Since January 2020 Elsevier has created a COVID-19 resource centre with free information in English and Mandarin on the novel coronavirus COVID-19. The COVID-19 resource centre is hosted on Elsevier Connect, the company's public news and information website.

Elsevier hereby grants permission to make all its COVID-19-related research that is available on the COVID-19 resource centre - including this research content - immediately available in PubMed Central and other publicly funded repositories, such as the WHO COVID database with rights for unrestricted research re-use and analyses in any form or by any means with acknowledgement of the original source. These permissions are granted for free by Elsevier for as long as the COVID-19 resource centre remains active.
Vaccine supply, demand, and policy: A primer
Jagannath M. Muzumdar and Richard R. Cline

Abstract

Objective: To provide an overview of supply and demand issues in the vaccine industry and the policy options that have been implemented to resolve these issues.

Data sources: Medline, Policy File, and International Pharmaceutical Abstracts were searched to locate academic journal articles. Other sources reviewed included texts on the topics of vaccine history and policy, government agency reports, and reports from independent think tanks. Keywords included vaccines, immunizations, supply, demand, and policy.

Study selection: Search criteria were limited to English language and human studies. Articles pertaining to vaccine demand, supply, and public policy were selected and reviewed for inclusion.

Data extraction: By the authors.

Data synthesis: Vaccines are biologic medications, therefore making their development and production more difficult and costly compared with “small-molecule” drugs. Research and development costs for vaccines can exceed $800 million, and development may require 10 years or more. Strict manufacturing regulations and facility upgrades add to these costs. Policy options to increase and stabilize the supply of vaccines include those aimed at increasing supply, such as government subsidies for basic vaccine research, liability protection for manufacturers, and fast-track approval for new vaccines. Options to increase vaccine demand include advance purchase commitments, government stockpiles, and government financing for select populations.

Conclusion: High development costs and multiple barriers to entry have led to a decline in the number of vaccine manufacturers. Although a number of vaccine policies have met with mixed success in increasing the supply of and demand for vaccines, a variety of concerns remain, including developing vaccines for complex pathogens and increasing immunization rates with available vaccines. New policy innovations such as advance market commitments and Medicare Part D vaccine coverage have been implemented and may aid in resolving some of the problems in the vaccine industry.

Keywords: Vaccines, medication supply, medication demand, drug policy.

J Am Pharm Assoc. 2009;49:e87–e99. doi: 10.1331/JAPhA.2009.09007

Learning objectives
- Describe the vaccine research and development process.
- List three factors that have affected vaccine supply.
- List three factors that have affected vaccine demand.
- Describe at least three “push” strategies in vaccine policy.
- Describe at least three “pull” strategies in vaccine policy.

ACPE Activity Type: Knowledge-Based
Currently, vaccine-preventable disease levels are at near record lows. This was not the case at the beginning of the 20th century, when infectious diseases were the greatest threat to public health and the leading cause of death in the United States and elsewhere. During that period, few effective treatments or measures were available for preventing large numbers of deaths from these diseases, despite the fact that in 1796, Edward Jenner performed the Western world’s first vaccination. During the 20th century, the “Golden Age” of vaccines witnessed the development and acceptance of vaccines for diphtheria (discovered in 1921, but not used widely until the 1930s), tetanus toxoids (1924), influenza vaccine (first used in 1945), polio vaccine with inactivated virus (1955) and live attenuated virus (1961), measles (1963), and combination measles–mumps–rubella (MMR) vaccine (1971). Estimates indicate that these vaccines have prevented more than 3 million deaths per year worldwide from infectious diseases.

Vaccines have been well documented as one of the greatest achievements of medicine and are among the most cost-effective interventions in public health. For example, Zhou et al. evaluated the economic impact of the routine U.S. childhood immunization schedule. They reported that for every dollar invested in childhood vaccination against nine vaccine-preventable diseases, $5.80 was saved in direct medical care costs. Further, when indirect benefits were taken into account, such as parental absenteeism costs incurred in caring for ill children, the amount saved rose to $17.70. Salo et al. assessed the cost effectiveness of influenza vaccination of children aged 6 months to 13 years and found that influenza vaccination for healthy children (all age groups) was more effective and less costly than not vaccinating children against influenza. These findings are due in part to the fact that many vaccines result in long-term or lifelong protection of the recipient and people they contact. Through the process of “herd immunity” and “herd effect,” vaccines protect not only those who receive them but also those who cannot or do not receive the vaccine because of medical conditions, parental indifference, or religious or philosophical objections to vaccinations. (The probability of unvaccinated individuals contracting a disease when part of a larger group with a certain seroprevalence [herd immunity] is called the herd effect.) However, of note, if a susceptible person strays outside the herd or if the herd changes, that person is still susceptible. Compared with pharmaceutical products, the number of lives saved per invested dollar is substantial. Economists have reported that this increased life expectancy has made a considerable contribution to economic growth.

In fact, it has been argued that more than one-half of the growth in real income in the first half of the 20th century is attributable to the declining mortality associated with the discovery of vaccines. Mass immunization programs have resulted in 100% eradication of smallpox from the world, elimination of diphtheria and polio, and 99% eradication of measles, mumps, and rubella in the United States. Haemophilus influenzae type b (Hib) vaccines have been successful in reducing childhood mortality. In addition, vaccination of healthy adults has resulted in decreased work absenteeism and decreased use of health care resources, including less use of antibiotics.

Nevertheless, this success of vaccines is threatened because of several factors. Problems related to vaccine research and development (R&D), manufacturing complexities, supply and distribution, safety issues, and financing have become areas of major concern. Symptoms of this crisis include a decline in the number of vaccine producers from 26 in 1967 to 5 in 2004 and a decline in the number of licensed vaccine products from 380 in 1967 to 51 in 2005. (Some of these are combination products.) Eight of these vaccine products are currently produced by five major companies: Sanofi Pasteur, Chiron (a business unit of Novartis Vaccines and Diagnostics), GlaxoSmithKline, Merck Vaccines & Infectious Diseases, and Wyeth Vaccines. Should any one of these suppliers cease production, it could take years for a replacement vaccine to be licensed and become available publicly.

Beginning in late 2000, the United States faced shortages of 8 of the 11 recommended childhood vaccines. Affected vaccines included diphtheria–tetanus–acellular pertussis (DTaP), MMR, varicella, and pneumococcal conjugate vaccines. Suspension of production of PedvaxHIB and COMVAX by Merck and a subsequent voluntary recall of certain lots of both vaccines on December 13, 2007, led to a considerable disruption in the supply of Hib-containing vaccines. Thus, the dearth of suppliers appears to have affected the stability of vaccine supply.
Compounding these problems, the epidemiology of several diseases is changing. West Nile virus killed at least 98 people in the United States in 2007, and cases of Dengue fever, formerly known only in tropical areas, have been reported in Texas. The Centers for Disease Control and Prevention (CDC) received reports of 1,528 cases of malaria in 2005 among individuals in the United States or its territories. This total represents an increase of 15.4% from the 1,324 cases reported for 2004. With rapid intercontinental transportation and a larger global population, diseases can travel and spread to many countries in little time. CDC issued a health advisory on April 2, 2008, regarding a measles outbreak in Arizona that was linked to importation of the measles virus from Switzerland. The first case, with rash onset on February 12, 2008, occurred in an adult visitor from Switzerland who was hospitalized with measles and pneumonia. In another dramatic example, severe acute respiratory syndrome spread from Asia to North America quickly, eventually infecting 8,098 people worldwide, of whom 774 died, when a 78-year-old woman carried the infection from Hong Kong to Toronto, where it eventually caused 44 deaths.

**Objectives**

The current report seeks to provide an overview of the vaccine industry and public policy affecting it. Specifically, we sought to (1) highlight issues faced by vaccine manufacturers that make the vaccine industry a unique segment of the prescription drug industry, (2) provide an overview of the vaccine market with regards to vaccine supply and demand, and (3) provide an overview and critical evaluation of policy options proposed and implemented by various parties to address vaccine supply and demand problems.

**Methods**

This research consists of a narrative literature review and critical analysis of the information retrieved. Search criteria were limited to English language and human studies. Keywords used for the search included vaccines, immunizations, supply, manufacturing, demand, policies, and push–pull solutions. Indices such as Medline, Policy File, and International Pharmaceutical Abstracts were searched and the results augmented with reports produced by government agencies (e.g., Government Accountability Office) and independent think tanks. A variety of sources were reviewed, including reports from academic journals and current texts on vaccine history and policy. Articles pertaining to vaccine demand, supply, and public policy were selected and reviewed for inclusion in the current work.

**Vaccine supply**

Vaccines are biologics that introduce “weakened or killed disease-causing bacteria, viruses, and/or their components” or toxoids into a person or animal to stimulate an immune reaction that the body will remember if exposed to the same pathogen in the future. This unique property sets them apart from other segments of the pharmaceutical industry, such as “small-molecule” or products derived from traditional organic chemistry methods and from other biologically derived products used in a therapeutic capacity. As such, when a private firm considers entering the vaccine market, they face several important barriers to entry, some of which are shared with these product segments and others that are unique to vaccines. These are discussed in detail below.

**Vaccine R&D**

New vaccines begin with the recognition of an infectious disease burden worth preventing. Basic research regarding pathogens and immune responses, often funded by the National Institutes of Health (NIH), vaccine manufacturers, and nonprofit organizations such as the Bill & Melinda Gates Foundation, is performed mainly at universities. Certain vaccines for yellow fever, typhoid, and anthrax are funded and developed in the Department of Defense. Before entering clinical trials, prototype vaccines undergo toxicity testing that is conducted in a Good Laboratory Practice–compliant laboratory. Private firms then build on this knowledge to develop clinically feasible vaccine products and shepherd them through clinical testing. The vaccine’s manufacturer then must submit a Biological License Application (BLA) to the Food and Drug Administration (FDA) for evaluation and approval before marketing. The approval process tests extensively for safety and efficacy, along with purity and absence of contaminants. If data raise serious concerns about product safety or efficacy during any phase, FDA may request additional information or studies or may halt ongoing clinical studies. The entire research, development, and approval process may require 10 years or more. Estimates of the cost of this process range from $110 million to $802 million (US$ 2000).

Table 1 summarizes information on the different phases in vaccine research.

**Manufacturing complexities.** Although vaccine manufacturing regulation originally was controlled by the U.S. Public Health Service under the Biologics Control Act of 1902, this authority now rests with FDA. The majority of vaccines approved by FDA are manufactured from live (attenuated) or killed (inactivated) organisms. Some are based on partially purified components of an organism such as diphtheria and tetanus, and a handful are recombinantly produced, such as the hepatitis B vaccine. Vaccines are manufactured by at least three methods: egg-based (e.g., influenza vaccine), cell-derived (e.g., polio vaccine), or recombinant (e.g., hepatitis B vaccine). For bacterial vaccines, the bacterial pathogens are grown in bioreactors using media developed for optimizing the yield of the antigen (e.g., Hib) (Figure 1).

As such, small deviations in the manufacturing process can have a major impact on the potency and/or purity of these products. Thus, FDA production facility requirements are rigorous, and these stringent regulatory hurdles add to the production costs of vaccines. Because new vaccines generally are more complex than older products, vaccine suppliers face increasingly stringent regulation of manufacturing facilities even after a vaccine is approved. Suppliers undergo frequent inspections of their production facilities by each country in which the vaccine product is licensed and by FDA. Individual product batches require separate approval for release, and slight modifications...
to production processes or the packaging of products may trigger expensive and time-consuming product reviews.\textsuperscript{33} FDA also requires frequent upgrades of vaccine production facilities to reflect state-of-the-art manufacturing processes. Recently, FDA quality control inspections led to Merck's recall of 1.2 million doses of childhood vaccines to protect against meningitis, pneumonia, and hepatitis B because of contaminated manufacturing equipment.\textsuperscript{21,34} The recall involved 11 lots of the Hib vaccine Pediaflexib and two lots of a combination vaccine for both Hib and hepatitis B sold under the brand name Comvax.\textsuperscript{34}

**Market size problems**

Most vaccine manufacturers are profit-seeking firms, not public health agencies. As such, they are not obligated to develop vaccines.\textsuperscript{18} These manufacturers face the decision of whether to invest large amounts of capital in vaccine R&D for a small portion of the global pharmaceutical market representing approximately 1.5% of all pharmaceutical revenues.\textsuperscript{35} Most vaccines are not "blockbuster" pharmaceuticals that yield large profits or returns on investment. Although pharmaceuticals in the aggregate are a large market representing approximately $340 billion annually ($US 2000) worldwide, sales of vaccines are estimated at just $4.8 billion to $6 billion per year, with about one-quarter of total sales in the United States.\textsuperscript{36} This $6-billion market is controlled primarily by the five major manufacturers. Moreover, most vaccines are used at most several times in a lifetime, whereas therapeutic biologics and small-molecule drugs often are used every day. Thus, markets for small-molecule and biotechnology drugs treating chronic diseases are considerably more attractive to investors than vaccines.

**Safety and liability issues**

Safety concerns, both real and unsubstantiated, continue to be a threat to the present vaccine market. Vaccines are biologics and therefore are more difficult to produce with consistent precision than small-molecule drugs. They are subject to variability in the manufacturing process and require careful handling.\textsuperscript{15} Despite intensive quality regulation, the biologic nature of vaccines, inherent uncertainties in manufacturing, and safety concerns make vaccine manufacturers targets for tort litigation for patients suffering an illness after vaccination. A surge of lawsuits in the 1980s resulted in serious concerns regarding the supply of the DTaP combination vaccine, as well as other vaccines.\textsuperscript{33}

Concerns have been raised in the United States regarding the safety of thimerosal, which is a mercury-containing preservative used in some vaccines. Another concern is with the false association of MMR combination vaccine and autism in children. However, to date, studies have not shown an association between neurodevelopmental disorders and thimerosal.\textsuperscript{37,38} In addition, no evidence has been found demonstrating a link between vaccination with the MMR vaccine and autism in children.\textsuperscript{39}

Rotashield, a rotavirus vaccine licensed in 1998, was permanently withdrawn in 1999 when it was found to cause a rare but serious intestinal obstruction in some recipients.\textsuperscript{40} These safety concerns have been a reason for a change in the attitudes of some parents regarding having their children immunized.\textsuperscript{3} Taken together, liability issues and safety concerns provide important disincentives to manufacturers considering developing and manufacturing vaccines.

**Vaccine demand**

Immunization rates for recommended vaccines among children in the United States have been consistently high. The immunization regimen was simple, costs incurred were small, and many (if not most) public schools required proof of immunization as a condition of attendance.\textsuperscript{35,41} Most children received vaccines from private practitioners with their parents paying for this service through third-party insurance or out of pocket. Underprivileged children often received free immunizations from local health departments, with costs paid from general revenue funds at the local and state level.

**Vaccine costs**

In the 1990s, the cost of recommended immunizations began to increase, primarily as a result of the introduction of

| Phase | Purpose | Approximate time required (years in each phase) |
|-------|---------|-----------------------------------------------|
| Preclinical phase (animal studies) | Help in evaluating dosing and schedules | 5 |
| Phase I | Safety and immunogenicity studies performed in a small number of closely monitored patients | 4 |
| Phase II | Dose-ranging studies; may enroll hundreds of patients | |
| Phase III | Studies typically enroll thousands of patients and provide the critical documentation of effectiveness and important additional safety data required for licensing | 3 |
| BLA | During this stage, the proposed manufacturing facility undergoes a preapproval inspection during which production of the vaccine as it is in progress is examined in detail | 1 |

Abbreviation used: BLA, Biological License Application.

Adapted from references 2 and 30.
new vaccines (e.g., acellular pertussis vaccines, varicella vaccine). These costs increased more in the early years of the current decade with the introduction of pneumococcal vaccine and meningococcal conjugate vaccine. The cost of the rotavirus vaccine from Merck is $69.59 per dose (three doses recommended). Table 2 displays a comparison of the costs for recommended vaccines for children 0 to 6 years of age for 1987 and 2008. According to the 2007 National Immunization Survey (NIS) for children, although the number of children vaccinated had reached record highs, for some vaccines, coverage among children was lower and varied with poverty level. Also, according to recent CDC data, substantial gaps continue to remain in vaccination coverage for adults. These shortcomings may be due in part to the increasing costs of vaccines.

Vaccine financing

Given the increasing costs associated with vaccination and the increasing number of vaccine doses, financing for this service has taken on greater importance. Currently, U.S. vaccine financing is a joint responsibility shared by the private and public sectors. As of 2002, more than one-half of the vaccines recommended for children were purchased through federal contract, whereas vaccines for adults typically are covered by private insurance. Private health plans often have insurance coverage for vaccines. However, some children enrolled in private health plans do not have coverage for vaccines and are considered underinsured for immunization.

Finally, some studies have shown that health care provid-

ers have concerns regarding the costs of purchasing and administering vaccines and their level of reimbursement from public and private insurers. Providers must order and purchase many vaccines (e.g., influenza) months before they are administered, resulting in substantial capital outlay coupled with delayed reimbursement. Recently, Freed et al. conducted a survey exploring physicians’ perspectives on reimbursement for childhood immunizations. Approximately one-half of the study respondents reported financial reasons and low profit margins from immunizations as factors affecting their purchase and administration of vaccines. These authors concluded that physicians who provide vaccines to children and adolescents are dissatisfied with third-party reimbursement levels and the increasing financial strain on their practices from immunizations. Thus, increasing vaccine prices, a greater number of vaccine doses, and declining provider reimbursement for these products appear to be factors constraining both patient and provider demand for these products.

Parental attitudes toward vaccine safety

Parental beliefs regarding vaccine safety and efficacy have led to a decrease in the demand for recommended vaccines. For example, Kennedy et al. reported that 12% of parents with a child still living at home in 2002 were opposed to compulsory vaccination laws and that this opposition was associated significantly with beliefs in the safety and efficacy of vaccines. In an analysis of the 2003–2004 NIS, Gust et al. found that more than 13% of parents had delayed their child's

Figure 1. General steps in vaccine manufacturing

Abbreviations used: C, cell-derived; E, egg-based; R, recombinant.
Adapted from references 4 and 31.

---

Generation of the antigen

- Generation of the pathogen itself. Viruses are grown on cells, either primary cells such as chicken fibroblasts (e.g., influenza), or on continuous cell lines such as MRC-5 (e.g. hepatitis A).
- Bacterial pathogens are grown in bioreactors using medium developed for optimizing the yield of the antigen (e.g., Haemophilus influenzae type b).
- In cell-based technique, mammalian kidney cells are used in this step.

Isolation of the antigen

- Isolation of free virus from cells.
- Isolation of secreted protein from the cells.

Purification of the antigen

- Inactivated viral vaccine; there may simply be inactivation of isolated virus with no further purification.
- For recombinant vaccines, this involves many unit operations of column chromatography and ultrafiltration.

Formulation of the vaccine

- Formulated vaccine may include an adjuvant to enhance the immune response, stabilizers to prolong shelf life, and/or preservatives to allow multidose vials to be delivered.
first vaccination and that 6% had refused vaccination. Concerns about vaccine safety were associated significantly with both of these behaviors.

**Vaccine policy**

As described above, at least two important positive externalities (i.e., benefits accruing to individuals other than the original supplier and patient)\(^52\) can be attributed to vaccines: (1) vaccination helps protect even those individuals not receiving the vaccine by reducing the transmission of a given disease and (2) reductions in the burden of infectious disease in the 20th century have been linked to considerable economic expansion during that period. However, vaccine manufacturers cannot capture these third-party benefits. This problem, together with other supply-side (e.g., barriers to entry) and demand-side (e.g., vaccine financing) issues have resulted in market failure (i.e., a quantity and variety of vaccine products supplied that is below the social optimum) in the vaccine market. Thus, both government policy makers and various health philanthropies have implemented a number of proposals aimed at overcoming these issues. These policies can be described as either “push” or “pull” strategies.\(^2\) Push strategies seek to address supply-side issues in the vaccine market by providing direct assistance to ease the burden of research, development, and production costs, whereas pull strategies are designed to manipulate demand for vaccines, thereby improving the likelihood of a return on investment by increasing the number of immunizations administered. Thus, push mechanisms can be thought of as funding inputs, while pull mechanisms can be thought of as paying for outputs.

**Push mechanisms**

**Financial incentives.** Large, government-funded research and academic institutions play a vital role in basic vaccine research. Public funding of vaccine discovery and early developmental efforts coupled with tax subsidies to private firms can reduce manufacturers’ upfront financial outlays substantially and alter return on investment calculations for vaccine research favorably.\(^2,3,28\) For example, NIH sponsors approximately one-third of all vaccine-related basic research. Most of this funding is in the form of grants to academic institutions and health-related agencies.

The Bioshield Act of 2004 (P.L. 108-276) conferred more authority and leadership in the vaccine development effort on the National Institutes of Allergy and Infectious Diseases (NIAID).\(^3,3,3\) The law increased the federal share of bioterrorism projects and allowed NIAID to hire technical experts and to award grants and contracts for advancing R&D efforts for specific vaccines. To date, funds from the act have provided support for the R&D of new smallpox and anthrax vaccines.\(^3,4\) After the Bioshield Act, in 2006, Congress enacted the Pandemic and All-Hazards Preparedness Act (P.L. 109-417).\(^3,5\) This act gave authority for the advanced development and acquisitions of medical countermeasures to the Biomedical Advanced Research and Development Authority.\(^3,5\)

**FDA fast-track mechanism.** The FDA Modernization Act of 1997 (P.L. 105-115) directed FDA to issue guidance describing its policies and procedures pertaining to fast-track products.\(^3,6\) FDA’s fast-track mechanism is designed to facilitate the development and expedite the review of new vaccines intended to treat serious or life-threatening conditions.\(^3,6\) The mechanism emphasizes early communication between the manufacturer and FDA. This allows the manufacturer and FDA to discuss development plans and strategies that can improve the efficiency of preclinical studies of the drug and focus efforts on the design of the major clinical efficacy studies before a formal submission of a BLA.\(^3,6\) This early interaction can help clarify goals and plan early for obstacles that might delay approval decisions for a new vaccine. Biovest International Inc.’s BiavaxID (a therapeutic vaccine focused on follicular non-Hodgkin’s lymphoma)\(^3,7\) and Intracel’s OncoVAX vaccine (designed to prevent recurrence in stage 2 colon cancer)\(^3,8\) are recent examples of vaccines that have been granted fast-track status.

**FDA accelerated approval.** For certain biological products that are being tested for treatment of a serious or life-threatening illness, FDA regulations allow “accelerated approval” of the biologic product based on the biologic products’ “meaningful therapeutic benefit over existing treatments.”\(^3,9,40\) FDA grants this approval on the basis of adequate and well-controlled clini-

---

**Table 2. Comparison of vaccine prices, 1987 and 2008**

| Year/product | No. of doses | Private sector cost |
|--------------|--------------|---------------------|
|              |              | Cost per dose ($)   | Total cost ($)     |
| **1987**     |              |                     |                    |
| DTaP         | 5            | 8.67                | 34.88              |
| OPV          | 4            | 11.22               | 56.10              |
| MMR          | 1            | 17.88               | 17.88              |
| Hib          | 1            | 0.68                | 6.68               |
| Td           | 1            | 0.65                | 0.65               |
| Total for 1987 |             |                      | 115.99            |
| **2008**     |              |                     |                    |
| DTaP         | 5            | 20.96               | 104.80             |
| IPV          | 4            | 22.80               | 91.20              |
| MMR          | 2            | 46.54               | 93.08              |
| Hib          | 3            | 22.77               | 68.31              |
| Hepatitis B  | 3            | 64.11               | 64.11              |
| Rotavirus    | 3            | 69.59               | 208.77             |
| Pneumococcal | 4            | 78.44               | 313.76             |
| Influenza    | 1            | 11.72               | 11.72              |
| Varicella    | 1            | 77.51               | 77.51              |
| Hepatitis A  | 2            | 27.41               | 54.82              |
| Meningococcal| 1            | 93.87               | 93.87              |
| Total for 2008|            |                      | 1181.95            |

Abbreviations used: DTaP, diphtheria–tetanus–acellular pertussis; Hib, Haemophilus influenzae type b; IPV, inactivated poliovirus; MMR, measles–mumps–rubella; OPV, oral poliovirus; Td, tetanus–diphtheria toxoids.

Source: Centers for Disease Control and Prevention (prices as of February 23, 1987, and April 10, 2008).

*Recommended vaccines for individuals aged 0-6 years.
Vaccine cost includes $0.75/dose federal excise tax.
Vaccine cost includes $2.25/dose federal excise tax.
cal trials establishing that the biological product has an effect on a surrogate endpoint that is reasonably likely to predict clinical benefit.\textsuperscript{60} For example, in an effort to meet the increasing need for a flu vaccine, the FDA approved Fluarix, an influenza vaccine for adults that contains inactivated virus through this mechanism. The manufacturer demonstrated that after vaccination with Fluarix, adults made levels of protective antibodies in the blood that FDA believes are likely to be effective in preventing influenza.\textsuperscript{61} Fluarix was the first vaccine approved using the accelerated approval process.

**FDA priority review.** Under the FDA Modernization Act, reviews for New Drug Applications (NDAs) or BLAs are designated as either standard or priority.\textsuperscript{62} The review period changes depending on the designation given to the drug. Drugs given a standard designation usually require 10 months to more than 1 year for review. The priority designation can, however, shorten the anticipated amount of time until approval decision from 10 months to 6 months for some products. The priority review process begins only when a manufacturer officially submits a BLA (or an NDA). Priority review, therefore, does not alter the steps taken in a vaccine's development or testing for safety and effectiveness.\textsuperscript{62} Merck's human papillomavirus vaccine—the first developed to prevent cervical cancer—was evaluated and approved in 6 months under the priority review process.\textsuperscript{63}

**Liability protections and safety solutions.** Because pharmaceutical manufacturers have expressed liability concerns as an important reason for abstaining from vaccine development, proposals addressing these concerns have been seen as necessary incentives to participation in vaccine development.\textsuperscript{28} In response to the safety concerns and the lawsuits against vaccine manufacturers, Congress enacted the National Childhood Vaccine Injury Act of 1986 (P.L. 99-660).\textsuperscript{64} This legislation established the Vaccine Injury Compensation Program in 1988, which ensures that individuals or families of individuals who may have been injured is as a result of a routinely recommended vaccine are quickly, easily, and appropriately compensated.\textsuperscript{64} An individual claiming injury or death from a vaccine files a petition for compensation with the court. The petition is reviewed to determine whether it meets the criteria for compensation. A vaccine injury table lists and explains injuries/conditions that are presumed to be caused by vaccines. It also lists time periods in which the first symptom of these injuries/conditions must occur after receiving the vaccine. To qualify for compensation, a petitioner must show that an injury found in the vaccine injury table occurred or must prove that the vaccine caused the condition. A case found eligible for compensation is scheduled for a hearing to assess the amount of compensation. Most uncompensable claims receive awards for attorney fees and costs. Congressional approval of this act also set in motion the Vaccine Adverse Event Reporting System for monitoring vaccine adverse events.

The Homeland Security Act of 2002 (P.L. 107-296) protects manufacturers and health care workers who administer the smallpox vaccine from tort liability and restricts the liability assumed by the United States to negligence of those parties.\textsuperscript{65} The Smallpox Emergency Personnel Protection Act of 2003 (P.L. 108-20) created a mechanism to compensate individuals who, in response to a Secretarial request for smallpox vaccine preparedness, are injured by the vaccinia virus used in the smallpox vaccine. Vaccine recipients and individuals contacted by them are eligible for medical care expense reimbursement, lost income benefits, and death benefits, administered through the Health Resources and Services Administration.\textsuperscript{66}

The Public Readiness and Emergency Preparedness Act of 2006, (P.L. 109-148) is a tort liability shield that immunizes vaccine manufacturers, distributors, program planners, and administrators.\textsuperscript{67} The act protects these entities from financial risk in the event of any loss related to the manufacture, testing, development, distribution, administration, and use of countermeasures against chemical, biological, radiological, and nuclear agents of terrorism, epidemics, and pandemics.\textsuperscript{67}

**Public–private partnerships.** Donors, foundations, and other partners have created a public–private partnership known as the Global Alliance for Vaccines and Immunization (GAVI), the mission of which is to save children’s lives and protect people’s health through the widespread use of vaccines.\textsuperscript{68} As a GAVI partner, the Bill and Melinda Gates Foundation has invested millions of dollars in R&D for vaccines for diseases such as malaria and human immunodeficiency virus, currently the leading killers of children and adults around the world. GAVI has established public–private partnerships to accelerate late-stage development and introduction of priority vaccines against disease such as rotavirus and pneumococcus.\textsuperscript{69}

**Pull mechanisms**

**Stockpiles.** Stockpiles are, put simply, an artificial enhancement to current market demand levels in anticipation of periods when supply will be insufficient to meet demand.\textsuperscript{2} Government funding of vendor-managed stockpiles of childhood vaccines ensures that some excess vaccine supply is always available to buffer supply problems when they occur. Currently, the United States has a large enough stockpile of smallpox vaccine to vaccinate every person in the country who might need it in the event of an emergency.\textsuperscript{70} The government also expects to stockpile nearly 8 million doses of an investigational vaccine against pandemic influenza, and studies are under way to develop mechanisms that could stretch that supply to cover more than one-third of the population.\textsuperscript{71} CDC also maintains a large anthrax vaccine stockpile.

**Advance market commitments.** Advance market commitments involve donors who commit to buying yet-to-be-developed vaccines in bulk for poor nations if drug makers are able to deliver a vaccine that meets specifications and a price can be settled on in advance.\textsuperscript{72} Supporters of advance market commitments range from the GAVI partners to Pope Benedict XVI. Donors have agreed to test this mechanism for a vaccine for pneumococcal disease. To date, the Gates Foundation, the United Kingdom, Italy, Canada, Norway, and Russia have committed a total of $1.5 billion for the project.

**Vaccine bonds.** The United Kingdom has taken a lead in promoting an International Financing Facility for Immunization (IFFIm)\textsuperscript{69} IFFIm has raised more than $1 billion in capital markets to immunize poor children in developing nations against...
vaccine-preventable diseases. The IFFIm plans to invest $4 billion over the next decade to immunize 500 million people who would not otherwise be protected from diseases that no longer represent public health threats in developed countries. The IFFIm mechanism concentrates on the funding for vaccine research by using long-term government commitments as security bonds issued in the capital markets. The cash received for the bonds then can be used for research and future purchase of vaccines. Whenever the bonds are issued, IFFIm pays bondholders a modest rate of interest. As money pledged by donor governments becomes available gradually over 30 years, these funds will be used to repay the capital value of the bonds. IFFIm was able to double the resources GAVI has been able to allocate—$945.6 million in 2007 compared with $418.3 million in 2006.

Vaccine financing programs. Historically, the U.S. immunization system has been financed through public–private sector partnerships. The public sector purchases vaccines for approximately 53% of the birth cohort. Section 317 (a federal discretionary grant program to all states), the Vaccines for Children (VFC) Act of 1993 (P.L. 103-66), and state funds are major public sector sources for vaccine financing. Private sector vaccine purchases are covered through private health insurance and account for 45% to 50% of the pediatric vaccines sold annually in the United States.

The federal government has played an evolving role in building the immunization structure in the United States. The earliest legislation pertaining to vaccine financing is the Social Security Act of 1935. Title V of this act pertains to immunization services for children and their mothers. In 1963, Congress enacted the Vaccine Assistance Act (Section 317 of the Public Health Service Act). This legislation provided grants to social service agencies and local health departments for immunization infrastructure and vaccine purchases. However, barriers to immunization access still remained in some areas as a result of considerable variability in immunization efforts by state and local governments.

The deficiencies in this legislation were highlighted by the measles epidemic of 1989–1991, which involved more than 55,000 cases and led to 123 deaths. Substantial numbers of unimmunized preschool children, particularly in inner-city areas, contributed to this event. To ensure that vulnerable children had more reliable access to vaccines, the government refocused their funding resources on helping individual states in building immunization infrastructure. VFC is a state-operated federal entitlement program that provides free Advisory Committee on Immunization Practices–recommended vaccines to children 18 years of age or younger who are uninsured, Alaska Native or Native American, eligible for Medicaid, or receive their vaccines in a federally qualified health center.

At the state level, funds are earmarked for vaccine purchase and immunization programs. State funds also have been used to purchase vaccines for children and adolescents not eligible for VFC. A combination of VFC, state/local, and Section 317 program funds (i.e., VFC only, VFC and Underinsured, VFC and Underinsured Select, Universal, and Universal Select) has been used by a number of states to purchase all recommended vaccines for children in the state, including the privately insured.

Many states use universal programs that expand the eligibility for VFC vaccines by supplementing VFC purchases at federally discounted prices. The universal purchase states have been successful in raising vaccination rates among the underinsured and increasing access to newer and more expensive vaccines for children without insurance. However, criticisms of the universal purchase programs have been raised, including (1) vaccine manufacturers’ claims that universal purchase programs unfairly provide for the purchase of all vaccines at lower government contract prices, thus eliminating the private market for vaccines and decreasing revenue; (2) although immunization charges are reduced under this program, patients still pay for the vaccine administration fee; and (3) some content that taxpayer money should not be spent to provide free vaccines for children whose insurance would otherwise pay for it. State Medicaid and State Children’s Health Insurance Program funds also are provided for vaccine purchase, although the level of Medicaid funding varies from state to state.

In contrast to vaccine coverage for children, adults are far less likely to be covered for immunization services and frequently face a problem of underinsurance. The federal Medicare program covers some immunizations for all eligible beneficiaries through the Medicare Part B program. The selected immunizations include influenza, pneumococcal, and hepatitis B vaccinations. Certain other vaccines (e.g., tetanus toxoid) also are covered if their administration is considered necessary in the treatment of another covered illness. The Part D program generally covers those vaccines not available for reimbursement under Medicare Parts A or B when administration is reasonable and necessary for the prevention of illness. Private insurance coverage of immunizations for working-age adults varies widely by the type of health plan. For example, health maintenance organizations typically have the highest coverage levels, while preferred provider organizations and indemnity plans historically have covered immunization services less frequently.

Conclusion

By saving millions of lives and millions of dollars, vaccines have been responsible for some of the greatest successes in public health. However, the struggle against infectious disease is a continual process requiring new vaccines for the challenges that may confront human health in the future. The vaccine market is fragile and requires both supply- and demand-side interventions. Vaccine availability has been limited by the number of suppliers, high R&D and production costs, and safety problems leading to increased regulatory requirements. Demand has been constrained by rapidly increasing vaccine costs, financing issues that have constrained efforts to achieve targets set for population immunization rates, and parental attitudes regarding the safety and efficacy of vaccine products. To date, the U.S. government, in concert with private philanthro-
has implemented a patchwork of policies to make the vaccine market more attractive for private firms and to increase access to these products for individuals. We would argue that what is needed is an integrated policy approach that preserves incentives for market entry and innovation in the vaccine industry while simultaneously addressing parental vaccine concerns and increasing immunization funding and reimbursement for both providers and patients.

**References**

1. Orenstein WA, Douglas RG, Rodewald LE, Hinman AR. Immunizations in the United States: success, structure, and stress. Health Aff. 2005;24:599–610.
2. Salinsky E, Werbel C. The vaccine industry: does it need a shot in the arm? National Health Policy Forum. Washington, DC: George Washington University; 2006;1–34.
3. Arthur A. Vaccines: the controversial story of medicine’s greatest lifesaver. Part II. New York, W.W. Norton & Company; 2007:12, 27.
4. Ulmer JB, Valley U, Rappuoli R. Vaccine manufacturing: challenges and solutions. Nat Biotechnol. 2006; 24:1377–83.
5. Zhou F, Santoli J, Messonnier ML, et al. Economic evaluation of the 7-vaccine routine childhood immunization schedule in the United States, 2001. Arch Pediatr Adolesc Med. 2005;159:1136–44.
6. Salo H, Kilpi T, Sintonen H, et al. Cost-effectiveness of influenza vaccination of healthy children. Vaccine. 2006;24:4934–41.
7. Paul Y. Herd immunity and herd protection. Vaccine. 2004;22:301–2.
8. Ritvo P, Wilson K, Willms D, Upshur R. Vaccines in the public eye. Nat Med. 2005;11(4 suppl):S20–4.
9. Bloom D, Canning D, Malaney P. Demographic change and economic growth in East Asia. Popul Dev Rev. 2000;26:257–90.
Bloom D, Canning D. The health and wealth of nations. Science. 2000;Feb 18):1207–9.

Andre FE, Booy R, Bock HL, et al. Vaccination greatly reduces disease, disability, death and inequity worldwide. Bull World Health Organ. 2008;86:140–6.

Nordhaus W. The health of nations: the contribution of improved health to living standards. In: Murphy KH, Topel RH, Eds. Measuring the gains from medical research: an economic approach. Chicago: University of Chicago Press; 2003.

Centers for Disease Control and Prevention. Vaccines & immunizations: 2002 immunization news. Accessed at www.cdc.gov/vaccines/news/news-pubs/news2002.htm, December 04, 2007.

Iglehart J. Financing vaccines: in search of solutions that work. Health Aff. 2005;24:594–5.

Offit P. Why are pharmaceutical companies gradually abandoning vaccines? Health Aff. 2005;24:622–30.

Bridges CB, Thompson WW, Meltzer MI, et al. Effectiveness and cost-benefit of influenza vaccination of healthy working adults: a randomized control trial. JAMA. 2000;284:908–13.

Demicheli V, Rivetti D, Deeks JJ, Jefferson TO. Vaccines for preventing influenza in healthy adults. Cochrane Database Syst Rev. 2004;CD001269.

Iglehart J. Financing vaccines: in search of solutions that work. Health Aff. 2005;24:594–5.

Caffee JE, Gottlieb S. Putting markets to work in vaccine manufacturing. Accessed at www.aei.org/publications/pubID.21659/pub_detail.asp, October 22, 2007.

Offit P. Why are pharmaceutical companies gradually abandoning vaccines? Health Aff. 2005;24:622–30.

Bridges CB, Thompson WW, Meltzer MI, et al. Effectiveness and cost-benefit of influenza vaccination of healthy working adults: a randomized control trial. JAMA. 2000;284:908–13.

Demicheli V, Rivetti D, Deeks JJ, Jefferson TO. Vaccines for preventing influenza in healthy adults. Cochrane Database Syst Rev. 2004;CD001269.

American Academy of Pediatrics. Red Book online: special alert: Hib shortage. Accessed at http://aapredbook.aappublications.org/news, January 5, 2008.

Hinman AR, Orenstein WA, Santoli JM, et al. Vaccine shortages: history, impact, and prospects for the future. Annu Rev Public Health. 2006;27:235–59.

Centers for Disease Control and Prevention. Vaccine shortages: history, impact, and prospects for the future. Annu Rev Public Health. 2006;27:235–59.

Mercer Management Consulting. Lessons learned: new procurement strategies for vaccines: final report to the GAVI Board. New York: Mercer Management Consulting; 2002.

Thompson WW, Price C, Goodson B, et al. Early thimerosal exposure and neuropsychological outcomes at 7 to 10 years. N Engl J Med. 2007;357:1281–92.

Tozzi AE, Biasiachi P, Tarantino V, et al. Neuropsychological performance 10 years after immunization in infancy with thimerosal-containing vaccines. Pediatrics. 2009;123:475–82.

Offit P. Autism’s false prophets: bad science, risky medicine, and the search for a cure. 1st ed. New York: Columbia University Press; 2008.

Centers for Disease Control and Prevention. Withdrawal of rotavirus vaccine recommendation. Accessed at www.cdc.gov/mmwr/preview/mmwrhtml/mm4843a5.htm, November 23, 2007.

Hinman AR, Orenstein WA, Rodewald L. Financing immunizations in the United States. Clin Infect Dis. 2004;38:1440–6.

Hinman AR, Orenstein WA, Santoli JM, et al. Vaccine shortages: history, impact, and prospects for the future. Annu Rev Public Health. 2006;27:235–59.

Centers for Disease Control and Prevention. Mumps: United States, January 1–April 25, 2008. Accessed at www.cdc.gov/mmwr/preview/mmwrhtml/mm5718a5.htm, June 8, 2008.

Donnelly CA, Fischer MC, Fraser C, et al. Epidemiological and genetic analysis of severe acute respiratory syndrome. Lancet Infect Dis. 2004;4:672–83.

Food and Drug Administration. Just the facts: vaccines provide effective protection and FDA makes sure they are safe. Accessed at www.fda.gov/opacom/factsheets/justthefacts/19vaccine.html, November 22, 2007.

Thaul S. CRS report for Congress: vaccine policy issues. Accessed at www.fas.org/sgp/crs/misc/RL31793.pdf, November 30, 2007.

Glass RI, Kilgore PE, Holman RC, et al. The epidemiology of rotavirus diarrhea in the United States: surveillance and estimates of disease burden. J Infect Dis. 1996;174(1 suppl):S5–11.

Food and Drug Administration, Center for Biologics Evaluation and Research. Vaccine product approval process: 2002. Accessed at www.fda.gov/Cber/vaccine/vacappr.htm, November 12, 2007.

Plotkin S, Orenstein W, Offit P. Vaccines. 5th ed. Toronto, Canada: Elsevier; 2008:37, 39.

DiMasi JA, Hansen RW, Grabowski HG. The price of innovation: new estimates of drug development costs. J Health Econ. 2003;22:151–85.

Sloan F, Berman S, Rosenbaum S, et al. The fragility of the US vaccine supply. N Engl J Med. 2004;351:2443–7.

Institute of Medicine. Financing vaccines in the 21st century. 1st ed., chapters 1 and 3. Washington, DC: National Academies Press; 2003.
48. Freed GL, Cowan AE, Clark SJ. Primary care physician perspectives on reimbursement for childhood immunizations. Pediatrics. 2008;122:2008–33.

49. Benin AL, Wisler-Scher DJ, Colson E, et al. Qualitative analysis of mothers’ decision-making about vaccines for infants: the importance of trust. Pediatrics. 2006;117:1532–41.

50. Kennedy AM, Brown CJ, Gust DA. Vaccine beliefs of parents who oppose compulsory vaccination. Public Health Rep. 2005;120:252–8.

51. Gust DA, Darling N, Kennedy A, Schwartz B. Parents with doubts about vaccines: which vaccines and reasons why. Pediatrics. 2008;122:718–25.

52. Boardman AE, Greenberg DH, Vining AR, Weimer DL. Cost-benefit analysis: concepts and practice. Upper Saddle River, NJ: Prentice Hall; 1996(appendix 3B):99–110.

53. Gottron F. CRS report for Congress: RS21507 Project BioShield. Accessed at www.au.af.mil/au/awc/awcgate/crs/rs21507.pdf, December 27, 2007.

54. Food and Drug Administration. Project BioShield: protecting Americans from terrorism. Accessed at www.fda.gov/fdac/features/2004/604_terror.html, August 2, 2008.

55. U.S. Department of Health and Human Services. Pandemic and All-Hazard Preparedness Act. Accessed at www.hhs.gov/aspa/ops/pahpa/index.html, May 29, 2009.

56. Food and Drug Administration. Guidance for industry, fast track drug development programs: designation, development, and application review. Accessed at www.fda.gov/cber/gdlns/fsstrk.pdf, November 25, 2007.

57. Hendrickson D. Biovest moves to Fast Track with cancer vaccine. Accessed at www.masshightech.com/story/2006/05/22/story11-Biovest-moves-to-Fast-Track-with-cancer-vaccine.html, August 2, 2008.

58. Frederick. FDA grants “fast track” designation for the development of OncoVAX. July 2006. Accessed at www.vaccinogeninc.com/news_0706.cfm August 08, 2008.

59. U.S. Government Printing Office. 21 CFR 601 subpart E: accelerated approval of biological products for serious or life-threatening illnesses. Accessed at http://edocket.access.gpo.gov/cfr_2008/apr08/pdf/21crf601.40.pdf, November 24, 2007.

60. Food and Drug Administration. CFR - Code of Federal Regulations Title 21. Accessed at www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcr/CFRSearch.cfm?CFRPart=601&showFR=1&subpart Node=21:7.0.1.1.2.5, November 24, 2007.

61. Gelb L. FDA approves new influenza vaccine for upcoming flu season. Accessed at www.fda.gov/bbs/topics/news/2005/NEW01227.html, July 18, 2008.

62. Food and Drug Administration. Fast track, priority review and accelerated approval. Accessed at www.accessdata.fda.gov/scripts/cder/ontools/Accel.cfm, December 7, 2007.

63. Food and Drug Administration. FDA licenses new vaccine for prevention of cervical cancer and other diseases in females caused by human papillomavirus. Accessed at www.fda.gov/bbs/topics/news/2006/new01385.html, July 31, 2008.

64. U.S. Department of Health and Human Services, Health Resources and Services Administration. National Vaccine Injury Compensation Program (VICP). Accessed at www.hrsa.gov/vaccinecompensation, November 26, 2007.

65. Cohen H. CRS report for Congress: RL31649, Homeland Security Act of 2002: tort liability provisions. Accessed at www.policyarchive.org/bitstream/handle/10207/1557/RL31649_20050923.pdf?sequence=1, November 30, 2007.

66. Thaul S. CRS report for Congress: RL31960, smallpox vaccine injury compensation. Accessed at http://biotech.law.lsu.edu/blaw/bt/smallpox/Congress/RL31960.pdf, November 30, 2007.

67. U.S. Department of Health and Human Services. Public Readiness and Emergency Preparedness Act questions and answers. Accessed at www.hhs.gov/disasters/emergency/manmade-disasters/bioterrorism/medication-vaccine-qa.html, March 12, 2009.

68. GAVI Alliance. Accessed at www.gavialliance.org, January 10, 2008.

69. Batson A. The problems and promise of vaccine markets in developing countries. Health Aff. 2005;24:690–3.

70. U.S. Department of Health and Human Services. CDC efforts in implementing a smallpox vaccination program. Accessed at www.hhs.gov/ash/ testify/n030129.html, January 10, 2008.

71. Gillis J. U.S. builds stockpile of vaccine for flu pandemic. Accessed at www.washingtonpost.com/wp-dyn/content/article/2005/11/29/AR2005112901849.html, June 23, 2008.

72. Timiraos N. Why a market-driven vaccine plan faces big obstacles. Accessed at http://online.wsj.com/public/article_print/SB1199061293009568545.html, January 10, 2008.

73. Macninis L. Vaccine bonds provide model for other aid projects. Accessed at www.medscape.com/viewarticle/573432, April 30, 2008.

74. GAVI Alliance. GAVI Alliance announces dramatic funding boost for Hib vaccine. Accessed at www.gavialliance.org/media_centre/press_releases/2007_11_29_en_pr_hib_boost.php, August 11, 2008.

75. Lindley MC, Orenstein WA, Shen AK, et al. Assuring vaccination of children and adolescents without financial barriers: recommendations from the National Vaccine Advisory Committee (NVAC). Washington, DC: U.S. Department of Health and Human Services; 2009.

76. Atkinson WL, Hadler SC, Redd SB, Orenstein WA. Measles surveillance: United States, 1991. MMWR CDC Surveill Summ. 1992;41:1–12.

77. Centers for Disease Control and Prevention. Vaccines & immunizations: Vaccines for Children Program (VFC). Accessed at www.cdc.gov/vaccines/programs/vfc, June 12, 2008.

78. Centers for Disease Control and Prevention. Childhood vaccine supply policy 2007. Accessed at www.cdc.gov/vaccines/programs/vfc/products/data/vacc-supply-public-2007.htm, May 29, 2009.

79. Freed GL, Clark SJ, Pathman DE, et al. Impact of North Carolina’s universal vaccine purchase program by children insurance status. Arch Pediatr Adolesc Med. 1999;153:748–54.

80. Centers for Medicare and Medicaid Services. Adult immunization. Accessed at www.cms.hhs.gov/adultImmunizations, June 25, 2008.
Assessment Questions

Instructions: The assessment test for this activity must be taken online; please see “CPE processing” below for further instructions. There is only one correct answer to each question. This CPE will be available at www.pharmacist.com no later than July 31, 2009.

1. Which of the following is the process by which vaccines protect not only those who receive them but also those who cannot or do not receive the vaccine?
   a. Passive immunization
   b. Active immunization
   c. Herd immunity
   d. Mass immunization

2. After successful completion of clinical testing, the vaccine’s manufacturer must submit which of the following to the Food and Drug Administration (FDA) for evaluation and approval before marketing?
   a. Biological License Application
   b. Investigational New Drug Application
   c. New Drug Application
   d. Abbreviated New Drug Application

3. Which of these is not a vaccine manufacturing method?
   a. Egg-based
   b. Recombinant technique
   c. Cell-derived
   d. Mix method

4. Which of the following has led to a decrease in the number of pharmaceutical manufacturers producing vaccines?
   a. A large number of new brand-name drug manufacturers entering the market during this period
   b. The large proportion of revenue vaccines are responsible for at most drug manufacturers
   c. The difficulty involved in keeping vaccine production facilities up to current regulatory standards
   d. The National Childhood Vaccine Injury Act of 1986

5. Which of the following vaccines was withdrawn in 1999 when it was found to cause a rare but serious intestinal obstruction in some recipients?
   a. Prevnar
   b. Rotashield
   c. Pneumovax
   d. Diphtheria–tetanus–acellular pertussis

6. In the 1990s, the cost of recommended immunizations began to increase, primarily as a result of which of the following?
   a. Vaccines for Children Act
   b. Vaccine awareness programs
   c. Herd immunity
   d. Introduction of new vaccines

7. Which of the following strategies seeks to address supply-side issues in the vaccine market by providing direct assistance to ease the burden of research, development, and production costs?
   a. Push
   b. Active immunization
   c. Pull
   d. Positive market

8. Which of the following is not a push mechanism?
   a. Fast-track mechanism
   b. Accelerated approval
   c. Vaccine bonds
   d. Vaccine Adverse Event Reporting System

CPE Credit:

To obtain 2.0 contact hour of continuing pharmacy education credit (0.2 CEUs) for “Vaccine supply, demand, and policy: A primer,” go to www.pharmacist.com and take your test online for instant credit. CPE processing is free for APhA members and $15 for nonmembers. A Statement of Credit will be awarded for a passing grade of 70% or better. You have two opportunities to successfully complete the posttest. Pharmacists who complete this exercise successfully before July 1, 2012, can receive credit.

The American Pharmacists Association is accredited by the Accreditation Council for Pharmacy Education as a provider of continuing pharmacy education. The ACPE Universal Activity Number assigned to the program by the accredited provider is 202-000-09-209-H04-P.

“Vaccine supply, demand, and policy: A primer” is a home-study continuing education activity for pharmacists developed by the American Pharmacists Association.
9. Which of the following conferred more authority and leadership in the vaccine development effort on Biomedical Advanced Research and Development Authority?
   a. Pandemic and All-Hazards Preparedness Act
   b. Project Bioshield Act
   c. Biologics Control Act
   d. Homeland Security Act

10. Which of the following directed FDA to issue guidance describing its policies and procedures pertaining to fast-track products?
    a. FDA Modernization Act
    b. Project Bioshield Act
    c. Biologics Control Act
    d. Homeland Security Act

11. Which of the following vaccines has received fast-track status?
    a. BiovaxID
    b. Menactra
    c. Gardasil
    d. Cervarix

12. Which of the following is the first vaccine approved using the accelerated approval process?
    a. OncoVAX
    b. Fluarix
    c. Gardasil
    d. BiovaxID

13. Which of the following vaccines was approved using the priority review process?
    a. BiovaxID
    b. Menactra
    c. Fluarix
    d. Gardasil

14. Which of the following established the Vaccine Injury Compensation Program?
    a. Biologics Control Act
    b. The Vaccine Act
    c. National Childhood Vaccine Injury Act
    d. Homeland Security Act

15. Which of the following can be considered a pull mechanism?
    a. The Public Readiness and Emergency Preparedness Act
    b. National Childhood Vaccine Injury Act
    c. Homeland Security Act
    d. Vaccine Assistance Act

16. Which of the following is a pull mechanism?
    a. Priority review for human papillomavirus vaccine
    b. Stockpiles of anthrax vaccines
    c. Fast-track mechanism for stage 2 colon cancer vaccine
    d. Accelerated approval process for influenza vaccine

17. Which of the following involves donors who commit to buying yet-to-be-developed vaccines in bulk for poor nations?
    a. Stockpiles
    b. Advance market commitments
    c. Vaccines for children
    d. Generic Open

18. A combination of VFC, state/local, and Section 317 program funds for vaccines is called?
    a. Stockpiles
    b. Universal purchase
    c. Vaccine assistance
    d. Generic Open

19. Which of the following was enacted after the measles epidemic of 1989–1991, which involved more than 55,000 cases and led to 123 deaths?
    a. Vaccine Assistance Act
    b. Section 317 of the Public Health Service Act
    c. Vaccines for Children Act
    d. State Children’s Health Insurance Program

20. Which of the following tend to provide the highest levels of immunization coverage for working-age adults?
    a. Universal purchase programs
    b. Health maintenance organizations
    c. Vaccines for children programs
    d. Advance purchase commitment programs

CPE Processing:
Get your documentation of credit now! Completing a posttest at www.pharmacist.com/education is as easy as 1-2-3.
1. Go to Online CE Quick List and click on the title of this activity.
2. Log in. APhA members enter your user name and password. Not an APhA member? Just click “Create one now” to open an account. No fee is required to register.
3. Successfully complete the CPE exam and evaluation form to gain immediate access to your documentation of credit.

Live step-by-step assistance is available Monday through Friday 8:30 am to 5:00 pm ET at APhA Member Services at 800-237-APhA (2742) or by e-mailing InfoCenter@pharmacist.com.