that biological products are safe and effective and available to those who need them. CBER also provides the public with information to promote the safe and appropriate use of biological products.
- **Center for Devices and Radiological Health (CDRH)** - is responsible for regulating firms who manufacture, repackage, relabel, and/or import medical devices, such as *in vitro* diagnostics, sold in the United States. In addition, CDRH regulates radiation-emitting electronic products (medical and non-medical) such as biodisometers, lasers, x-ray systems, ultrasound equipment, microwave ovens and color televisions.

Specific FDA medical product center roles and responsibilities within the MCMi include:

- Working with medical countermeasure product sponsors on developing medical countermeasures
- Ensuring the reliability of Animal Rule efficacy studies and the integrity of the data generated to support the approval of drug and biologic medical countermeasures
- Reviewing medical countermeasure review submissions

- Working with OCET to implement and manage the three MCMi pillars
- Conducting intramural medical countermeasure regulatory science
- Working with Enterprise partners to further medical countermeasure development and preparedness

Office of Regulatory Affairs (ORA)

ORA protects consumers and enhances public health by maximizing compliance of FDA regulated products and minimizing risk associated with those products. ORA is the lead office for all FDA Field activities as well as providing FDA leadership on imports, inspections, and enforcement policy. ORA supports FDA's medical product centers by inspecting regulated products and manufacturers, conducting sample analysis on regulated products, and reviewing imported products offered for entry into the United States. ORA also develops FDA-wide policy on compliance and enforcement and executes FDA's Import Strategy and Food Protection Plans.

Specific ORA roles and responsibilities within the MCMi include:

- Conducting inspections of medical countermeasure manufacturing sites
- Acting as subject matter experts for manufacturing quality issues on Action Teams, as needed

Appendix B: Alignments and Linkages

The following is a summary listing of key strategic drivers for the *MCMi Strategic Plan: 2012-2016*.

Strategy and Implementation Plans

- **National Security Strategy**, May 2010, available at http://www.whitehouse.gov/sites/default/files/rss_viewer/national_security_strategy.pdf
- **National Strategy for Counterterrorism**, June 2011, available at http://www.whitehouse.gov/sites/default/files/counterterrorism_strategy.pdf
- **Quadrennial Homeland Security Review**, February 2010, available at http://www.dhs.gov/xlibrary/assets/qhsr_report.pdf
- **National Health Security Strategy**, December 2009, available at <http://www.phe.gov/Preparedness/planning/authority/nhss/strategy/Documents/nhss-final.pdf>
- **National Strategy for Countering Biological Threats**, November 2009, available at http://www.whitehouse.gov/sites/default/files/National_Strategy_for_Countering_BioThreats.pdf
- **US Department of Health and Human Services Strategic Plan 2010-2015**, available at <http://www.hhs.gov/secretary/about/priorities/strategicplan2010-2015.pdf>
- **US Food and Drug Administration Strategic Priorities 2011-2015**, April 20, 2011, available at <http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Reports/UCM252092.pdf>
- **Advancing Regulatory Science at FDA: A Strategic Plan**, August 2011, available at <http://www.fda.gov/downloads/ScienceResearch/SpecialTopics/RegulatoryScience/UCM268225.pdf>
- **Advancing Regulatory Science for Public Health**, October 2010, available at <http://www.fda.gov/downloads/ScienceResearch/SpecialTopics/RegulatoryScience/UCM228444.pdf>
- **Center for Biologics Evaluation and Research Strategic Plan FY 2012 – 2016** (July 2011), available at <http://www.fda.gov/downloads/AboutFDA/CentersOffices/CBER/UCM266867.pdf>
- **ASPR Strategic Plan 2011-2015**, available at <http://www.phe.gov/about/aspr/strategic-plan/Pages/default.aspx>
- **The Public Health Emergency Medical Countermeasures Enterprise Review: Transforming the Enterprise to Meet Long-Range National Needs**, August 2010, available at <https://www.medicalcountermeasures.gov/media/1138/mcmreviewfinalcover-508.pdf>
- **HHS Public Health Emergency Medical Countermeasures Enterprise Strategy for Chemical, Biological, Radiological and Nuclear Threats**, March 20, 2007, available at https://www.medicalcountermeasures.gov/BARDA/documents/federalreg_vol72no53_032007notices.pdf
- **HHS Public Health Emergency Medical Countermeasures Enterprise Implementation Plan for Chemical, Biological, Radiological and Nuclear Threats**, April 2007, available at https://www.medicalcountermeasures.gov/BARDA/documents/phemce_implplan_041607final.pdf
- **National Strategy for Pandemic Influenza**, November 2005, available at <http://www.pandemicflu.gov/professional/federal/pandemic-influenza.pdf>

- **National Strategy for Pandemic Influenza Implementation Plan**, May 2006, available at <http://www.pandemicflu.gov/professional/federal/pandemic-influenza-implementation.pdf>
- **HHS Pandemic Influenza Plan**, November 2005, available at <http://www.hhs.gov/pandemicflu/plan/pdf/HHSPandemicInfluenzaPlan.pdf>
- **HHS Pandemic Influenza Implementation Plan**, November 2006, available at <http://www.hhs.gov/pandemicflu/implementationplan/pdf/Pandemic.pdf>
- **Report to the President on Reengineering the Influenza Vaccine Production Enterprise to Meet the Challenges of Pandemic Influenza**, August 2010, available at <http://www.whitehouse.gov/sites/default/files/microsites/ostp/PCAST-Influenza-Vaccinology-Report.pdf>
- **NIAID Strategic Plan for Biodefense Research, 2007 Update**, September 2007, available at <http://www.niaid.nih.gov/topics/BiodefenseRelated/Biodefense/Documents/biosp2007.pdf>
- **NIH Strategic Plan and Research Agenda for Medical Countermeasures against Radiological and Nuclear Threats**, June 2005, available at <http://www.niaid.nih.gov/about/whoWeAre/Documents/radnucstrategicplan.pdf>
- **NIH Strategic Plan and Research Agenda for Medical Countermeasures against Chemical Threats, August 2007**, available at <http://www.niaid.nih.gov/topics/BiodefenseRelated/ChemicalCountermeasures/Documents/nihstrategicplanchem.pdf>

Presidential Policy Directives

- **PPD-8: National Preparedness**, March 30, 2011, available at http://www.dhs.gov/xabout/laws/gc_1215444247124.shtm

Homeland Security Presidential Directives

- **HSPD – 4: National Strategy to Combat Weapons of Mass Destruction**
- **HSPD – 10: Biodefense for the 21st Century**, April 28, 2004, available at http://www.dhs.gov/xabout/laws/gc_1217605824325.shtm
- **HSPD – 18: Medical Countermeasures against Weapons of Mass Destruction**, January 31, 2007, available at http://www.dhs.gov/xabout/laws/gc_1219175362551.shtm
- **HSPD – 21: Public Health and Medical Preparedness**, October 18, 2007, available at http://www.dhs.gov/xabout/laws/gc_1219263961449.shtm

Legislation

- **Public Health Security and Bioterrorism Preparedness and Response Act of 2002**, P.L. 107-188, June 12, 2002, available at http://frwebgate.access.gpo.gov/cgi-bin/getdoc.cgi?dbname=107_cong_public_laws&docid=f:publ188.107.pdf
- **Project BioShield Act of 2004**, P.L. 108-276, July 21, 2004, available at <http://www.gpo.gov/fdsys/pkg/PLAW-108publ276/pdf/PLAW-108publ276.pdf>
- **Public Readiness and Emergency Preparedness Act**, enacted as Division C of the Defense Appropriations Act for fiscal year 2006. PL No. 109-148, December 30, 2005, available at <http://www.gpo.gov/fdsys/pkg/PLAW-109publ148/pdf/PLAW-109publ148.pdf>

- ***Pandemic and All-Hazards Preparedness Act***, P.L. 109-417, December 19, 2006, available at <http://www.gpo.gov/fdsys/pkg/PLAW-109publ417/pdf/PLAW-109publ417.pdf>

Appendix C: Summary of MCMi Strategic Goals and Key Objectives

MCMi Strategic Goals 2012 - 2016	MCMi Key Objectives
Goal 1: Strengthen the Workforce and Improve the Infrastructure Necessary to Support the MCMi	Objective 1.1— Build the Workforce Necessary to Implement the MCMi
	Objective 1.2 – Develop and Sustain a Culture of Learning and Professional Development within FDA to Support the MCMi
	Objective 1.3 – Acquire the Infrastructure Necessary to Support the MCMi
Goal 2: Build and Sustain Integrated and Coordinated MCMi Programs	Objective 2.1 – Coordinate MCMi Program Implementation and Activities
	Objective 2.3 – Evaluate MCMi Program Execution
Goal 3: Actively Engage MCMi Stakeholders and Foster Transparency	Objective 3.1 – Engage MCMi Stakeholders in Developing MCMi Priorities
	Objective 3.2 – Establish and Maintain Strategic Partnerships to Further MCMi Program Goals and Objectives
	Objective 3.3 – Clearly Articulate MCMi Program Priorities and Timelines
Goal 4: Integrate MCMi Program with Enterprise Public Health Preparedness Planning and Response Activities	Objective 4.1 – Represent MCMi in Enterprise Strategic Planning and Policy Development
	Objective 4.2 – Coordinate MCMi Activities and Programs with Enterprise Response Activities
Goal 5: Establish and Support Public Health and Security Action Teams	Objective 5.1 – Establish Action Teams based on near-, mid-, and long-term Enterprise Priorities
	Objective 5.2 – Establish the Infrastructure and Policies to Support and Guide Action Team Activities
Goal 6: Establish and Sustain a Medical Countermeasures Regulatory Science Program	Objective 6.1 – Assess and Prioritize Medical Countermeasure Regulatory Science Needs
	Objective 6.2 – Strengthen and Sustain the Intramural FDA Medical Countermeasures Regulatory Science Program
	Objective 6.3 - Establish and Sustain an Extramural Medical Countermeasures Regulatory Science Program
	Objective 6.4 - Establish Processes to Maintain Effective Oversight of the Medical Countermeasures Regulatory Science Program
Goal 7: Modernize the Legal, Regulatory, and Policy Environment for Effective Public Health Response	Objective 7.1 – Identify Priorities for Modernizing the Legal, Regulatory, and Policy Framework for Effective Public Health Response
	Objective 7.2 – Work with Enterprise Partners and External Stakeholders to Modernize the Legal, Regulatory, and Policy Environment for Effective Public Health

Appendix D: Crosswalk of FDA Strategic Goals and Long-Term Objectives with MCMi Strategic Goals and Key Objectives

FDA Strategic Goals 2011 - 2015	FDA Long-Term Objectives	MCMi Strategic Goals 2012 - 2016	MCMi Key Objectives
3.2 Promote Public Health by Advancing the Safety and Effectiveness of Medical Products	3.2.1 Advance Human Drug Safety and Effectiveness 3.2.2 Advance Biologics Safety and Effectiveness 3.2.4 Advance Medical Device Safety and Effectiveness	Goal 4: Integrate MCMi Program with Enterprise Public Health Preparedness Planning and Response Activities	Objective 4.1 – Represent MCMi in Enterprise Strategic Planning and Policy Development
			Objective 4.2 – Coordinate MCMi Activities and Programs with Enterprise Response Activities
		Goal 5: Establish and Support Public Health and Security Action Teams (Action Teams)	Objective 5.1 – Establish Action Teams based on near-, mid-, and long-term Enterprise Priorities
			Objective 5.2 – Establish the Infrastructure and Policies to Support and Guide Action Team Activities
		Goal 6: Establish and Sustain a Medical Countermeasures Regulatory Science Program	Objective 6.1 – Assess and Prioritize Medical Countermeasure Regulatory Science Needs
			Objective 6.2 – Strengthen and Sustain the Intramural FDA Medical Countermeasures Regulatory Science Program
			Objective 6.3 - Establish and Sustain an Extramural Medical Countermeasures Regulatory Science Program
			Objective 6.4 - Establish Processes to Maintain Effective Oversight of the Medical Countermeasures Regulatory Science Program
		Goal 7: Modernize the Legal, Regulatory, and Policy Environment for Effective Public Health Response	Objective 7.1 – Identify Priorities for Modernizing the Legal, Regulatory, and Policy Framework for Effective Public Health Response
			Objective 7.2 – Work with Enterprise Partners and External Stakeholders to Modernize the Legal, Regulatory, and Policy Environment for Effective Public Health
3.4 Managing for Organizational Excellence and	3.4.1 Recruit, develop, retain, and strategically manage a world-class workforce	Goal 1: Establish the Workforce and Infrastructure Necessary to Support the	Objective 1.1— Build the Workforce Necessary to Implement the MCMi

FDA Strategic Goals 2011 - 2015	FDA Long-Term Objectives	MCMi Strategic Goals 2012 - 2016	MCMi Key Objectives
Accountability		MCMi	Objective 1.2 – Develop and Sustain a Culture of Learning and Professional Development within FDA to Support the MCMi
	3.4.2 Ensure program integrity and responsible stewardship through effective administration of fiduciary responsibilities	Goal 2: Build and Sustain Integrated and Coordinated MCMi Programs	Objective 2.1 – Coordinate MCMi Program Implementation and Activities
			Objective 2.3 – Evaluate MCMi Program Execution
		Goal 6: Establish and Sustain a Medical Countermeasures Regulatory Science Program	Objective 6.4 - Establish Processes to Maintain Effective Oversight of the Medical Countermeasures Regulatory Science Program
	3.4.3 Implement an information technology modernization program to support state-of-the-art networked information and shared data resources	Goal 1: Strengthen the Workforce and Improve the Infrastructure Necessary to Support the MCMi	Objective 1.3 – Acquire the Infrastructure Necessary to Support the MCMi
	3.4.4 Ensure facilities infrastructure provides dynamic capabilities	Goal 1: Strengthen the Workforce and Improve the Infrastructure Necessary to Support the MCMi	Objective 1.3 – Acquire the Infrastructure Necessary to Support the MCMi
	3.4.5 Improve the management of FDA by providing ongoing oversight, evaluation, and analysis of policies and programs and by ensuring effective strategic communications	Goal 3: Actively Engage MCMi Stakeholders and Foster Transparency	Objective 3.3 – Clearly Articulate MCMi Program Priorities and Timelines
	3.4.6 Foster a culture of continual business process improvement to improve the overall operation and effectiveness of FDA	Goal 2: Build and Sustain Integrated and Coordinated MCMi Programs	Objective 2.3 – Evaluate MCMi Program Execution
3.4.7 Improve transparency, collaboration, and participation	Goal 3: Actively Engage MCMi Stakeholders and Foster Transparency	Objective 3.1 – Engage MCMi Stakeholders in Developing MCMi Priorities	
		Objective 3.2 – Establish and Maintain Strategic Partnerships to Further MCMi Program Goals and Objectives	
		Objective 3.3 – Clearly Articulate MCMi Program Priorities and Timelines	

Appendix E: Acronyms

ASPR	Assistant Secretary for Preparedness and Response
BARDA	Biomedical Advance Research and Development Authority
CBRN	Chemical, Biological, Radiological, and Nuclear
CBER	Center for Biologics Evaluation and Research
CDC	US Centers for Disease Control and Prevention
CDER	Center for Drug Evaluation and Research
CDRH	Center for Devices and Radiological Health
DARPA	Defense Advanced Research Projects Agency
DTRA-JSTO	Defense Threat Reduction Agency Joint Science and Technology Office
DHS	Department of Homeland Security
EID	Emerging Infectious Disease
EUA	Emergency Use Authorization
FDA	US Food and Drug Administration
HHS	US Department of Health and Human Services
JPEO-CBD	Joint Program Executive Office for Chemical and Biological Defense
MCMi	Medical Countermeasures Initiative
MIDRP	Military Infectious Diseases Research Program
NIH	US National Institutes of Health
NHSS	National Health Security Strategy
OCS	Office of the Chief Scientist
OCET	Office of Counterterrorism and Emerging Threats
OPEO	Office of Preparedness and Emergency Operations
ORA	Office of Regulatory Affairs
PHEMCE	Public Health Emergency Medical Countermeasures Enterprise
Action Teams	Public Health and Security Action Teams
PREP Act	Public Readiness and Emergency Preparedness Act
USAMMDA	US Army Medical Material Development Activity
WMD	Weapons of Mass Destruction



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