News Release

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Review calls for new federal approach to medical countermeasures

HHS Secretary releases review and recommendations driven by pandemic flu experience

U.S. Department of Health and Human Services Secretary Kathleen Sebelius today released an examination of the federal government' s system to produce medications, vaccines, equipment and supplies needed for a health emergency, known as medical countermeasures. *The Public Health Emergency Medical Countermeasure Enterprise Review: Transforming the Enterprise to Meet Long Range National Needs* reviews the process and makes recommendations for a better approach.

" Our nation must have a system that is nimble and flexible enough to produce medical countermeasures quickly in the face of any attack or threat, whether it' s a threat we know about today or a new one," Secretary Sebelius said. " By moving towards a 21st century countermeasures enterprise with a strong base of discovery, a clear regulatory pathway, and agile manufacturing, we will be able to respond faster and more effectively to public health threats."

Secretary Sebelius requested the comprehensive review when the department encountered challenges with the 2009 H1N1 pandemic flu vaccine, highlighting the need for a modernized countermeasure production process. The review covered the steps involved in the research, development, and FDA approval of medications, vaccines, and medical equipment and supplies for a health emergency.

The review identified a need to upgrade science and regulatory capacity at the FDA. As a result, HHS will make a significant investment to provide FDA scientists with the resources to develop faster ways to analyze promising new discoveries and give innovators a clear regulatory pathway to bring their products to market.

The review also found that U.S. must more quickly develop manufacturing processes that can be used for multiple medications or vaccines rather than processes that can be used to produce only one type of countermeasure. As a result of this finding, in the coming weeks HHS expects to release a draft solicitation for one or more Centers of Innovation for

Advanced Development and Manufacturing. The center(s) will focus on new manufacturing platforms that can produce a variety of countermeasures. The equipment and methods could provide a way to meet a surge in demand using facilities in the U.S. rather than relying on foreign manufacturing.

The review found that some of the most promising research and development on countermeasures is done by small, emerging biotech companies with little experience in large-scale manufacturing. Therefore, the Centers of Innovation for Advanced Development and Manufacturing will also serve as resources for young companies, helping them bring products to market and helping the U.S. government increase the number of new countermeasures available in an emergency.

The review made clear that the federal government must do a better job nurturing discoveries in their earliest stages to push them to greater maturity. Therefore, HHS will be creating new teams at the National Institutes of Health to identify promising research and facilitate its translation into vaccines, drugs, and treatments that keep Americans safe.

The review placed a special focus on the federal government's flu response, identifying a need to upgrade flu vaccine manufacturing – from modernizing ways to test a vaccine's strength, known as potency, to new methods to show that the vaccine is safe, as well as ways to produce the early "seed virus" for vaccines faster. Taken together, this will shave weeks of time off vaccine manufacturing. HHS will make investments in these areas as a result of the review.

The review also found that private companies have difficulty attracting investors in countermeasures where there is little or no market for these products outside of that currently needed for government stockpiles. As a result of this finding, HHS will explore ways to help small companies attract investors to develop promising countermeasures that have multi-use potential.

The HHS Assistant Secretary for Preparedness and Response led the review. All federal agencies working with medical countermeasures participated, including the Department of Homeland Security, Department of Defense, and HHS divisions of ASPR and ASPR's Biomedical Advanced Research and Development Authority, the National Institutes of Health, the Centers for Disease Control and Prevention, and the Food and Drug

Administration. The review also incorporated input from state and local health departments, two federal advisory committees of outside experts, industry groups, venture capital experts, and the Institute of Medicine.

Read the review and its recommendations at www.hhs.gov/secretary/.

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