

## Why GAO Did This Study

Production delays for the 2009 H1N1 pandemic vaccine using the current egg-based production technology heightened interest in alternative technologies that could expand the supply or accelerate the availability of influenza vaccine. Within the federal government, the Department of Health and Human Services (HHS) and the Department of Defense (DOD) support the development of technologies that can be used in producing influenza vaccines. HHS's Food and Drug Administration (FDA) reviews licensing applications for new vaccine, and the Department of State is the U.S. diplomatic liaison to the international entity that declares worldwide pandemics.

GAO was asked to review federal activities for the development of alternative technologies used in producing influenza vaccine. This report examines (1) federal funding from fiscal year 2005 through March 2011 for alternative technologies and the status of manufacturers' efforts, (2) challenges to development and licensure identified by stakeholders, and (3) how HHS is addressing those challenges.

GAO reviewed HHS and DOD documents and funding data. GAO also interviewed stakeholders, including manufacturer representatives, industry associations, and other experts on challenges to development and licensure. GAO interviewed HHS officials on how they are addressing those challenges.

# INFLUENZA VACCINE

## Federal Investments in Alternative Technologies and Challenges to Development and Licensure

### What GAO Found

From fiscal year 2005 through March 2011, HHS and DOD provided about \$2.1 billion in funding for the development of alternative technologies that could potentially expand the supply or accelerate the availability of influenza vaccine. Specifically, HHS and DOD have funded two alternative production technologies—cell-based and recombinant technologies, which produce vaccine in cells instead of eggs—and adjuvants, which can reduce the amount of vaccine needed to stimulate an immune response. HHS's funding supports the development of a new influenza vaccine using alternative technologies with the goal of manufacturers submitting licensing applications to FDA. DOD's funding supports the research and development of a technology that can make various vaccines, including influenza vaccines. HHS awarded \$1 billion in contracts to manufacturers to develop cell-based technology, with manufacturers making progress toward licensure. HHS and DOD funded \$296.5 million in contracts and \$86.9 million in technology investment agreements, respectively, for the development of recombinant technology. HHS also awarded about \$152 million in contracts for the development of adjuvanted influenza vaccines. Two manufacturers receiving HHS funds plan to submit licensing applications for their adjuvanted vaccines to FDA within the next 2 years.

Some stakeholders said low demand, high research and development costs, and regulatory challenges can hinder the development and licensure of new vaccines using alternative technologies. For example, despite the United States using more seasonal vaccine than any other country, some stakeholders told us that low vaccination rates can decrease incentives for manufacturers to develop new influenza vaccines using alternative technologies because there is not sufficient demand for new products. Some stakeholders said high research and development costs can also decrease manufacturers' incentives; however, HHS noted that increased investments in this area have generated a significant interest in this type of research and development. Some stakeholders also told us that some of FDA's guidance documents are not sufficiently comprehensive. FDA officials told us that their guidance documents cannot cover all possible scenarios; thus, they regularly meet with manufacturers to discuss issues and provide advice.

HHS is addressing challenges in the development and licensure of new influenza vaccines using alternative technologies. For example, HHS intends to fund the establishment of specialized facilities that will provide support and expertise to manufacturers. Additionally, through FDA, HHS plans to facilitate the review of licensing applications for new influenza vaccines using alternative technologies and to enhance FDA's staff expertise.

HHS, DOD, and the Department of State reviewed a draft of this report. In commenting on a draft of this report, HHS and DOD agreed with GAO on its findings. The Department of State did not provide comments. HHS provided suggestions to clarify the discussion.