County of San Diego

PHYSICIANS' BULLETIN

July 2001 *"Focusing on Families as Our Customers"* No. 432

Influenza Immunization Recommendations Issued

Note: Medicare B reimburses for influenza vaccines.

The influenza recommendations for the 2001-2002 season include information about a) the influenza vaccine supply problems and cost-related issues; b) the expected mortality from influenza both in the U.S. and San Diego County; c) the cost-effectiveness of influenza vaccination; d) local adult immunization coverage rates; e) the 2001-2002 trivalent vaccine virus strains (A/Moscow/10/99 [H3N2]-like, A/New Caledonia/20/99 [H1N1]-like, and B/Sichuan/ 379/99-like strains), and influenza vaccination recommendations ; e) timing of influenza vaccine activities; f) vaccine side effects and adverse reactions; g) neuraminidase-inhibitor antiviral drugs; and h) other pertinent information.

Flu Vaccine Price, Funding Shortages, Virus Growth Rate Pose Problems

There has been a nearly three-fold increase in the price of publicly-funded influenza vaccine (from $1.70/dose to $4.50/dose), initially causing concern that the local County Immunization Program would receive only about 25,000 doses instead of last year's over 70,000 doses. However, due to action at the state level identifying $1.9 million of additional funding, San Diego County is now allocated to receive 70,990 doses for the coming flu season.

Also, because this year's vaccine will contain two of the same strains as last year's vaccine, the problem of the slow growth rate of one of the strains remains an issue. Thus, vaccine delivery delays or vaccine shortages are possible. *Providers are encouraged to contact vaccine manufacturers typically by May each year to reserve supplies of vaccine (see page 7 for contact information). Additionally, providers are urged to prioritize use of their flu vaccine supplies and immunize high-risk patients in September, October and November, and all other patients later. The effects of production delays in 2000-2001 were exacerbated by the expectation of providers and the public that flu shots should be received by Thanksgiving or not at all, even though a flu shot after this time would provide a reasonable level of protection in most years. Physicians should emphasize that a flu shot after Thanksgiving still provides needed protection, especially for non-high-risk persons wishing to avoid the illness.*

Influenza Mortality

Epidemics of influenza typically occur during the winter months and are responsible for an average of approximately 20,000 deaths per year in the U.S (1,2). In San Diego County, which contains approximately 1 percent of the U.S. population, it is therefore likely that about 200 deaths from influenza and its complications will occur.

Influenza Vaccine Cost-Effectiveness

Influenza vaccination can help prevent at least some of these deaths and also reduce both health-care costs and productivity losses associated with influenza illness. Economic studies of influenza vaccination of persons aged ≥65 years conducted in the U.S. have found overall societal cost-savings and substantial reductions in hospitalization and death (3,4,5). Also, in a study that included all age groups, cost-utility improved with increasing age and among those with chronic medical conditions(6).

Adult Immunization Coverage Rates in San Diego County

According to locally conducted Random Digit Dial surveys in 1998-2000, for persons ≥65 years, the reported rates of immunization against influenza (73-77 percent), pneumococcal disease (63-69 percent) and appropriate tetanus immunization (57-60 percent) have stayed at consistent levels for these three years. The coverage levels were higher than the reported percentages for California and the nation as a whole. However, not all seniors who need these immunizations are receiving them. The Healthy People 2010 Objectives attempt to address this shortfall by setting a goal to increase coverage levels for influenza and pneumococcal vaccines to 90 percent. Interventions such as standing orders for vaccine, using provider and patient reminders and recalls, have been proven effective in increasing

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adult immunization levels (Centers for Disease Control and Prevention [CDC]. Vaccine-Preventable Diseases: Improving Vaccination Coverage in Children, Adolescents and Adults. MMWR 1999;48:RR-8).

2001-2002 Vaccine Composition and Recommendations

The recommended vaccine for the coming flu season contains protection against A/Moscow/10/99 (H3N2)-like, A/New Caledonia/20/99 (H1N1)-like, and B/Sichuan/379/99-like hemagglutinin antigens. For the A/Moscow/10/99 (H3N2)-like antigen, U.S. manufacturers will use the antigenically equivalent strain A/Panama/2007/99 (H3N2) and for the B/Sichuan/379/99-like antigen, they will use one of the antigenically equivalent viruses B/Johannesburg/5/99, B/Victoria/504/2000 or B/Guangdong/120/2000; these viruses will be used because of their growth properties and because they are representative of currently circulating A (H3N2) and B viruses. Although the current vaccine can contain one or more antigens used in previous years, immunity declines during the year following vaccination. Therefore, a history of vaccination for the previous season does not preclude the need to be revaccinated.

Influenza vaccine is strongly recommended for anyone ≥6 months of age who, because of age or underlying medical condition, is at increased risk for complications of influenza. Health care workers and others (including household members) in close contact with high-risk groups also should be vaccinated. *Due to the possibility of vaccine supply problems, persons who fall into the categories below (***Groups at Increased Risk** and **Groups That Can Transmit Influenza to Persons at High Risk***) should be encouraged to get vaccine in October or November, whereas other groups should be considered for vaccine in December or January.*

Groups at Increased Risk

Specifically, the following groups should be encouraged to receive protection, according to the latest CDC guidelines:

1. Persons aged ≥65 years; (County Health and Human Services will follow California legislative guidelines and provide state-supplied vaccine to persons ≥60 years);
2. Residents of nursing homes and other chronic-care facilities that house persons of any age who have chronic medical conditions;
3. Children and adults who have chronic disorders of the pulmonary or cardiovascular systems, including asthma;
4. Children and adults who have required regular medical follow-up or hospitalization during the preceding year because of chronic metabolic diseases (including diabetes mellitus), renal dysfunction, hemoglobinopathies (including anemia), or immuno-suppression (e.g., caused by medications or human immunodeficiency virus);
5. Persons aged 6 months-18 years who are receiving long-term aspirin therapy and therefore might be at risk for developing Reye syndrome after influenza;
6. Women who will be in the second or third trimester of pregnancy during the influenza season; and
7. Persons aged 50-64 years; vaccination is recommended for persons aged 50-64 years because this group has an increased prevalence of persons with high-risk conditions.

Although influenza vaccination levels have increased substantially for seniors, further improvements are needed, particularly among persons at high risk aged <65 years. The ACIP recommends the use of strategies to improve vaccinations levels, including the use of reminder/recall systems and standing orders programs.

Groups That Can Transmit Influenza to Persons at High Risk

The following groups also should be encouraged to receive vaccine:

1. Physicians, nurses and other personnel in both hospital and outpatient care settings, including emergency response workers;
2. Employees of nursing homes and chronic-care facilities who have contact with patients or residents;
3. Employees of assisted living and other residences for persons in high-risk groups;
4. Providers of home care to persons at high risk (e.g., visiting nurses, volunteer workers); and,
5. Household members (including children) of persons in high-risk groups.

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The *Physicians' Bulletin* is published on an as-needed basis by the County of San Diego Health and Human Services Agency to provide updated information on health issues of concern to San Diego County's medical community.

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Recommended Influenza Vaccine* Dose By Age, 2001-2002

Age group #	Product †	Dose	Number of doses	Route §
6-35 mos.	Split virus only	0.25 mL	1 or 2 ¶	Intramuscular
3-8 yrs.	Split virus only	0.50 mL	1 or 2 ¶	Intramuscular
9-12 yrs.	Split virus only	0.50 mL	1	Intramuscular
>12 yrs.	Whole or split virus	0.50 mL	1	Intramuscular

* Contains 15 mg. each of A/New Caledonia/20/99 (H1N1)-like, A/Moscow/10/99 (H3N2)-like, and B/Sichuan/379/99-like strains. For the A/Moscow/10/99 (H3N2)-like antigen, manufacturers will use the antigenically equivalent A/Panama/2007/99 (H3N2) virus, and for the B/Sichuan/379/99-like antigen, U.S. manufacturers will use one of the antigenically equivalent viruses B/Johannesburg/5/99, B/Victoria/504/2000, or B/Guangdong/120/2000. Manufacturers include Aventis Pasteur, Inc. (Fluzone® split); Evans Vaccines, Ltd. (Fluvirin® purified surface antigen vaccine); and Wyeth Lederle Laboratories (Flushield™ split). For further product information call Aventis Pasteur, (800) 822-2463; Evans Vaccines, (800) 200-4278, or Wyeth Lederle, (800) 358-7443.

Simultaneous administration at separate sites of influenza, pneumococcal, Td or childhood vaccines should not lessen immunogenicity or enhance adverse reactions.

† Because of the lower potential for causing febrile reactions, only split-virus vaccines should be used for children. They may be labeled as "split," "subvirion," or "purified-surface-antigen" vaccine. Immunogenicity and side effects of split- and whole-virus vaccines are similar among adults when administered at the recommended dosage.

§ For adults and older children, the recommended site of vaccination is the deltoid muscle using a needle at least 1" in length. The preferred site for infants and young children is the anterolateral aspect of the thigh.

¶ Two doses administered at least 1 month apart are recommended for children <9 years of age who are receiving influenza vaccine for the first time.

** No whole virus vaccine will be distributed in the U.S. during the 2001-2002 influenza season.

Other Groups With Special Conditions Who May Get Vaccine After High-Risk Groups if Supplies Are Delayed

Because influenza can result in serious illness and complications and because influenza vaccination can result in the production of protective antibody titers, vaccination will benefit many HIV-infected patients, including HIV-infected pregnant women. Many experts consider influenza vaccination safe during any stage of pregnancy. Influenza vaccine does not affect the safety of breastfeeding for mothers or infants. Breastfeeding does not adversely affect immune response and is not a contraindication for vaccination.

When persons in high-risk groups have been immunized, persons who provide essential community services should then be considered for vaccination to minimize disruption of essential activities during influenza outbreaks. Influenza vaccine is appropriate for travelers, particularly those planning to travel to the tropics or travel as part of large organized tourist groups any time of the year, and also for persons traveling to the Southern Hemisphere from April through September. In addition to the groups for which annual influenza vaccination should be recommended, physicians should administer influenza vaccine to any person who wishes to reduce the likelihood of becoming ill with influenza depending on vaccine availability.

Who Should Not Be Immunized

1. Persons known to have anaphylactic hypersensitivity to eggs (see Side Effects below). However, those who also are at higher risk for complications of influenza may benefit from vaccine after appropriate allergy evaluation and desensitization.
2. Adults with acute febrile illnesses usually should not be vaccinated until their symptoms have abated. However, minor illnesses with or without fever should not contraindicate flu vaccine, particularly among children with a mild upper respiratory tract infection or allergic rhinitis.

Timing of Influenza Vaccine Activities

The optimal time to vaccinate persons in groups at high risk is usually during October-November. However, to avoid missed opportunities for vaccination, influenza vaccine should be offered to persons at high risk when they are seen by health-care providers for routine care or are hospitalized in September, provided that vaccine is available. In addition, health-care providers should also continue to offer vaccine to unvaccinated persons after November and throughout the influenza season even after influenza activity has been documented in the community. In the United States, seasonal influenza activity can begin to increase as early as November or December but has not reached peak levels in the majority of recent seasons until late December through early March. Therefore, although the timing of influenza activity can vary by region, vaccine administered after November is likely to be beneficial in most influenza seasons. Adults develop peak antibody protection against influenza infection 2 weeks after vaccination.

Persons planning substantial organized vaccination campaigns might consider scheduling these events after

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mid-October. Although influenza vaccine generally becomes available by September, the availability of vaccine in any location cannot be ensured consistently in the early fall. Scheduling campaigns after mid-October will minimize the need for cancellations because vaccine is unavailable. In facilities housing elderly persons (e.g., nursing homes), vaccination before October generally should be avoided because antibody levels in such individuals can begin to decline within a few months after vaccination.

Children <9 years of age who have not been vaccinated previously should receive two doses of vaccine at least 1 month apart to maximize the likelihood of a satisfactory antibody response to all three vaccine antigens. The second dose should be administered before December, if possible. Vaccination efforts for all groups should continue into December and later as long as influenza vaccine is available.

Side Effects and Adverse Reactions

When educating patients about potential side effects, clinicians should emphasize that: a) inactivated influenza vaccine contains only noninfectious killed viruses, it cannot cause influenza; and b) coincidental respiratory disease unrelated to influenza vaccination can occur after vaccination. The most frequent side effect of vaccination is soreness at the vaccination site that lasts up to 2 days. These local reactions generally are mild and rarely interfere with the ability to conduct usual daily activities. In addition, two types of systemic reactions have occurred:

- Fever, malaise, myalgia, and other systemic symptoms can occur following vaccination and most often affect persons who have had no exposure to the influenza virus antigens in the vaccine (e.g., young children). These reactions begin 6 to 12 hours after vaccination and can persist for 1 or 2 days. Recent placebo controlled trials suggest that among elderly persons and healthy young adults, split-virus influenza vaccine is not associated with higher rates of systemic symptoms (e.g., fever, malaise, myalgia, and headache) when compared with placebo injections.
- Immediate, presumably allergic, reactions (such as hives, angioedema, allergic asthma, or systemic anaphylaxis) rarely occur after influenza vaccination. These reactions probably result from sensitivity to some vaccine component, most likely residual egg protein. Protocols have been published for safely administering influenza vaccine to persons with egg allergies(7).

Note: Influenza vaccine distributed in the U.S. contains thimerosol, a mercury-containing compound, as a preservative. This preservative has been used in U.S. vaccines since the 1930s. No data or evidence exists of any harm caused by the level of mercury exposure that might occur from influenza vaccination. Because pregnant women are at increased risk for influenza-related complications and because a substantial safety margin has been incorporated into the health guidance values for organic mercury exposure, the benefit of influenza vaccine outweighs the potential risks for thimerosol.

Antiviral Agents: Amantadine, Rimantadine, Zanamivir and Oseltamivir

Physicians should note that none of the antiviral agents is a substitute for influenza vaccine, although they are critical adjuncts in the prevention and control of influenza.

When determining the timing and duration for administering influenza antiviral medications for prophylaxis, factors related to cost, compliance and potential side effects should be considered. To be maximally effective as prophylaxis, the drug must be taken each day for the duration of influenza activity in the community. However, to be most cost-effective, one study of amantadine or rimantadine prophylaxis reported that the drugs should be taken only during the period of peak influenza activity in a community(8). None of the four antiviral agents has been demonstrated to be effective in preventing serious influenza-related complications (e.g. bacterial or viral pneumonia or exacerbation of chronic diseases). Evidence for the effectiveness of these four antiviral drugs is based principally on studies of patients with uncomplicated influenza. Data are limited and inconclusive concerning the effectiveness of amantadine, rimantadine, zanamivir, and oseltamivir for treatment of influenza among persons at high risk for serious complications of influenza.

Note: The current guidelines for all antiviral agents, including a recommended dosage chart, are in the April 20, 2001 Morbidity and Mortality Weekly Report (MMWR) on influenza. Please see page 8 of this Bulletin for a copy of the chart, and see web resources listed on pp. 6-7.

Amantadine and **rimantadine** are two chemically related drugs which interfere with the replication cycle of **type A (but not type B)** influenza viruses. These drugs do not interfere with the antibody response to influenza vaccine(9). They can be used prophylactically or therapeutically. As with all drugs, they may cause adverse reactions in some persons.

Therapeutic Use: In otherwise healthy adults, amantadine or rimantadine can reduce by approximately one day the duration of signs and symptoms of influenza illness caused by **type A** virus when administered within 48 hours of illness onset.

Prophylactic Use: When adminis-

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tered prophylactically to healthy adults or children before and throughout the epidemic period, both drugs are approximately 70-90 percent effective in preventing illness caused by naturally occurring strains of **type A** influenza viruses. Both have been studied extensively among nursing home populations as a component of influenza outbreak control programs, which can limit the spread of influenza within chronic care institutions (9,10, 11-13). In addition to the use of antiviral medications, other outbreak control measures include instituting droplet precautions and establishing cohorts of patients with confirmed or suspected influenza, re-offering influenza vaccinations to unvaccinated staff and patients, restricting staff movement between wards or buildings, and restricting contact between ill staff or visitors and patients.

Zanamivir (an inhalant), and **oseltamivir** (a pill), two other prescription antiviral drugs, were approved in 1999 by the FDA for treatment of uncomplicated influenza illness caused by **type A and B** virus. Then, in 2000, oseltamivir was approved for prophylaxis as well as treatment for both **types A and B** virus. Again, as with all drugs, they may cause adverse reactions in some persons.

Therapeutic Use: In otherwise healthy adults, zanamivir and oseltamivir can reduce the duration of signs and symptoms of influenza A and B illness by approximately one day when administered within 48 hours of illness onset.

Note that zanamivir treatment of influenza-like illness among persons with asthma or chronic obstructive pulmonary disease can result in respiratory function deterioration. If physicians decide to prescribe zanamivir to patients with underlying chronic respiratory disease after carefully considering potential risks and benefits, the drug should be used with caution under conditions of proper monitoring and supportive care, including the availability of short-acting bronchodilators. No clear evidence is available regarding the safety or efficacy of zanamivir for persons with underlying respiratory or cardiac disease or for persons with complications of acute influenza.

Prophylactic Use (oseltamivir only): Community studies of healthy adults indicate that oseltamivir is 82% effective in preventing febrile, laboratory-confirmed influenza illness. One 6-week study of oseltamivir prophylaxis among nursing home residents found a 92% reduction in influenza illness(14, 15).

Again, current guidelines for all antiviral agents can be found on page 8 of this Bulletin and in the April 20, 2001 MMWR on influenza

It is important to stress to patients that none of these antiviral drugs is a substitute for influenza vaccine. Immunization is the most effective way to prevent the flu. (Note: Nasal inhalant vaccine is not yet available.)

Influenza Vaccine Campaign Offers Opportunity to Provide Other Needed Adult Vaccines

Seniors and others at high risk of complications from influenza visit medical care providers each fall to receive influenza vaccine. Medical care providers should use this opportunity to evaluate these adults for other needed vaccines as well. Recommended vaccines are listed below.

Pneumococcal polysaccharide vaccine is effective against the 23 most common strains of *Streptococcus Pneumoniae*, a bacterial pathogen that causes illness and death, especially among the elderly and among persons who have certain medical conditions. *S. pneumoniae* has become increasingly resistant to antibiotics. Annual cases of invasive pneumococcal infections in the United States include 500,000 cases of pneumonia, 3000 cases of meningitis and 50,000 cases of bacteremia. The pneumococcal vaccine is recommended for persons age 65 and over. It is also recommended for anyone age 2 years and over with chronic illness, asplenia, or immune compromising conditions. Complete information and the "one time revaccination recommendations" are available in the Centers for Disease Control & Prevention's April, 1997 report, *Prevention of Pneumococcal Disease, Recommendations of the Advisory Committee on Immunization Practices (ACIP).* This document is available on the CDC website noted above. While pneumococcal vaccine is not a substitute for the annual flu shot, it can provide protection against a major complication of influenza. Physicians should ensure that their senior and high-risk patients have received this important vaccine protection as an adjunct to their annual flu shot.

Measles, mumps and rubella combination vaccine (MMR) is advised for anyone born since 1957 and two doses are advised for most persons.

Tetanus and diphtheria vaccine (Td) is recommended every 10 years for those adults who have completed a basic Td series. (Note that if there are still national shortages of Td vaccine in Fall 2001, assess patients for Td boosters; if needed, put these patients into a recall system and then provide them with this vaccine in 2002 when supplies are available.) Many persons born before the 1940s have never completed the basic 3-dose series of tetanus- and diphtheria-containing vaccine. These seniors should be given priority for Td vaccine supplies.

Varicella vaccine is also advised for those who do not have a history of chickenpox disease.

Hepatitis B vaccine is recommended for those at risk.

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Physicians are urged to capitalize on office visits by those at risk for influenza to provide all needed vaccines. To receive a free chart on adult vaccine recommendations, call the Immunization Program at (619) 692-8661.

Strategies for Physicians and Health Care Providers

Vaccines are a vital part of preventive care and should be routinely offered by providers in office/outpatient facilities providing ongoing care. Successful vaccination programs combine:

1) education for health care workers;
2) education and publicity targeted toward the potential recipients;
3) a plan for identifying persons at high risk, usually by medical record review; and
4) efforts to remove administrative and financial barriers.

Staff in physicians' offices, community health centers, employee health clinics, hemodialysis centers, hospital specialty-care clinics and outpatient rehabilitation programs should identify and label the medical records of patients who should receive vaccine. Patients in high-risk groups who do not have regularly scheduled visits during the fall should be reminded by mail or telephone of the need for vaccination.

Staff in acute health care facilities such as emergency rooms and walk-in clinics should offer vaccine to persons in high-risk groups or provide written information on why, where, and how to obtain the vaccine.

Source Notes

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Influenza- and Immunization-Related Resources

The Centers for Disease Control & Prevention's 2001 report, *Prevention & Control of Influenza, Recommendations of the Advisory Committee on Immunization Practices (ACIP),* (*MMWR* Volume 50, No. RR-4) includes information on the disease, vaccine, target groups, strategies and the use of all antiviral agents in preventing and/or treating influenza. **For a copy of the *Prevention & Control of Influenza* report, please go to the CDC website noted below or call the Immunization Program at (619) 692-8661.**

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The following is a list of World Wide Web sites for accessing information and promotional materials on influenza, influenza vaccine and related topics:

www.cdc.gov/ncidod/diseases/flu/fluvirus.htm: In addition to the CDC's influenza reports mentioned above, this site contains pneumococcal vaccine educational materials and weekly influenza surveillance reports beginning in October. This site has a wide variety of links to other sites with fact sheets for providers and patients.

www.cmri-ca.org/healthcare-prevent-immun.html: California Medical Review, Inc., the Medicare quality assurance organization, provides specific information on Medicare billing, including roster billing. "Immunization Tip Sheets for Providers" detail how to organize systems to promote flu and pneumococcal vaccines in different settings. Free postcards (non-postage-paid), pamphlets and posters for California Medicare providers can be ordered online, by phone (877-363-5555) or fax (877-364-5555). There are also many links to other sites with pertinent information.

www.sdchip.org: This site contains information about Community Health Improvement Partners (CHIP), a collaboration of health care organizations, providers and community groups working in San Diego County to increase awareness of and responsiveness to community health needs. Also, the site has downloadable flu and pneumococcal information in English and 7 other languages, and links to other immunization-related sites.

www.cdc.gov/nip/issues/flu: This website has information, updated as it becomes available, about developments related to the production, distribution and administration of influenza vaccine for the 2001-2002 influenza season.

www.immunize.org: The Immunization Action Coalition has a wealth of print materials that can be downloaded and reproduced. Included are childhood and adult materials and official Vaccine Information Statements including, *"Influenza Vaccine, What You Need To Know"* in many languages. Note that this last document is to be given to patients to read before flu vaccine is administered. It does NOT contain an area for the patient's signature.

www.immunizeseniors.org: This site contains information especially for senior citizens, sponsored by the American Society of Consultant Pharmacists.

www.hcfa.gov/flu: This is the Health Care Financing Administration site, and contains information on Medicare, Medicaid and other programs, including how they relate to influenza vaccine.

www.nfid.org: Web site of the National Foundation for Infectious Diseases (NFID), which offers information on various infectious diseases and has an "influenza web presentation."

www.nfid.org/ncai: This part of NFID's site is devoted to the National Coalition for Adult Immunization. It offers adult immunization standards, schedules, recommendations and more. The Coalition promotes Adult Immunization Week each October (Oct. 14-20 in 2001) and has reproducible materials available.

www.co.san-diego.ca.us/cnty/cntydepts/health/services/immunizations.html: This is the County of San Diego Health and Human Services Agency website, which has location and contact information for clinics which provide low-cost childhood and adult immunizations. *(Please note that influenza immunization clinic information will probably not be available at this site until early October, when the days, hours and locations of flu shot clinics are finalized.)*

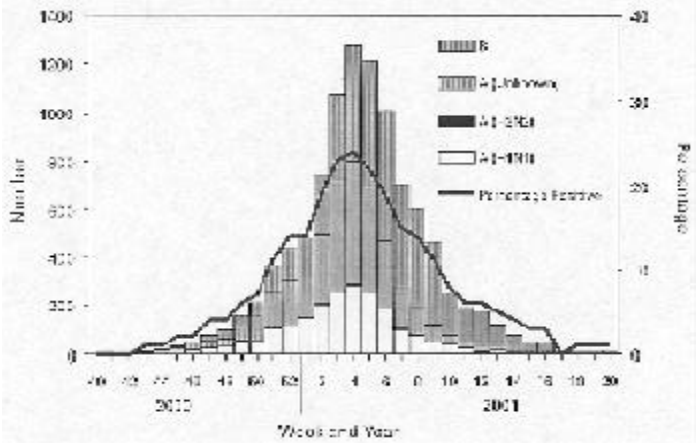
2001-2002 Influenza Vaccine Manufacturers/Distributors

Aventis-Pasteur (*Fluzone*®)
1-800-VACCINE (1-800-822-2463)

Wyeth-Lederle-Ayerst (***Flushield***™)
1-800-358-7443

Evans/Medeva (***Fluvirin***®):

General Injectables (distributor in US) 1-800-521-7468



Number and percentage of respiratory specimens testing positive for influenza reported by World Health Organization and National Respiratory and Enteric Virus Surveillance System collaborating laboratories, by week and year--United States, 2000-2001 season (CDC. Update:Influenza Activity--United States, 2000-2001 season. MMWR 2001;50:466-470.)