

## BOARD OF DIRECTORS REPORT O TO THE 2006 CONGRESS OF DELEGATES

### AAFP TASK FORCE ON INFLUENZA VACCINE

#### Background

(1) The AAFP Task Force on Influenza Vaccine was created by the AAFP Board of Directors in response to a shortage of influenza vaccine affecting a large number of Academy members. This shortage occurred because one of the two manufacturers of inactivated influenza vaccine was unable to produce half of its originally predicted 25 million doses and the remaining half was not available for delivery until well into the fall. Unfortunately, a large number of family physician offices ordered their influenza vaccine from distributors who bought their supply from the manufacturer with the production problem. As such, many AAFP members were not able to obtain vaccine when they normally would administer it in the fall. They were reluctant to order vaccine late in the calendar year when more became available since they did not know how many of their patients still needed to be immunized. The availability of influenza vaccine in grocery stores, other retail outlets and even a casino, confused the public and frustrated family physicians whose patients look to them as their usual and expected source of influenza immunization.

(2) The task force was created as a short-term work group to investigate the concerns of members regarding the purchase, distribution, and payment for influenza vaccine. It was to investigate and understand the manufacturing and distribution process in order to better educate and advise members on strategies that gave them the highest probability of obtaining influenza vaccine. It was to report and make recommendations for consideration at the March 2006 Board meeting.

(3) The Board Chair appointed a seven member task force chaired by the President-Elect and one representative each from the Commissions on Governmental Advocacy, Health of the Public, Practice Enhancement, and Science as well as a member of the Congress of Delegates and a state officer. In addition, there was a liaison from the American College of Osteopathic Family Physicians. Lead staffing was provided by the Divisions of Scientific Activities and Socioeconomics (now called Practice Support). Staff from the Communications and Corporate Development Divisions supported the task force.

(4) The task force met twice in person as well as conducted business by teleconference and e-mail. Portions of its first face-to-face meeting involved presentations by representatives from the Centers for Disease Control and Prevention (CDC) and the American Medical Association (AMA). These two organizations are the co-conveners of the National Influenza Vaccine Summit that has met for a number of years to address influenza vaccine issues including supply. Also attending part of the first meeting were representatives from companies that manufacture influenza vaccine as well as one major distributor. Ongoing communication occurred among all of these parties as the year progressed to deal with both immediate and long-term issues.

(5) The work of the task force was also informed by surveys and other information from chapters, member e-mails and phone calls, news stories, and formal surveys of members and the public. The task force analyzed this information and developed an initial list of 27 possible actions. As a result of systematic discussion including an assessment of the likelihood of success of each intervention, it arrived at eight consolidated recommendations, which were made to the Board of Directors for consideration at the March 2006 meeting. The Board approved all the recommendations and progress on each is noted later in the report.

### **Vaccine Manufacturing and Distribution for 2006-2007**

(6) As of early August 2006, the supply of both inactivated and live attenuated seasonal influenza vaccine for the United States is projected to be at least 100-million doses. This would be over 16 percent more than was available in the 2005-2006 season. The possible licensing of an additional vaccine may further boost the supply by another 15 or more million doses.

(7) The market place in 2006 responded to the concerns raised by the AAFP, physicians, hospitals, skilled nursing homes and others. Production has been increased this year including the entry of one new manufacturer. Another manufacturer tried a new pre-booking system which was promoted to physicians. Unfortunately, this system was overwhelmed, receiving hundreds of thousands of attempted phone and e-mail orders. A major distributor initiated a new on-line ordering system that allows a physician's office to specify the delivery dates for vaccine and offers a refund of part of the cost of the vaccine if the company does not deliver on the specified date. Reflecting the expanded supply, only two of nine major distributors identified by manufacturers as sources of their vaccine were no longer taking orders in late July 2006.

(8) There is the possibility of a vaccine shortage for the 2006 – 2007 season for children who are aged 36-47 months of age. This year, there is only one manufacturer of licensed vaccine for children in this age range and that vaccine was fully booked by physicians and distributors in early 2006. This shortage is a result of the new expanded CDC recommendations to immunize children 6 months to 59 months of age.

(9) Influenza vaccine is a biological product that involves the manufacture of three separate monovalent products that are combined into a new trivalent vaccine each year. Because different influenza virus strains have different rates of growth and production there is uncertainty about the amount of vaccine that can be produced each year. The federal government must test and approve the product at different stages in the manufacturing process. All of the manufacturing is performed in a free market system that involves major plant investments and decisions that can take years to execute.

(10) In addition to the manufacturers and distributors increasing production and being more innovative in developing distribution processes, the federal government has taken steps to improve tracking of influenza supplies in case of shortages. The CDC and state health departments are working with industry to track production and shipment of vaccine. Customers of the company that did not have vaccine available until much later in the immunization season were reluctant to take delivery of vaccine. Ironically, at the end of the immunization season, as in every prior year, influenza vaccine went unused at all levels physicians, distributors, and manufacturers. Preliminary data from a recent large AAFP survey showed that of the 91 percent of AAFP members who reported giving influenza vaccine in their office last year, 31 percent had left over vaccine. For nearly one-third of these members, more than 10 percent of their order was unused.

(11) The percent of members reporting they plan to give vaccine this year is the same as last year. According to preliminary data from a recent large AAFP survey, as of July 24, 2006, 14 percent of AAFP members report having not yet ordered their influenza vaccine for this year, 51 percent report having ordered it and 36 percent do not know if it has been ordered. At the June 2006 National Influenza Vaccine Summit, the manufacturers, distributors and governmental representatives expressed the opinion that the anticipated problem for the 2006-2007 immunization season will be using up all the vaccine that will be produced rather than having a shortage of vaccine. As such, many of the concerns and solutions for the problems identified last year do not fit the current situation. Of course, if there is a major manufacturing disaster this could change. As of the date of this report, vaccine production is proceeding smoothly except for one minor problem experienced by one manufacturer that has been remedied.

### **Task Force Recommendations**

(12) The Task Force made eight recommendations for Academy action. They fall into the following categories:

- Work with influenza vaccine manufacturers, distributors and others to ensure family physicians receive the vaccine they need.
- Work with third party payers to provide adequate payment for both the cost of the vaccine and its administration.
- Seek to have the CDC establish that influenza vaccine is most appropriately administered in the patient's medical home.
- Develop an influenza vaccine tool kit, which provides background and practical information for members.
- Work with the CDC and others to educate clinicians and the public that the immunization season extends into the new year.
- Work with the CDC to develop public messages in times of shortage and maldistribution.
- Investigate federal buy back plans for unused vaccine.
- Investigate the feasibility of an AAFP Group Purchasing Organization.

### **Availability and Timeliness**

(13) In recent years the production of seasonal influenza vaccine has been compromised resulting in an insufficient supply of vaccine, distribution challenges, access problems for patients and administrative hassles and financial losses for many family physicians. Many but not all of these issues would be ameliorated by a stable or excess supply of vaccine such as is predicted for the 2006-2007 influenza season. However, all problems will not be addressed by an adequate supply of vaccine and family physicians must be prepared to deal with future periods of shortage. For these reasons, the Board approved a series of task force recommendations directed to manufacturers, distributors, and their associations. They include: increasing the percentage allotment to physicians by those sources that assign a specific percent of their supply to various categories of customers; offering a pre-booking period for physicians before opening the order process to the general marketplace; ensuring that prepayment guarantees timely receipt of vaccine; ensuring that small orders are completely filled and shipped; prioritizing vaccine distribution to physician offices and clinics, hospitals, long term care facilities and other medical facilities that serve high priority patients; educating industry how distribution problems affect physicians caring for high priority patients; and developing manufacturer/distributor financial responsibility policies for late delivery of vaccine and buy back programs for unused vaccine. Some of these activities were approved too late for implementation prior to the 2006-2007 influenza vaccine ordering season. In light of the increased amount of vaccine now projected to be available, it is unlikely that manufacturers will introduce some of these approaches this year.

(14) To implement these recommendations the Academy has developed a document to share with the companies manufacturing influenza. The recommendations have already been conveyed in conversations with the manufacturers and others including CDC, AMA and during the most recent National Influenza Vaccine Summit.

(15) The Academy has worked independently and with select manufacturers and distributors to address the issues articulated above. The Academy has greatly expanded its web resources to provide members timely information and to assist them in the ordering process. Some distributors and manufacturers have implemented programs attempting to address the ordering and timely delivery issues, though not always successfully. The Academy will continue to emphasize the importance of these issues with industry leaders and in venues such as the AMA-CDC convened National Influenza Vaccine Summit.

(16) The effectiveness of these efforts is difficult to predict since vaccine is produced within a free market system. One characteristic of such a system is to respond to customer demands. The physician practice is viewed as the preferred location for the delivery of immunizations. In a Gallup Survey commissioned by the CDC last year, 50 percent of adults 18 and older who received an influenza immunization responded that they would prefer to get immunized in a doctor's office or HMO. Only 39 percent were actually immunized there. Ten percent were immunized in a grocery or pharmacy but only three percent preferred to be immunized there while 17% preferred to be immunized at work.

### **Insurance Coverage and Payment Policies**

(17) AAFP policy states that all public and private health insurance plans should cover vaccines recommended by the Advisory Committee on Immunization Practices (ACIP) and the AAFP, including seasonal influenza vaccine. Medicare covers both the cost of the vaccine and its administration in addition to a medically necessary and separately identifiable preventive or problem-oriented visit provided at the time the influenza vaccine is administered. There is no beneficiary cost sharing associated with the Medicare benefit. The task force recommended, and the Board approved, that all insurers' influenza vaccination coverage and payment policies should be comparable to Medicare's.

(18) The Academy meets and communicates regularly with the nation's largest insurers to adopt the coverage and payment policies described. Aetna, Cigna, Wellpoint, and United Healthcare generally comply, although, Aetna currently bundles the vaccination with problem-oriented or preventive visits. Co-payment policies vary by employer. The benefits to health insurers of seasonal influenza vaccine are proximate to its administration, which makes the desired coverage more attractive than for many other vaccines with a more distant benefit. Private sector advocacy efforts will continue to focus on expanding coverage for the seasonal influenza vaccine benefit and appropriate payment policies. The Academy will continue to intervene with member-identified companies that are non-compliant.

(19) The Medicare payment "rate" for the vaccine is based on 95 percent of the Average Wholesale Price (AWP). The Academy believes that physicians should be paid based on their actual cost of the vaccine rather than the AWP. The Academy will continue to work with private insurers and the Center for Medicare and Medicaid Services (CMS) to address their vaccine payment rules to assure that practices are paid appropriately for the vaccine and its administration.

### **Advocating for Immunizing Patients in their Medical Home**

(20) The majority of patients prefer to be immunized in their doctor's office, HMO or other clinical setting. Current AAFP policy states that the AAFP "believes that the interests of patients are best served when their care is provided in their personal medical home." This message has been taken to the CDC. Some patients prefer to be immunized in other locations. In a Gallup Survey commissioned by the CDC, 17 percent of adults who were immunized last year received that immunization at their workplace and an equal number said they preferred to be immunized there. Two percent preferred to be immunized at a senior center. The CDC move toward increasing the total number of persons for whom immunization is recommended is likely to mean that more immunizations will be given outside traditional office hours and at locations other than physician practices. AAFP policy "charges any entity providing immunizations to provide appropriate documentation and instructions to patients to share the information with their primary care physician in a timely fashion." This is particularly important—and this has been shared with the National Influenza Vaccine Summit—in a time when a common physician performance measure is the percent of patients who have been immunized.

### **Influenza Vaccine Tool Kit**

(21) Even before the task force formalized this recommendation, the AAFP had established a web page on influenza vaccine. This online “tool kit” provides information on ordering vaccine, the Vaccines for Children program, and payment advice. In addition, it lists the recommendations for who should be immunized this year and has links to the CDC and other immunization resources. The online “tool kit” is being updated continuously.

### **Working with Stakeholders to Promote a Longer Immunization Season**

(22) One of the barriers to effective immunization has been the public—and at times clinician—belief that the best or exclusive time to be immunized is in the early fall when vaccine first becomes available. Study of the time of occurrence of influenza in the United States, as well as the reality that not enough vaccine can be manufactured for use in a one to two month time period, logically leads to extending the time to administer vaccine. In fact, some research now suggests that the elderly lose their protection over time and benefit from being immunized closer to the time of outbreaks. The AAFP through the National Influenza Vaccine Summit and the CDC and in partnership with industry is working to educate patients about the value of immunization throughout the influenza season. This would relieve physician practice concern about accepting vaccine later in the fall.

### **Public Health Messages in Time of Shortage or Maldistribution**

(23) The AAFP has repeatedly shared with CDC communications staff the need for the government to coordinate public health messages with the Academy and other physicians groups. A CDC message last year that there were only spot shortages but no national shortage of vaccine caused confusion and frustration among both patients and physicians. The AAFP and CDC are establishing a good working relationship regarding public messaging. Likewise, the Academy is working through the National Influenza Vaccine Summit and with industry to coordinate public messages.

### **Federal Buy Back Plans**

(24) There was some thought that a federal buy back program for physicians with unused influenza vaccine might be developed. However, given the current federal budget, this was not viewed as possible. On the other hand, discussions with manufacturers revealed that when vaccine supplies again become ample and competition increases, the marketplace might respond with such offers. In fact, one company did offer a buy back option late in the last immunization season for vaccine purchased at that time.

### **Group Purchasing Organization**

(25) The task force considered at some length the need for the Academy to create and/or partner with a group purchasing organization (GPO). A GPO might allow family physicians to leverage their purchasing power and better guarantee a stable supply of vaccine at a reasonable price and terms. Some physicians have access to GPOs through hospitals with which they are affiliated and through groups organized at the local or state levels to purchase vaccine, other medical supplies, and drugs. These arrangements usually allow individual practices to directly order and receive needed products without the GPO handling product.

(26) The Academy has previously considered establishing GPOs for medical supplies and determined that there was insufficient member need and interest relative to the complexity and expense to the

Academy of establishing such an organization. The Academy has in recent years entered into agreements with companies that sell office supplies to leverage discounts for Academy members.

(27) Currently, the Academy is investigating the legal and business implications and the resources that would be required to establish its own group purchasing organization for influenza vaccine. Following this initial analysis and review by the Academy's Board of Directors, a decision will be made whether to develop a business plan for a GPO, pursue a member discount arrangement for purchasing influenza vaccine similar to that described above or some other type of a purchasing arrangement with one or more manufacturers or distributors of the vaccine. Members' concerns are not limited to the cost of vaccine but also its availability and the timing of its delivery, especially in the times of vaccine shortages. However, a GPO may not solve the problems in a year when there is a shortage if the GPO preferentially ordered its vaccine from a manufacturer or distributor that is experiencing a shortage. If the vaccine supply were to be stabilized or to be in an oversupply, it's not clear that a GPO for influenza vaccine would be needed. It's the unstable supply resulting from manufacturing difficulties that brought this issue to the fore during the 2005-2006 influenza season.

### Summary

(28) The task force thoroughly analyzed the root causes of seasonal influenza vaccine shortages and maldistribution in recent years. The task force sought and considered the input of the vaccine manufacturers and distributors, the Centers for Disease Control and Prevention and other experts. Based upon that analysis the task force formulated a series of recommended actions, approved by the Board, to work with influenza vaccine manufacturers and distributors, private and public insurers, the CDC and others to ensure that family physicians are able to provide their patients with the vaccine they need and to administer it in the context of their personal medical home. The recommendations have also resulted in the Academy enhancing its member education on seasonal influenza immunization and providing more in depth and timely information on the vaccine supply and distribution. Finally, the Academy will investigate the need for and feasibility of leveraging its purchasing power to stabilize vaccine supply, and provide timely distribution and a discounted price structure for its members.