Film Screenings
Marion Gruber: Preparedness Is Prevention
Frequently Asked Questions (FAQ)

How, when, and why was the FDA established?
After multiple incidents of injury or illness caused by a lack of oversight and regulation in medical products, cosmetics, and food processing, the U.S. government established the Pure Food and Drugs Act and the Meat Inspection Act in 1906 to outlaw interstate sale of inaccurately branded or unsafe products and foods. These new rules were enforced by the U.S. Department of Agriculture's (USDA) Bureau of Chemistry until 1927, when a new government agency, called the Food, Drug, and Insecticide Administration was created to better manage these responsibilities, and was later renamed the Food and Drug Administration (FDA).
For additional information, check the article, "A Closer Look: The History and Authority of the FDA."

What kinds of backgrounds do people working in the FDA have?
The FDA's regulatory responsibilities are very broad, so people with many different backgrounds work there. Most have some education or experience in the fields of healthcare, science, and engineering, but the institution oversees a wide variety of products, so the positions and roles at the FDA also vary. For example, some FDA employees have training in areas such as medicine, scientific research, economics, behavioral science, biology, mathematics, and statistics. Roles include medical officers, analysts, pharmacists, inspectors, veterinarians, and chemists. There are also employees who operate special equipment, manage offices and labs, advise on policy, monitor soil conservation, oversee crop and animal health, and much more.

What defines a biological product?
Biological products are products produced in a living system. Examples include blood, tissues, therapeutic proteins, monoclonal antibodies, and vaccines. Reference the FDA document, "Biological Product Definitions," to learn more about this type of product.

How does vaccination differ in developing countries?
Many countries do not have the number of vaccines available that wealthier countries do. This is the case for several reasons, including limitations related to vaccine development, logistics, and administration. First, many countries lack the resources to develop or produce their own vaccines. Second, even when vaccines are available, many countries do not have the financial resources to purchase vaccine doses for their entire population. Finally, lack of healthcare infrastructure can also affect vaccine delivery, particularly in areas without roads or electricity or in places experiencing military conflict or natural disasters. A community's trust in vaccines and those administering them is also critical to the success of vaccination programs in other countries.

Has the ring vaccination strategy ever been implemented in other places and/or for other diseases?

The ring vaccination strategy was pioneered with smallpox in several places and later used during a 2014 Ebola outbreak in West Africa.

Can we use 'Operation Warp Speed' as a model for getting other vaccines developed and approved quickly?

Operation Warp Speed (OWS) was one of the most successful government public health initiatives in modern history, but it was an emergency measure designed to address a crisis rather than providing a pathway for all new vaccine development. It was effective because the U.S. government invested resources to de-risk what is a very expensive process for manufacturers. They did this by agreeing to purchase doses of vaccine even if the vaccine did not work. The government would not normally make such an offer, and manufacturers would not normally invest large amounts of resources into a product that they don't know will work. Rather, manufacturers typically develop a product in stages and make determinations regarding whether the product will move ahead in development at each stage. For these reasons, OWS is not a viable model in a non-emergency situation.

Do governments have plans for future pandemics?

Scientific collaboration, surveillance of potential pandemic-causing pathogens, and pandemic preparedness and planning are all important aspects of being ready for a future pandemic. And, because pandemics are by definition global in nature, the best-case scenario would be for this work to occur at the regional and global level. However, the effectiveness and longevity of such efforts are often determined by political and societal factors that are beyond the reach of scientists and public health officials.

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