



JUST THE FACTS

1ST VACCINE DEVELOPED

was for smallpox in 1798 and the disease has been eradicated¹

1ST THERAPEUTIC CANCER VACCINE

approved in 2010¹

MORE THAN 2/3

of new vaccines in the last 25 years have been developed in the U.S.¹

124 VACCINES

in development for infectious diseases²

105 VACCINES

in development for cancer²



MEDICINES IN DEVELOPMENT FOR VACCINES

More Than 250 Vaccines in Development Pipeline; Research Focuses on Prevention and Treatment

Vaccines have played a critical role in reducing the threat, and in many cases eliminating any reported cases, of some of the world's most devastating infectious diseases. In the United States, transmission of poliovirus, measles and rubella have been eliminated, while smallpox has been eliminated worldwide. These tremendous achievements in biomedical research and public health have spanned more than 200 years of research and development (R&D), protecting millions of people from preventable illness.

Through our growing understanding of how disease works at the molecular level and advances in technology, many new vaccines have been developed to both prevent and treat a variety of illnesses. For example, since the introduction of the first human papillomavirus (HPV) vaccines, prevalence of HPV infection has dropped 64 percent among girls ages 14 to 19, helping to protect against cervical cancer.³ Researchers have also discovered a vaccine to guard against the anthrax virus before exposure, and a vaccine to prevent pneumococcal infections in high-risk populations.

But vaccines are not only used to prevent infectious diseases; some are used as treatments for disease. For instance, "immunotherapeutic" vaccines activate the body's immune system, helping it to recognize and attack disease. Immunotherapeutic vaccines have shown promise in treating cancer, with one vaccine approved in the United States for the treatment of prostate cancer and many more vaccines in development.

Today, 258 vaccines are in development by biopharmaceutical research companies for infectious diseases. All of the vaccines in

development are either in clinical trials or awaiting review by the U.S. Food and Drug Administration.

Challenges in Vaccine Development

Even with the progress made, vaccines face a particularly challenging R&D process. The rapid pace of science has revealed exciting new biological processes by which vaccines can work, but has also added to the complexity of developing and manufacturing these vaccine candidates. As with the development of all drugs, vaccines must undergo extensive clinical testing to demonstrate safety and efficacy before they can be approved for use by the general public.

Conducting clinical research for vaccines presents unique challenges, in that the vaccine must be given to healthy individuals to demonstrate safety, and recruitment for these studies can often take significant time. Assessing efficacy can be especially difficult for infectious disease vaccines, due to the sporadic and unpredictable nature of the way many of these illnesses spread (like Zika and Ebola viruses). It can also be a hurdle to find patients with the illness for clinical trials. Where it would be unethical to conduct efficacy studies in humans, the FDA may allow the conduct of special studies that use animal modeling, as in the development of an anthrax vaccine.

Researchers at America's biopharmaceutical companies and across the R&D ecosystem are pursuing new techniques and strategies in vaccine development to address these and other challenges, creating tremendous opportunities to protect against many more life-threatening diseases in the future.

For a complete list of the 258 medicines in development, please visit: <http://phrma.org/sites/default/files/pdf/medicines-in-development-drug-list-vaccines.pdf>

Sources:

1. Vaccine Fact Book 2013, PhRMA
2. 2016 Update: Vaccines in Development, PhRMA
3. A Decade of Innovation in Cancer, PhRMA