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Chapter 1 : Pandemic Preparedness | Tools, Publications & Resources

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Page 51 Share Cite Suggested Citation: The National Academies Press. There are countless other dynamic pandemic threats, and Mansoura noted that creating a dynamic and strategic stockpile strategy should be considered. We are focused on the cost of buying a stockpile, but we are not necessarily focused on the cost of inaction. The recommendations from the White House focused on new or enhanced science and technological advances, including investment in new vaccine manufacturing platforms. The PCAST report also called for studies of the use of adjuvants and development of the FDA guidance on the use of adjuvants with seasonal influenza vaccines to improve vaccine efficacy. The H7N9 influenza response was an unprecedented response to a pre-pandemic threat, she said. Within 8 months of identifying the first case, HHS had a vaccine stockpile. Much was learned along the way about integrating new technologies, synthetic seeds, adjuvants, clinical trials, antigens, measured response, and stockpiling. This, she said, is a very challenging way to do business. Mansoura went on to note that the vaccine industry is among the first responders to pandemic influenza threats, and as a result, manufacturers need to have reliable pandemic plans that need to be exercised to ensure effective performance under pandemic conditions. Vaccine development is challenging, and the ability to produce seasonal influenza vaccine is not the only preparedness activity for a pandemic response. Mansoura highlighted the importance of testing and evaluating innovative technologies, strategies, and policies e. With each practice round, she said, we understand more about the nature of this dynamic threat. She advocated for the need to expand the strain-specific knowledge base and develop regulatory science to integrate new technologies. The GSK AS03 adjuvanted H5N1 vaccine was licensed in the United States in November , but the usual economic incentives that typically encourage companies to develop influenza vaccines did not apply for a vaccine to address the virulent strain of H5N1, Vaughn said. However, when H1N1 influenza emerged in , focusing on an H5N1 vaccine became difficult because all attention had shifted to the crisis at hand. In this case the BLA was ultimately submitted, but he cautioned that, in some cases, a project is never seen to completion without the immediate demand. Vaughn also stressed the importance of considering pediatric development from the onset. Increasing Capabilities Between Pandemics Looking beyond H5N1 and H1N1 influenza, Vaughn said there is a need to improve the overall response to pandemics and ways to address interpandemic drift. In this regard, GSK is striving to increase its capabilities in research, development, and manufacturing in order to respond to a number of biosecurity threats. Through recent acquisitions, GSK has also gained new platform technologies that may facilitate a faster response, both in terms of development and production. Vaughn noted that any plug-and-play rapid technology needs to be repeatedly successful with a variety of disease threats so that regulatory authorities and governments can make decisions in urgent situations to deploy vaccines under an EUA with little or no clinical data. One of the best ways to ensure that technologies are scalable is to start the development process within the final manufacturer from beginning to end. Funding rapid response technologies will depend on multiyear federal appropriations to allow for continued pharmaceutical development and prevent the delay or termination of viable projects once they have been started. Vaughn concurred with others that current contracting approaches can be complex and time consuming, especially when programmatic responsibilities fall within one company and financial responsibilities another. Page 54 Share Cite Suggested Citation:

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Chapter 2 : Pandemic Influenza | Pandemic Influenza (Flu) | CDC

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But sometimes the public health community is its own worst enemy in explaining the critical need for pandemic planning and preparedness and the price the world will pay for not preparing. A report last week from a leading nongovernmental agency³ which was lauded in the public health community, and rightly so, for the most part⁴ is a classic example of misunderstanding on this critical issue. Its key to success has been its ability to accelerate innovation across five areas of critical medical and public health practice⁵—vaccines, drugs, diagnostics, devices, and system and service innovations. The PATH report provides a number of important issues for addressing emerging infectious disease threats, and I applaud this crucial effort. The report, however, generates some confusion about preparing and responding to pandemics versus preparing and responding to epidemics. The report has everything to do with preventing major epidemics, or least reducing the impact of these events. Why does this matter? And that greatly hinders the public health, medical, and business communities⁶—as well as governments and philanthropic organizations⁷—from clearly articulating and acting on meaningful preparedness activities. The PATH report, if it commented only on epidemic preparedness, would be a home run. But by stating that the recommendations in the report will stem the risk of the next pandemic, the report ends up contributing to the ongoing mischaracterization about what pandemic preparedness truly means and what is needed to reduce any impact of a future pandemic. Understanding the difference between a pandemic and epidemic is absolutely necessary for consequential preparedness and response planning and action to be accomplished. Let me illustrate the difference between the two and why it matters. First, a pandemic in public health terms is defined as: An epidemic occurring worldwide or over a wide area crossing international borders and usually affecting a large number of people. A Dictionary of Epidemiology. WHO, Collateral damage, vanishing key drugs and products A pandemic puts the entire world at risk of a markedly increased occurrence of severe morbidity and mortality. The collateral damage from a pandemic is twofold. It should never surprise us what we can do in the name of fear. And remember the entire world will be in the soup at the same time. The United States and other developed countries will not be sending public health first responders and medical supplies to developing countries in response to the pandemic. We will keep everything at home for our own needs. Second, the simultaneous occurrence of the pandemic worldwide means that the supply chains for critical products like life-saving drugs and essential medical supplies will be quickly threatened. For example, with our current global just-in-time economy, most drugs and medical products that we need every day are made in China and India; there are no stockpiles of these items anywhere in the world. These drugs and products will quickly disappear or be in very short supply. Because of that, another wave of severe illnesses and deaths will occur among patients with other illnesses like cancer, heart disease, diabetes, and immunocompromised conditions and acute events like trauma. Our War Against Killer Germs,⁴ there are only two infectious disease situations that can be considered inevitable, serious pandemic threats: An influenza pandemic will unfold quickly over a few months when the next new animal strain of influenza acquires the ability to be transmitted by humans to humans. On the other hand, antimicrobial resistance is a pandemic already beginning to unfold worldwide but now occurring at a "glacial tsunami speed. The Review on Antimicrobial Resistance report⁴ concluded that, by , antimicrobial-resistant infections could cause as many as 10 million deaths per year worldwide. Yes, this type of pandemic will look and feel different than one caused by a like influenza virus, but nonetheless it will have a catastrophic impact. But routine surgery will possibly become fatal, immunocompromised patients will face potential deadly infections daily, and previously uncomplicated puncture wounds and abrasions take on a whole new life-threatening dimension. In short, we will live in an infectious disease world more like the one that our

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ancestors lived in during World War I than the one we live in today. Some will disagree with my assessment of what constitutes a pandemic and conclude that other infectious diseases also do or can cause them, like HIV. Other diseases certainly cause global, extensive damage, and other worrisome pathogens could certainly one day go global. But influenza and "superbugs" remain the two greatest looming pandemic threats. No intent to downplay regional threats The PATH report does highlight the critical importance of early and effective detection and response to epidemic diseases. These diseases are defined as: The occurrence in a community or region of cases of illness or health-related events clearly in excess of normal expectancy A Dictionary of Epidemiology. In Deadliest Enemy, we provide an additional definition for an epidemic, discerning those that are sometimes considered as pandemic in nature and those that fit into the more conventional outbreak category. We classify diseases of critical regional importance as: An epidemic usually caused by a new pathogen ie, new disease , occurring in one or more regions of the world but not a pandemic. These diseases have the potential to cause rapidly increasing morbidity and mortality, as well as economic and sociopolitical disruption, but only at the national or regional level. Current examples of such diseases include those noted above. Critical product global supply chains and international trade and travel were never at risk. Yet all countries need to have the laboratory, trained workforce, surveillance, and emergency operations capabilities to prevent, detect, and respond to these disease threats. Unfortunately, the US government investments in GHSA-related activities have relied primarily on supplement funds, which are slated to end soon. In the Path press release to its report last week, Carolyn Reynolds, vice president of policy and advocacy at PATH, said, "US leadership and funding has catalyzed significant global progress on pandemic prevention since the Ebola crisis, and has mobilized more than 60 nations to strengthen preparedness through the Global Health Security Agenda. GHSA support, as essential as it is to addressing diseases of critical regional importance, will not begin to touch the most minimal of required preparedness activities for a pandemic. Confusing these two requirementsâ€”preparedness for a pandemic versus an epidemicâ€”is a costly mistake for public health. Pandemic clocks are ticking To prepare for a potentially catastrophic influenza pandemic we need an immediate "Manhattan-like Project" to develop and manufacture new game-changing influenza vaccines also referred to as universal vaccines and vaccinate billions of people with them before or very shortly after the emergence of the new pandemic virus. Until we prioritize the influenza vaccine effort, nothing we will do with GHSA-related activities will make us better prepared for pandemic influenza. Early detection and rapid response of an emerging pandemic flu virus is often cited as a step in stopping the next pandemic. This is simply a pipedream. Influenza virus, because of its infectiousness, will be around the world before we detect and identify it. In , the H1N1 pandemic virus was retrospectively recognized to be in 27 countries before it was first identified in Mexico and the United States. A similar case can be made for why GHSA activities will not make a dent in the evolving crisis of antimicrobial resistance. Infection surveillance by itself will do little to slow down the development and spread of antimicrobial-resistant infections. Nor will GHSA-related funding support major international antimicrobial stewardship programs for humans and animals, new vaccines to prevent resistant infections, new antibiotic development, or the research and development necessary to identify ancillary treatments using such agents as phages. To date we are not doing a very good job of understanding that point and responding accordingly. The PATH report is a clear reminder. Healthier world, safer America: A US government roadmap for international action to prevent the next pandemic. Oct 24, [Full text] Porta M ed. A dictionary of epidemiology. Oxford, [webpage] WHO. What is a pandemic? Mar [webpage] Osterholm MT. Global health securityâ€”an unfinished journey. US leadership and sustained funding urgently needed to prevent pandemics. The compelling need for game-changing influenza vaccines: Oct 15, [Full text] Share this page:

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