

FLU VACCINE DISTRIBUTION IN TEXAS

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I. Executive Summary

HB 3184 (80th Legislature, Regular Session, 2007) requires the Texas Health and Human Services Commission to conduct a study of the distribution of influenza vaccine in Texas to determine the feasibility of giving priority in filling flu vaccine orders to physicians and other licensed health care providers over retail establishments. The feasibility of implementing such a system is also reviewed and reported.

Findings. A conflict exists between the concerns of physicians that they may not be able to vaccinate their patients against the flu and the public health goal of vaccinating as many people as possible, regardless of the venue. While physicians in the past have pushed for priority in distribution of the flu vaccine, public health officials are reluctant to give preference to any immunization provider over another.

Flu distribution data. Data show that nationally, 40 percent of adults receiving the flu shot receive it in doctors' offices and distributors ship 80 percent of the flu vaccine they distribute to doctors. By all accounts, sufficient flu vaccine was available in the 2007/2008 flu season and little evidence exists that doctors were not able to get flu vaccine. Temporary shortages for physicians and other immunizers are not uncommon, however, as flu vaccine is produced in batches and shipped as each batch is completed. Immunizers may run out of flu vaccine between shipments.

Implications for physicians. Physicians may be less likely than other immunizers to pre-book orders in January prior to the flu season and may not meet minimum order requirements to order directly from a manufacturer, making temporary shortages more likely. Physicians can minimize the disruption in their supplies throughout the season by pre-booking orders and by ordering large enough quantities to receive more vaccine in each shipment. The purchasing power of physicians can be further enhanced by forming public or private purchasing pools, as has been done by the Texas Association of Family Physicians and in the state of Minnesota.

Legislative efforts in the United States. Some states have considered or implemented policies to change flu vaccine distribution through a variety of mechanisms, including physician priority, shipping and inventory information sharing, and state purchasing. Only one state has implemented and enforced such a policy change, although no state legislation was found giving priority to physicians over other providers. Three federal bills are currently being considered that seek to increase the availability of flu vaccine.

Physician priority in Texas. While legislating a system that gives priority to physicians over retail establishments is an option for Texas, it may impact distribution to other immunizers, which could negatively impact the ability to achieve public health flu vaccination goals. While there may be some advantages, including maintaining a patient's medical home and ensuring that medical records are complete and accurate, there are a number of disadvantages to implementing physician priority, including:

- Creating supply problems for other venues that provide vaccination
- Incurring implementation and monitoring costs for the state
- Decreasing vaccination rates
- Increasing the costs of vaccine
- Reducing vaccine production capacity, which is critical to preparation for a flu pandemic

Other options for Texas. Other options to consider for ensuring adequate supplies of flu vaccine in the state of Texas include the following:

- Require manufacturers and distributors to fill public health orders before those of retailers, ensuring that participants in public vaccine programs receive their vaccine before retailers do.
- Centralize flu vaccine purchasing at the state level as has been done in Rhode Island; physicians would order from the state as they do for childhood vaccines.
- Use the CDC flu tracking system to redistribute unused vaccine.
- Encourage the development of group purchasing pools to offer greater quantities of vaccine at lower prices to physicians and to receive an early (September –October) guaranteed shipping date for these orders.
- Support provisions of federal legislation currently under consideration that will impact flu vaccine production and distribution.

Conclusion. Texas will need to weigh the administrative and financial costs of implementing any tool to enhance distribution to physicians with the most recent experience, the 2007/2008 flu season, in which more flu vaccine was produced than ever before – 132 million doses. Six pharmaceutical companies are now producing flu vaccine and production is expected to increase for the next flu season as more of the population is recommended to receive the vaccine. Increased production will prevent overall shortages, although temporary shortages may persist for individual providers, especially those receiving small shipments.

II. Overview

Purpose

HB 3184 (80th Legislature, Regular Session, 2007) requires the Texas Health and Human Services Commission “to study the wholesale distribution of influenza vaccine in Texas to determine the feasibility of implementing a system that requires giving a priority in filling orders for influenza vaccine to physicians and other licensed health care providers authorized to administer influenza vaccine over retail establishments. The feasibility of implementing such a system is also reviewed and reported.” The bill allows the executive commissioner to “implement such a system if it is determined to be feasible.”

More flu vaccine was manufactured and distributed in the 2007/2008 flu season than in any previous year. According to national data collected by the U.S. Centers for Disease Control and Prevention (CDC), a majority of people who receive a flu shot get it in their doctor’s office, but the proportion of shots administered at retail establishments is growing¹, as are the number of people who are recommended to receive a flu shot.² Certainly, physicians are a vital part of the effort to administer the flu vaccine. According to the American Medical Association (AMA), a recommendation to get a flu shot from a physician is 85 percent effective in getting a patient to receive one.³ A closer look at the manufacturing and distribution processes sheds light on why delays have occurred in the past and what, if anything, can be done to mitigate irregularities that may exist in the distribution of flu vaccine to physicians.

Methodology

Information for this report was gathered from the following sources:

Literature Review

A search of recent journal articles was conducted using PUBMED and Medline. Additional journal articles were identified from websites and individuals contacted for interviews. News searches were conducted throughout the flu season. Literature from relevant associations and groups was also used, as were publications and reports from the CDC, the Government Accountability Office (GAO), and the Health Industry Distributors Association (HIDA). For a complete bibliography, see Appendix B.

Interviews

Immunization directors from various states were contacted and asked about flu vaccine distribution in their respective states. These states were selected because their size and demographics are similar to Texas and/or they have recently considered or implemented policies to change the way flu vaccine is distributed. See Appendix A for a complete list of interviewees.

Immunization Directors from the following states were interviewed:

¹ Layton, Christine and Nathan West, “Influenza Vaccine: Who Buys It and Who Sells It”, Research Triangle Institute, October 2005, p.4.

² GAO 08-27, p. 47.

³ Interview with Dr. Litjen Tan, 2/18/08.

- California
- Connecticut
- Florida
- Nevada
- New York
- Pennsylvania
- Texas
- Rhode Island
- Virginia

Representatives from the following organizations were interviewed:

- ASD Healthcare
- American Medical Association
- Centers for Disease Control and Prevention (CDC) National Immunization Program
- GlaxoSmithKline
- Health Industry Distributors Association
- Maine Medical Association
- Massachusetts Medical Society
- Sanofi Pasteur, Inc.
- Texas Academy of Family Physicians
- Texas Federation of Drug Stores
- Texas Hospital Association
- Texas Medical Association
- Texas Pharmacy Association
- Visiting Nurses Association of America
- Visiting Nurses Association of Texas

Representatives from the following organizations were contacted but were not available or declined to speak with us prior to the completion of this report.

- Immunization Directors from Iowa, New Jersey, and Massachusetts
- HEB
- Wal-Mart

III. Flu Vaccine Production and Distribution

Flu vaccine production and distribution is basically a private sector activity. In the absence of a vaccine shortage or other public health emergency, government agencies have limited authority to control vaccine production or distribution.⁴ Vaccine manufacturers and medical supply distributors own and control the bulk of the vaccine infrastructure in the United States. There are currently six companies manufacturing various flu vaccine products for the U.S. market:

Flu Vaccine Products 2007/2008				
Manufacturer	Vaccine	Formulation	Thimerosal	Age Indication
Sanofi Pasteur, Inc.	Fluzone Inactivated TIV	Multi-dose vial	yes	6 months and older
	Fluzone Inactivated TIV	Single-dose pre-filled .25 mL syringe	none	6-35 months
	Fluzone Inactivated TIV	Single-dose pre-filled .5 mL syringe	none	36 months and older
Novartis Vaccine	Fluvirin Inactivated TIV	Multi-dose vial	yes	4 years and older
	Fluvirin Inactivated TIV	Single-dose pre-filled .5mL syringe	1mcg or less mercury*	4 years and older
MedImmune Vaccines, Inc.	FluMist LAIV	Single-dose sprayer	none	healthy, 2-49 years
CSL Biotherapies	Afluria Inactivated TIV	Single-dose pre-filled .5 mL syringe	none	18 years and older
	Afluria Inactivated TIV	Multi-dose vial	yes	18 years and older
GlaxoSmithKline Biologicals	Fluvarix Inactivated TIV	Single-dose pre-filled .5 mL syringe	1mcg or less mercury*	18 years and older
ID Biomedical Corporation (subsidiary of GSK)	FluLaval Inactivated TIV	Multi-dose vial	yes	18 years and older

Source: CDC Influenza Vaccine Price List, <http://www.cdc.gov/vaccines/programs/vcf/cdc-vac-price-list.htm>, accessed 2/18/2008. *These vaccines are called "preservative-free" in the industry. Thimerosal is a preservative used in some vaccines.

According to the Health Industry Distributors Association (HIDA), there are currently 25 licensed flu vaccine distributors. These distributors ship the vaccine to health departments, physicians, nursing homes, hospitals, retail stores, and other vaccination sites. They are licensed by their respective state boards of pharmacy.⁵

There have been reported shortages and delays of flu vaccine in the United States for the last several years. However, when production, distribution, and usage data are examined, it becomes clear that actual shortages have been rare. In fact, every year, millions of doses go unused.⁶ Temporary shortages have frequently occurred, particularly for private providers who may place relatively small orders. A typical example of such a temporary shortage is the private provider who places an order which is then filled in three shipments of vaccine throughout the flu season. Between these shipments, however, the

⁴ Hodge, James and Jessica O'Connell, "The Legal Environment Underlying Influenza Vaccine Allocation and Distribution Strategies", *Public Health Management Practice*, 12(4), 2006, p.341.

⁵ Email communication with Andrew Van Ostrand, 2/14/08.

⁶ GAO 08-27, p. 14.

provider runs out of vaccine.

These temporary shortages are due to the specific nature of the flu vaccine manufacturing process in which vaccine production is gradual and cannot yield the total number of needed doses by the start of the vaccination period. The 2007/2008 flu season is the first in many years in which there has not been any substantial delay in receiving vaccine. Most state health officials and organizational representatives interviewed reported that physicians received plenty of vaccine this year and they received it earlier in the season as well. Many physicians and other immunizers maintain that receiving enough vaccine is as important as receiving it at the right time, particularly early in the season.

Vaccine Market

Pharmaceutical companies are providing a good that is considered to be instrumental in maintaining public health, but these companies operate in the private sector. Vaccine development is a long and costly process. Manufacturers assume serious financial risk due to the fragility of the egg-based production process and the instability of demand for the vaccine.⁷ In the past, when particularly virulent strains of the flu have resulted in wide-spread illness or even death, demand for the vaccine has exploded, often later in the vaccination period when adjustments in supply could not be made.⁸

Although there has been an increase in the last few years in the number of companies who are manufacturing the flu vaccine, these companies face diminishing incentives to produce flu vaccine, including large capital expenses, extensive regulations and licensing processes, and declining profits.⁹ A conflict exists between immunizers trying to get the lowest possible price per dose and the expectation that manufacturers will shoulder high start-up costs and extensive licensing and regulation so that sufficient flu vaccine can be produced. However, with increasing numbers of people included in the priority groups for flu vaccination, production is likely to continue increasing.¹⁰

In the 2007/2008 flu season, 132 million doses of flu vaccine were produced by the six manufacturers. This is a record number, up from 120 million doses in the previous flu season. However, during the 2007/2008 flu season, only 118 million doses had been distributed by February 6, 2008.¹¹ Manufacturers are left with the remainder. Though there is no reliable source of data for the number of doses left unused by immunizers, one manufacturer estimated that overall, 35 million doses were unused during the 2007/2008 flu season.¹² Of those already purchased by immunizers, some will be sold or traded to other immunizers and some will simply be discarded and the purchaser will be uncompensated. However, two manufacturers — Novartis and GlaxoSmithKline — offered 100 percent refunds for unused vaccine that was purchased in December and later.¹³ These buy-back programs are intended to encourage late season flu vaccination.

The global vaccine market is set to double by the year 2016, so it seems that flu vaccine supplies will continue to grow.¹⁴ However, this is countered by some concern that declining profits for the manufacturers could translate, over time, into lower production for upcoming flu seasons. That could eventually mean that the production capacity for flu vaccine in the event of a pandemic may not exist.¹⁵

⁷ Layton, Christine and Nancy Lenfestey, "Influenza Vaccine Manufacturing", Research Triangle Institute, October 2005, pp. 12-15.

⁸ Grady, Denise and Lawrence K. Altman, "With Flu Cases Spreading Vaccine Supplies Run Low", *New York Times*, 12/6/03.

⁹ Layton, Christine and Nancy Lenfestey, "Influenza Vaccine Manufacturing", Research Triangle Institute, October 2005, p. 13.

¹⁰ Landers, Susan. "Vaccines get a boost: Global Market increases profitability of making vaccine", *American Medical News*, 2/4/08.

¹¹ Interview with Dr. Jeanne Santoli, 2/4/08.

¹² Interview with Sanford Kaufman, 1/16/08.

¹³ Interview with Dr. Litjen Tan, 2/18/08.

¹⁴ Landers, Susan. "Vaccines get a boost: Global market increases profitability of making vaccine", *American Medical News*, 2/4/08.

¹⁵ Layton, Christine and Nancy Lenfestey, "Influenza Vaccine Manufacturing", Research Triangle Institute, October 2005, pp. 8-15; 18-22.

Some anecdotal evidence suggests that demand for thimerosal-free vaccine is growing sharply in some areas and that there may not be enough production capacity currently to meet this demand.

Manufacturing Process

The flu vaccine manufacturing process is lengthy and has many complicated steps. Throughout the summer and early winter prior to any given flu season, the U.S. Centers for Disease Control and Prevention (CDC), the Food and Drug Administration (FDA), and the World Health Organization (WHO) select three strains of the virus that will likely be in circulation in North America during the upcoming flu season. Seed viruses are developed from the three strains and these are injected into millions of fertile chicken eggs where they replicate. Vaccine manufacturers report that it takes from five to eight months to grow the viruses, after which time they are harvested from the eggs, inactivated, and purified. Next, the vaccine is tested. The biggest segment of production time is spent on testing by both manufacturers and the FDA.¹⁶ Each individual lot has to be separately tested and licensed. Only then can it be packaged and shipped. The earliest shipments begin at the end of September and continue through January.

The most problematic manufacturing issue is certainly that the flu vaccine is produced in batches. Each batch or lot, as mentioned above, must be independently licensed and tested before it can be packaged and shipped. The flu vaccine is essentially produced in what one health official called “drips and drabs,” making it impossible to fill all orders in their entirety early in the flu season. Furthermore, any delay or problem in production causes delays and problems in distribution. These can include contamination and failure of a particular strain to grow properly. The eggs are not a sturdy media in which to grow the product. Changes in demand are very difficult to adjust for because the eggs must be 6 months old before they can be used to grow the virus.

Critics charge that the production process is outdated and unnecessarily burdensome.¹⁷ New, cell-based technologies are being developed and tested to speed and otherwise perfect the production process. But there are some in the immunization community that warn that these processes will not be much faster than the egg-based methods.¹⁸ Other supply problems stem from the historically small production base. Although there are now six manufacturers making vaccine, in the recent past there have been as few as two. In 1980, seventeen manufacturers were producing flu vaccine, but total distribution was only twenty million doses, a fraction of the current doses produced.¹⁹

Distribution Process

Immunizers may order flu vaccine directly from the manufacturer or from a distributor. Distributors may purchase vaccine directly from the manufacturer or they may be a “secondary” distributor, purchasing from other distributors. Secondary distributors may deliver vaccines to doctors’ offices or pharmacies along with other medical supplies.²⁰ Some flu vaccine products are only available from certain distributors. Manufacturers may make some or all of their flu vaccine products available through distributors or they may not use distributors at all and instead ship directly to the customer.

Many orders are placed well in advance of the flu season, largely in January through a process known as

¹⁶ National Center for Immunization and Respiratory Diseases, Podcast: “Influenza Vaccine Production and Distribution”, 9/11/2007.

¹⁷ GAO 08-27, pp. 16-18.

¹⁸ Layton, Christine and Nancy Lenfestey, “Influenza Vaccine Manufacturing”, Research Triangle Institute, October 2005, p. 15.

¹⁹ GAO 08-27, p. 14, and Layton, Christine and Nancy Lenfestey, “Influenza Vaccine Manufacturing”, Research Triangle Institute, October 2005, p. 14.

²⁰ GAO 08-27, p. 13.

pre-booking. Clinics, hospitals, physicians offices, pharmacies, and all other immunizers may call or email orders for the number of doses they think they will need to cover the number of high-risk patients that will seek vaccination the following flu season. According to flu vaccine distributors interviewed for this study, most immunizers ordering their vaccine from distributors are also able to pre-book and most do. As soon as vaccine is available, manufacturers use what they refer to as multi-phased shipments, shipping partial orders to customers, including distributors, so that everyone gets some vaccine as soon as possible. Multi-phased shipments are used because the vaccine is produced in batches or lots and is not available all at once.²¹

Because manufacturers and distributors do not fully disclose all their shipping and distribution data, there is considerable confusion about how vaccines are shipped to immunizers. Immunizers report shipping practices that are not reported by manufacturers. For example, immunizers report that some manufacturers use distribution practices other than multi-phased shipments, such as first-come, first-served, while some manufacturers guarantee shipment dates for orders, particularly if they are made by a certain date and are for a large number of doses.²² Immunizers also indicate that some manufacturers and distributors use a minimum order as a guide for shipments and any order under that minimum may be shipped in its entirety rather than in phases.²³

Role of the Public Sector

Though the manufacture and distribution of the flu vaccine are controlled by the private sector, various governmental entities do play important roles in flu vaccination in the United States. In addition to selecting the flu strains that will go into the vaccine and licensing and testing vaccines before they are sold, public agencies also do the following:

Set Priority Groups

The CDC and the Advisory Committee on Immunization Practices (ACIP) issue recommendations for target groups, sometimes called priority populations or at-risk groups, to be vaccinated and in what order in a particular flu season. ACIP consists of 15 experts on immunization—physicians, virologists, and epidemiologists—who advise the CDC and the U. S. Department of Health and Human Services on the control of vaccine-preventable diseases. Priority or high-risk groups change from year to year, though the trend in recent years is to recommend vaccination to larger and larger groups of people. High-risk populations currently include 75 percent of the total population or 218 million Americans. ACIP priority populations for the most recent flu season include:

- All children 18 years of age and younger (recently adopted for the 2009-2010 season)
- Pregnant women
- People age 50 and older
- People with chronic medical conditions
- Residents of nursing homes or long-term care facilities
- Household contacts of people at high-risk of contracting the flu (listed above)
- Household contacts of children under age 6 months
- Health care workers

²¹ GAO 08-27, p. 22.

²² GAO 08-27, pp. 26-27 and interview with Charles Alexander, 2/5/08.

²³ Interview with Charles Alexander, 2/5/08.

Administer Over- and Undersupplies

The CDC and local and state health departments act as brokers in the case of a shortage or glut of vaccine.²⁴ An example of this might be a physician in one corner of a state who has several unused doses of flu vaccine; the physician emails colleagues and health department officials who can identify a clinic in another corner of the state where the flu is more active and more flu vaccine is needed. This role seems to work informally and only when needed. CDC National Immunization Program (NIP) grantees often send email to NIP staff to report any oversupply and staff put individuals in touch with one another so that immunizers who have too much flu vaccine can get it to providers who don't have enough.

According to the majority of the state immunization directors interviewed for this report, in the event of a temporary shortage or glut, many of the state and local health departments have organized the reallocation of vaccine in the same way. As with the CDC's role as broker, this seems to work on an informal, as-needed basis. State immunization officials estimate that state health departments purchase about 10 percent of all flu vaccine entering their respective states. The remainder is sold and distributed in the private sector and there is no consistent, comprehensive source of data to describe when and where it is shipped, where it is administered, or who receives it.

The CDC also has, in one instance, assumed limited control of vaccine distribution. In 2004 a major manufacturer pulled out of the market due to contamination of one of its production facilities. The manufacturer had expected to provide almost half of the flu vaccine for the 2004/2005 flu season. In response, the CDC purchased 25 percent of the as-yet undistributed flu vaccine supply and gave it to states based on need.²⁵

Also in response to shortages, the CDC developed Flu Vaccine Finder, a tracking system for each dose of vaccine manufactured. Every dose can be tracked to measure shipping duration, vaccination distribution, spot shortages, or gluts. This system is now operational but has substantial problems. Data is not real-time, but is about a week old by the time users see it. The categories describing sites of vaccination do not put retailers into their own group, but divide them among a few categories, including "other public" and "pharmacies". Therefore, it is unclear from this database exactly how many people are being vaccinated at places such as Wal-Mart and other large retailers.²⁶

Purchase and Distribute

The CDC purchases less than 10 percent of the flu vaccine that is distributed in the nation. This includes state purchases of flu vaccine on CDC contracts.²⁷ States receive their allocations of flu vaccine for the public flu vaccine programs described below through the CDC, but may purchase vaccine on their own with state or grant funds.²⁸ A few state immunization staff mentioned that federal allocations of flu vaccine were problematic. Many said that they were unsure of how the CDC allocates flu vaccine and that there did not seem to be any flexibility in these allocations. Dr. Jeanne Santoli at the CDC said that states almost always request more flu vaccine than the CDC has available.

The U.S. Department of Veteran Affairs and the U.S. Department of Defense (DoD) are also direct

²⁴ GAO 08-27, p. 33, Interview with Debbye Rosen, 1/25/08.

²⁵ Henley, Eric MD. "Case Study: The Real-World Experience of a Family Practitioner", *Managed Care*, August 2007.

²⁶ GAO 08-27, p. 32.

²⁷ Interview with Dr. Jeanne Santoli, 2/4/08. States frequently purchase vaccine on the CDC contract for a lower price. The CDC cost per dose is 2 to 3 dollars below that of the private sector.

²⁸ Association of Immunization Managers, "Recommendations and Lessons Learned from the 2004-2005 Flu Season", 2005.

purchasers of flu vaccine. The DoD buys flu vaccine for military personnel and their families and civilian contractors and employees. They also buy vaccine for and administer it to active and retired military personnel and their families. The Federal Occupational Safety and Health Agency and the Indian Health Service also purchase flu vaccine directly.²⁹

Another large public purchaser is the Minnesota Multi-State Contracting Alliance for Pharmacy (MMCAP). This is a voluntary group-purchasing organization run by the state of Minnesota that serves government-operated health care facilities in 42 states and the City of Chicago.

State and local health departments play an important role in disseminating information about flu vaccination. These departments also purchase and distribute flu vaccine through the Vaccines for Children Program (VFC) and Section 317 vaccine programs, although the volume of flu vaccine purchased in Texas through these programs (approximately 600,000 doses for the VFC program) is small compared to the number of flu vaccines administered in Texas (8 million doses).³⁰

At the state level, public health departments purchase flu vaccine for children under the VFC program, a federally-funded entitlement program that allows state and local governments to purchase and distribute vaccines to immunize children under the age of 19 who are uninsured, Medicaid recipients, Native Americans, or Alaska Natives. The CDC contracts with all manufacturers of pediatric flu vaccines, and state and local VFC programs purchase vaccines through these contracts.

Section 317 of the Public Health Services Act authorizes funds for state immunization grants to support the reduction of vaccine-preventable diseases through immunization of children who don't qualify for VFC programs and a limited number of adults. Funds are not adequate to meet the needs of either of these groups. Section 317 funds serve only 11 percent of the childhood population and less than 5 percent of these funds are spent on adult vaccine.³¹

²⁹ Layton, Christine and Nathan West, "Influenza Vaccine: Who Buys It and Who Sells It", Research Triangle Institute, October 2005, pp.5-6.

³⁰ Email correspondence with Jack Sims, 3/31/2008.

³¹ Association of Immunization Managers, "Recommendations and Lessons Learned from the 2004-2005 Flu Season", 2005.

IV. Findings

Current Distribution Experience

By all accounts, in the 2007/2008 flu season, all immunizers have received more flu vaccine earlier than in the last several years. In Texas, vaccine was arriving as early as September. State officials and representatives of physician groups report very few complaints from physicians this flu season. One official said he did receive a call from a physician who was angry that his Vaccines for Children flu doses arrived two weeks after his other flu vaccine. According to the Texas Medical Association (TMA), a few Texas physicians complained of shortages of Flu Mist and that they had received their flu vaccine in three or four shipments. Receiving it this way means that they were not able to offer all of their patients a flu shot that may have wanted one.³² Of all the state immunization officials interviewed, only Virginia reported significant delays and shortages of particular products. These delays were caused by a Virginia distributor, who for an unknown reason, held the vaccine for two weeks after receiving it from the manufacturer before shipping it to providers. Also, Virginia experienced a shortage of Flu Mist. Apparently, the Flu Mist was “short-dated”, meaning it had a very short shelf life and could not be distributed before the expiration date. Despite the problems in Virginia, many public health officials believe that the flu vaccine manufacturers and distributors were responding this flu season to proposed legislation in several states that would attempt to control flu vaccine distribution through shipping information disclosure, full state purchasing, priority for physicians or governmental entities, and other measures.

The Government Accountability Office (GAO) released a report on flu vaccine distribution in October 2007 that details manufacturers’ and distributors’ plans for the 2007/2008 flu season.³³ At the time of the writing of the GAO report, only five manufacturers were confirmed to be producing for the 2007/2008 season. Two of the five manufacturers said they were using medical supply distributors for the majority of their shipments. The three other manufacturers said they would ship some vaccine through medical supply distributors. All manufacturers and four of the six medical supply distributors contacted by the GAO said that for 2007/2008 they would continue to ship vaccine as it becomes available and therefore, will use multiple shipments, or multi-phased shipments. The U.S. Centers for Disease Control (CDC) encourages this practice as a way to ensure that all high-priority populations receive vaccine.

Physicians’ Point of View

Although physicians reported few supply problems in the 2007/2008 flu season, prior to this time, many physicians and physician groups were reporting that they received their shipments later in the flu season than did large retailers and chain pharmacies and that by the time they did receive their shipments, many of their patients had already been vaccinated elsewhere. In other cases, physicians have been left with vaccine that will not be used and will not be refunded. Physician groups are not supportive of a distribution system that they claim forces them to tell a priority patient to get vaccinated at a retail chain because doctors have not received their shipments of vaccine in a timely manner.³⁴

Representatives from the TMA state that not only are physicians not able to receive enough vaccine in

³²Interview with Gayle Love, 2/13/08.

³³GAO Report 08-27, pp. 25-27.

³⁴Interview with Tom Banning, 1/21/08.

a timely manner to vaccinate patients in high-priority groups, they are also being priced out of the flu vaccine market by large chain stores and pharmacies. Retailers are able to place large orders and store larger quantities of flu vaccine so they are able to negotiate a better price and even perhaps negotiate a guaranteed shipping date. Solo physicians and even small- and medium-sized physician groups do not have the purchasing power to cover their flu vaccine costs, which include, in addition to the price of each dose, shipping, storage, and administration costs.³⁵ Furthermore, the price of vaccine is on the rise.³⁶ Physicians have reported that they are opting not to offer vaccines to their patients, sending them to Wal-Mart or HEB, even though they know this is causing inaccuracies in their medical records and perhaps duplicative vaccination in elderly patients, among other problems. A recent *New York Times* article features a Kerrville, Texas physician who has joined the ranks of physicians opting out of providing flu vaccines.³⁷ There is plenty of evidence that part of the reason why the number of flu vaccines administered in non-medical settings is getting larger is because of the growing economic and administrative burdens physicians face by offering flu vaccine.³⁸

Physician groups have turned to purchasing pools to mitigate risk, ensure supply, and get a lower price on flu vaccine. The Texas Association of Family Physicians (TAFP) reported that Texas physicians are at such considerable disadvantage in ordering, purchasing, and receiving vaccine that they have entered into a group purchasing agreement to get a better price and to receive vaccine directly from the manufacturers instead of using medical supply distributors. TAFP also favors state purchasing of flu vaccine for distribution to physicians.³⁹

Hospitals. Texas hospitals purchase large quantities of vaccine, as they are required by Title 25, Rule 133.45(h) of the Texas Administrative Code to offer (per physicians' recommendation) a flu shot to any patient over 65 who is admitted to the hospital for more than 24 hours during the months of October through December. Flu vaccine procurement and inventory procedures vary by hospital, and there is no data available on the number of vaccines provided by hospitals in Texas.⁴⁰

The Public Health Perspective

Public health officials interviewed for this report maintain that physicians may not be aware of the inability of the manufacturers to fill orders completely at the beginning of the typical vaccination period. Some public health officials contend that physicians do not take full advantage of pre-booking and instead, order their vaccine in June rather than January. The majority of physicians use medical supply distributors so that they can receive their flu vaccine along with their other pharmaceuticals and medical supplies in one convenient shipment and some even purchase from hospitals to get a lower price. These practices may prolong the time physicians must wait to receive flu vaccine and increase the chances that they will run out of vaccine between shipments.

Maximizing vaccination rates. Public health officials are concerned that any public policy that gives a priority to physicians in receiving vaccine may reduce the number of people who are vaccinated. They contend that widespread administration of flu vaccine in non-medical settings is needed to vaccinate the vast numbers of people who are recommended by the CDC to receive a flu shot.

To ensure that flu vaccine reaches as many people as possible, the CDC sent a letter to flu vaccine

³⁵ Henley, Eric. "Case Study: The Real-World Experience of a Family Practitioner", *Managed Care*, August 2007, pp.12-14.

³⁶ Interview with Sanford Kaufman, 1/16/08.

³⁷ Pollack, Andrew. "In Need of a Booster Shot; Rising Costs Make Doctors Balk at Giving Vaccines", *New York Times*, 3/24/07.

³⁸ Interviews with Gayle Love, 2/13/08 and Tom Banning, 1/21/08.

³⁹ Interview with Tom Banning, 1/21/08.

⁴⁰ Interview with Elizabeth Sjoberg, 4/21/08.

manufacturers and distributors prior to the start of the 2007/2008 flu season asking them to use “equitable distribution” practices when shipping flu vaccine to all end users, but did not issue specific guidelines regarding these practices. With priority groups currently totaling close to 75 percent of the population—about 218 million people—and expected to increase, public health officials maintain that many different kinds of immunizers in many different sectors of the public and private spheres are needed to reach target populations and beyond. According to the CDC and American Medical Association (AMA) officials, the best way to ameliorate flu vaccine distribution problems is to encourage equitable distribution, not to give certain groups priority in receiving vaccine over others. According to public health officials, all venues for vaccination serve members of priority groups and are therefore equally important in achieving national flu vaccination goals.

Planning for mass vaccination. To prepare for mass vaccination in the event of a flu pandemic, vaccine production must be maintained and waste minimized. If a large amount of flu vaccine continues to go unsold, manufacturers may limit their production goals for the future. This may result in a lack of vital production capacity for flu vaccine in the event of a flu pandemic.⁴¹

Extending the flu vaccination period. Vaccinating people later in the flu season will both increase the number of people who are vaccinated and will help mitigate vaccine waste. In January of 2008, a New Jersey public health official told the *American Medical News*, “[t]he vaccine distribution infrastructure does not encourage the full use of influenza vaccine and is not fully supportive of the nation's goal of getting as many eligible people immunized as possible.”⁴² Demand for vaccine usually peaks in September and October, while supplies peak later in the fall and early winter.⁴³ Public health efforts to end the misperception that it is too late to vaccinate in December and January are essential to normalize the supply of the flu vaccine, say CDC officials. Current CDC recommendations are to administer the vaccine well past December, as there are reports that the flu season will extend into April and possibly May.⁴⁴ Public health officials interviewed for this report wonder why, given that the flu season does not peak until February in the United States, do doctors complain about “getting stuck” with vaccine as early as December. The public health community is encouraging doctors and patients alike to shift their expectations that the supply of vaccine will comply with a vaccination season that consists only of October and November.⁴⁵

As long as this perception persists, not only is there significant wastage of vaccine, but manufacturers are unlikely to increase their production significantly because so much of their product is not absorbed by the market. They decide how much vaccine they will make based on perceived demand for their product. If there is any indication that demand will taper off after the holidays, as has been typical, they will curtail production accordingly. This limits the total quantity produced and the availability of vaccine late in the season, which should typically extend into the spring.

The Role of Large Retailers

One of the primary complaints of physicians is that large retailers are vaccinating patients without doctor supervision. Unfortunately, it is very difficult to get specific information from retailers regarding how they acquire their flu vaccine, who administers it, and who purchases it. Distributors deliver a very small percentage of vaccine to retail destinations. While national CDC data indicates that about 6

⁴¹ Layton, Christine and Nancy Lenfestey, “Influenza Vaccine Manufacturing”, Research Triangle Institute, October 2005, pp. 14-15.

⁴² Elliot, Victoria, “Extending flu shot season not simple”, *American Medical News*, 1/14/2008.

⁴³ *Ibid.*

⁴⁴ CDC Recommendations, <http://www.cdc.gov/flu/protect/late-season.htm>, accessed 2/29/08.

⁴⁵ GAO 08-27, p. 20.

percent of people who receive a flu shot get it at a pharmacy⁴⁶, there is no comprehensive data that captures all retail environments, such as chain discount stores and grocery stores. Large retail pharmacies and chain stores are highly visible to the public and often run radio and print advertisements for available flu shots, so may seem as though they have a corner on the flu vaccine market. HEB and Wal-Mart were contacted but declined to provide information for this report.

According to the Texas Federation of Drug Stores, retail pharmacies provide flu vaccines to hundreds of thousands of Texans annually. Most of those vaccines are provided by pharmacists, “although some pharmacies allow a third party contractor to utilize their facility to administer immunizations,” usually nurses.⁴⁷

In Texas, pharmacists may receive training to administer flu shots in their pharmacies, which may or may not be connected to a large retailer. Independent pharmacists purchase small amounts of flu vaccine similar to the way that physicians purchase. Some private, for-profit companies, employing nurses and other medical staff such as Maxim Healthcare Services, contract with a retailer to administer injections onsite. Non-profit groups, such as the Visiting Nurses Association (VNA), may administer shots in flu clinics in a variety of settings. The Texas VNA states that most of the on-site clinics that they administer are workplace flu clinics, not retail locations.

Flu Vaccine Distribution Data

Only distributors and manufacturers have information about how much vaccine is distributed to which immunizers and when. That information is considered proprietary and is not reported. While specific information about where and when the vaccine is distributed is not publicly available, there are sources of information that provide some indication of where the flu vaccine is distributed and where people receive their flu vaccination.

According to preliminary national data from the CDC’s Flu Finder system, 34 percent of the total amount of flu vaccine distributed in the 2007/2008 flu season went to private providers.⁴⁸ The amount distributed to large retailers is unclear because retailers are included in several categories of immunization providers in Flu Finder. Also according to Flu Finder, 6 percent of flu vaccine doses were distributed to pharmacies, 13 percent were sent to distributors, some of which may have shipped the doses on to retailers, and 17.6 percent went to state and local health departments.

According to national data from the 2006/2007 flu season, the Health Industry Distributors Association (HIDA) reports that 50 percent of the flu vaccine produced went to end users directly from the manufacturers and the other half went through medical supply distributors. HIDA reports that 80 percent of the flu vaccine sold by distributors is provided to physicians. The other 20 percent goes to a variety of locations, including long-term care facilities, hospitals, and private clinics.⁴⁹ Only a small percentage of doses (an estimated 3-5 percent) goes to retail destinations from distributors.⁵⁰ HIDA distributors take from 1 to 3 days to ship their flu vaccine to their customers after receiving them from the manufacturing facilities.⁵¹

National data collected by the CDC after the 2006/2007 flu season indicate that most types of

⁴⁶ Santoli, Dr. Jeanne, “Distribution by Provider Type”, 2007-2008 Influenza Season Update, February 6, 2008.

⁴⁷ Email communication with Karen Reagan, 4/11/08.

⁴⁸ Santoli, Dr. Jeanne, “Distribution by Provider Type”, 2007-2008 Influenza Season Update, February 6, 2008.

⁴⁹ Health Industry Distributors Association, “2006-2007 Influenza Vaccine Production and Distribution Market Brief”, July 2007, p. 6.

⁵⁰ Interview with Andrew Van Ostrand, 1/25/08.

⁵¹ Health Industry Distributors Association, “2006-2007 Influenza Vaccine Production and Distribution Market Brief”, July 2007, p. 2.

immunizers, including private physicians, received flu vaccine in “similar time frames” and that no one group received preferential treatment.⁵² The only exception is public health entities that, for reasons that are unknown, received less of their total flu vaccine in early shipments than did all other immunizers. However, later in the season, this trend was corrected and these entities received larger shipments.⁵³

National data from the 2004-05 Behavioral Risk Factor Surveillance System (BRFSS) indicate that about 40 percent of adults and nearly 48 percent of priority or at-risk adult patients who receive a flu shot get it in their doctor’s office. Eight percent of adults in the priority groups get vaccinated in a retail establishment compared with four percent of other adults. Other venues for vaccination include the workplace, hospitals, community centers, and health departments.⁵⁴

Implications for Physicians

Shipments to physicians may be delayed if the distributor also brings other supplies ordered by the provider; the route of the vaccine will have more “stops” than it would coming directly from the manufacturer.⁵⁵ Shipments to physicians are small compared to those for a local public health department or retailer. There is anecdotal evidence and general agreement among public health officials that larger orders are filled first by manufacturers.⁵⁶ Even if the same percentage of their order is shipped in each shipment, immunizers ordering large amounts of vaccine will receive more vaccine in each shipment.

Furthermore, there is some evidence that physicians may delay placing their orders until they can place a large enough order to accommodate a vaccination clinic.⁵⁷ According to a physicians’ advocacy organization, most physicians do not pre-book until early summer, even though pre-booking begins in January. One manufacturer reported that they are seeing less pre-booking for the 2008/2009 flu season from physicians because there is less concern about supply after the experience in the 2007/2008 flu season.

Due to the nature of the flu vaccine production process, the total amount of flu vaccine needed cannot be produced at one time. Because of the use of multi-phased shipments, shipment delays are not uncommon, and a provider may run out of vaccine between shipments. The flu vaccine manufacturing and distribution processes are not well understood outside the vaccine industry and this has perhaps been the root of physicians’ concerns that they have been at a disadvantage in receiving vaccine. Although it is very important for physicians to offer flu vaccine to their priority patients, and most people prefer to receive their shot at their doctor’s office,⁵⁸ a growing number of people prefer to be vaccinated outside traditional medical settings.⁵⁹ This growth parallels the growth in the sectors of the population that are recommended for vaccination.

⁵² GAO 08-27, pp. 28-30.

⁵³ Ibid, pp. 27-30.

⁵⁴ Behavioral Risk Factor Surveillance System (BRFSS) 2004-2005 Supplement. The BRFSS is an ongoing telephone health survey conducted by the CDC. BRFSS figures for priority patients only include those with asthma and diabetes.

⁵⁵ National Center for Immunization and Respiratory Diseases, Podcast: “Influenza Vaccine Production and Distribution, 9/11/2007.

⁵⁶ GAO 08-27, p. 30.

⁵⁷ Ibid.

⁵⁸ Behavioral Risk Factor Surveillance System 2004-2005 Supplement.

⁵⁹ Layton, Christine and Nathan West, “Influenza Vaccine: Who Buys It and Who Sells It”, Research Triangle Institute, October 2005, p. 4.

Legislative Efforts to Control Distribution

Though the supply of flu vaccine in the 2007/2008 flu season was stable, it is possible, given the nature of the flu vaccine manufacturing process, that shortages or delays could occur in the future. The current egg-based method of production has remained unchanged since the 1950's and requires manufacturers to estimate at least six months in advance how much vaccine to make for the upcoming flu season. This makes it very difficult for one manufacturer to make up for another's shortfall if one should have to pull out of the market due to contamination, as occurred in 2004. If a particular strain fails to grow, or grows slowly, manufacturers may face significant shortfalls and delays in shipping vaccine as well.⁶⁰

To address temporary shortages and delays of the past and to prevent them in the future, some states have recently begun to consider implementing centralized control over flu vaccine distribution.⁶¹ These efforts range from mandating access to manufacturers' and distributors' inventory and shipping information to state purchasing of flu vaccine for large groups of the population. Some states, including Texas, have considered giving physicians priority in receiving flu vaccine. Since the legislation enacted after the shortage of 2004, only one bill has passed and been implemented—the Rhode Island state purchasing bill, which is discussed below.

Legislative efforts following the 2004/2005 flu season. In 2004, a major manufacturer of the flu vaccine left the market due to contamination of one of its factories. This left only two manufacturers in operation and about half of the needed vaccine in the market. During the 2004/2005 flu season, 27 states and the District of Columbia took direct legal action in response to shortages. Most of this legislation made it illegal to vaccinate a non-priority individual during a flu vaccine shortage. Other legislation passed during this time included prohibiting flu vaccine price gouging and the acceptance by various states of the ACIP guidelines for priority or high-risk populations. Much of this legislation remains in effect but some states enacted these bills only for the 2004/2005 flu season.⁶²

Physician priority. Introduced in the 2007 legislative session in Massachusetts, House Bill 2192 and Senate Bill 1222 would have given physicians priority in receiving flu vaccine from manufacturers and distributors. The bills were considered in committee but were not voted out of committee.

Public health priority. In the New Jersey 2006/2007 legislative session, Assembly Bill 3887 was proposed and sent to committee but did not progress from there. The bill would have required flu vaccine distributors to give purchasing preference to governmental entities over all other purchasers except private health care providers.

Expanded state purchasing of flu vaccine. In addition to state purchasing for Vaccines for Children and the Section 317 program discussed previously, some states have proposed expanded state purchasing of flu vaccine. These programs are intended to reduce or eliminate financial risk for physicians and to ensure more plentiful supplies of flu vaccine.

Rhode Island implemented the first program in the nation in which the state purchases and distributes all of the flu vaccine for adults. The state health department manages the purchasing and distribution of 250,000 doses of flu vaccine among the state's participating providers for vaccination of adults, ages 19

⁶⁰ GAO 08-27, pp.16-18.

⁶¹ Health Industry Distributor Association. Government Affairs, State by State Flu Matrix, 1/25/08.

⁶² Hodge, James and Jessica O'Connell, "The Legal Environment Underlying Influenza Vaccine Allocation and Distribution Strategies", *Public Health Management Practice*, 12(4), 2006, p. 345.

and up, free of charge. To be eligible for a flu shot under the new program, adults must have health insurance. To finance the program, the state charges an assessment fee to insurance companies that received any premium dollars for medical or accident policies sold in the state. Because the state is assuming all the financial risk in ordering all the vaccine, they included a five percent wastage clause in contracts with immunizers. Under this clause, immunizers must reimburse the state for any unused supply exceeding five percent of the immunizers' order. The program was established in response to physicians' frustration over large retailers receiving their vaccines before physicians and is intended to provide equity in distribution of flu vaccine. In other words, every immunizer—from physicians to pharmacies—now receive their flu vaccine at exactly the same time. The state actually set a vaccination start date in mid-October and made it illegal to offer flu vaccine before that date. All immunizers followed the policies and supported the program.⁶³ Critics charge that the program is successful because Rhode Island is a small state with fewer insurers on which a fee is assessed.⁶⁴

In January of 2007, the Connecticut General Assembly proposed House Bill 5512, which called for the establishment of a pilot program for the state to purchase flu vaccine in bulk. The program would have enabled physicians to buy their vaccine directly from the Department of Public Health. The bill was referred to committee and a hearing was held, but the legislature adjourned without passing the bill.

Group purchasing. The state of Nevada passed Assembly Bill 410 in 2007 which requires the Department of Health to consider group purchasing of vaccines for the benefit of private providers. A study examining possible advantages for physicians if the state were to join a group purchasing pool was due by January 30th of this year, but has not been released to the Nevada legislature.

State access to inventory and shipping data. In the 2005/2006 California legislative session, Assembly Bill 669 was passed, requiring distributors and manufacturers, plus large purchasers of vaccine, such as hospital systems or managed care organizations, to share information on vaccine distribution and supply to local health jurisdictions as requested. Manufacturers consider this information to be strictly proprietary and because of this, the legislation has never been enforced.

In 2006, Maine passed Legislative Document 2106 which requires manufacturers and distributors of flu vaccine to report "information on the distribution" of vaccine in the state to the Department of Health and Human Services (DHHS). Reports must be made every two weeks during flu season and on a monthly basis thereafter. The bill also requires DHHS to estimate the supply and demand for flu vaccine at the beginning of each flu season. Rulemaking for state agencies affected by this bill was completed in January 2008, and manufacturers and distributors have begun submitting reports.

Federal legislation. Three federal bills introduced in Congress in 2007 and 2008 seek to increase the availability of vaccines, including flu vaccine, and plan for mass vaccination against the flu in the United States. The Influenza Vaccine Security Act of 2007 (Senate Bill 2456) was introduced by Senator Clinton and co-sponsored by Senators Bayh and Roberts. The bill calls for equity in flu vaccine distribution and offers manufacturers incentives to enter the vaccine market and to expand production capacity. The bill requires the U.S. Department of Health and Human Services to establish a flu vaccine production target and stockpile, to organize a buyback program to redeploy unused vaccines to state and local health departments, to provide educational grants to increase late season vaccination rates, and to establish a flu vaccine tracking system. The bill is currently being considered in the Senate Health, Education, Labor, and Pensions Committee.

⁶³ Interview with Mark Francesconi, 2/6/08.

⁶⁴ Landers, Susan, "Rhode Island to distribute adult flu vaccine free to doctors", *American Medical News*, 5/21/07.

The Vaccine Shortage Preparedness Act of 2008 (House Resolution 4703) was introduced in December of 2007 by Representative Waxman and would amend the Social Security Act, the federal Food, Drug and Cosmetic Act, and the Public Health Services Act to ensure a sufficient supply of vaccines, including flu vaccine. The bill would require manufacturers to give the federal government 12 months prior notice of any discontinuation of vaccine production, and to share shipping and inventory information. The bill mandates a study of successful models for tracking and facilitating the local reallocation of vaccine in times of shortage or emergency. The bill is currently being considered in the Subcommittee on Health.

Vaccines for the Uninsured Adult Act of 2008 (House Resolution 4705) was also introduced by Representative Waxman in December of 2007. The bill aims to increase the availability of flu vaccine by expanding the Section 317 immunization program to vaccinate uninsured adults, among other provisions. The bill is also currently being considered in the Subcommittee on Health.

V. Impacting Flu Vaccine Distribution in Texas

No existing legal mechanisms in Texas or in the United States regulate the channels through which flu vaccine is distributed. Although physicians have been vocal in their criticisms of the flu vaccine distribution system in the past, manufacturing and distribution during the 2007/2008 flu season was not problematic.

By all accounts, the distribution of the flu vaccine worked well in Texas and nationally during the most recent flu season, primarily due to the increase in supply and early shipments of the vaccine. However, several options are available to the state of Texas to ensure that distribution continues to provide sufficient vaccine in a timely manner. These options range from state legislative action to control distribution to encouraging the creation of group purchasing pools that increase purchasing power for some providers, particularly physicians.

Physician Priority

Under a policy of physician priority, the state of Texas could require that manufacturers and distributors fill physicians' orders of flu vaccine before those of retailers, ensuring that physicians can offer a shot to every patient in a high-priority group. Physicians have reported that they would like the ability to offer a shot to every patient in their practice that is in a priority group.⁶⁵ While there may be some advantages to physician priority, such as maintaining a medical home and ensuring that medical records are complete and accurate, there are a number of disadvantages to implementing physician priority.

Disadvantages

Public health officials, manufacturers, and distributors are not likely to support any effort that gives priority to any immunizer over another. Public health officials want as many people vaccinated as possible, regardless of the venue. Manufacturers need to sell as much vaccine as possible and any policies that impede sales make manufacturing vaccine less cost effective. The Health Industry Distributors Association finds the physician priority option to be problematic and is unsure how to apportion more vaccine to physicians when nationally, 80 percent of orders shipped by distributors already go to physicians.

No other states have implemented physician priority, so there is no model on which to base such a system.

Supply problems for other venues that provide vaccination. Compared to retailers, hospitals, and local public health departments, shipments to physicians are small and numerous. Shipping to physicians exclusively early in the season may be inefficient and worse, may result in supply problems for other immunizers. If other immunizers in the community do not have their supplies of vaccine early in the season—which so many people seeking shots have come to rely on—levels of immunization could fall.

⁶⁵ Interview with Gayle Love, 2/13/08.

Implementation and monitoring costs. In order to implement physician priority, the state will have to legislate physician priority and design a system for monitoring adherence to such legislation. The state will incur costs related to these activities; those costs have not been estimated for this report. Advantages to physician priority may include the eradication of flu vaccine supply problems for physicians and an increase in the proportion of flu vaccines administered in physicians' offices, which could result in higher numbers of at-risk patients receiving flu vaccinations.

Decrease in vaccination rates. Disadvantages may include a decrease in vaccination rates among segments of the population who prefer to receive their shots outside of their physicians' office, as such venues (retailers, workplaces, etc.) will receive their share of vaccine only after all physician orders have been filled. Patrons of these venues may simply opt not to get a shot because they will have to wait longer than they had to prior to the implementation of physician priority. Another disadvantage may be the administrative and fiscal burden to the state to monitor and enforce physician priority.

Increase in costs of vaccine. Additionally, there may be an increase in the price of vaccine due to increased shipping and distribution costs borne by distributors and manufacturers who will now be legally required to make numerous small deliveries to physician offices before any larger orders to other immunizers can be filled. Because of the size of the Texas market, state legislation requiring physician priority may reduce the amount of flu vaccine manufacturers are willing to produce, as such increased costs will impact manufacturers' profits.

Planning for mass vaccination. Vaccine production during a flu pandemic will be limited by the number of production facilities in operation and the number of venues in which people can receive a vaccine. Any legislative action that provides disincentives to manufacturers to produce flu vaccine and that limits the channels through which vaccine is distributed could impact implementation of mass vaccination.

Other Options for Texas

The state of Texas could consider implementing the following through legislative or administrative action:

Public health priority. Policies requiring manufacturers and distributors to fill public health orders before those of retailers will ensure that participants in the VFC and section 317 programs receive their vaccine before retailers do. Data show that public health has received smaller portions of the total orders earlier in the flu vaccination season than other immunizers,⁶⁶ and some anecdotal evidence supports this in Texas.⁶⁷ However, to legislate priority for any one group—be it physicians or public health—may create additional problems, such as the disruption of distribution to other venues serving priority populations.

State purchasing. The state of Texas could purchase all or some portion of all of the flu vaccine doses administered in the state. This arrangement will allow the state to receive a large supply of vaccine in either a series of large shipments or perhaps in one large shipment early in the flu season. Cost savings would be realized through state purchasing, whether the vaccine is purchased for immunizers or immunizers simply purchase off state contracts with manufacturers and distributors.

⁶⁶ GAO 08-27, pp. 27-29.

⁶⁷ Interview with Gayle Love, 2/13/08.

The CDC cost per dose is about two to three dollars below that of the private sector.⁶⁸ Therefore, doctors will receive more vaccine earlier in the season while shouldering less of the financial risk themselves. State purchasing has been implemented in Rhode Island. This program will require increased expenditures for state vaccine purchasing and the cost of this option was not estimated for this report.

Flu vaccine tracking. Despite its flaws, the CDC Flu Finder system is an excellent tool for tracking flu vaccine. Many states have found that individual providers use this system during temporary shortages to locate vaccine and implement voluntary redistribution efforts.⁶⁹ The state of Texas can support the on-going use of this tool by providers in Texas.

Group purchasing. Physicians are already entering into group purchasing agreements in Texas to mitigate high vaccine costs, financial risk, and supply problems. The Texas Academy of Family Physicians has recently entered into such an agreement. An example in another state is the Minnesota Multi-State Contracting Alliance for Pharmacy (MMCAP), a voluntary group-purchasing organization administered by the state of Minnesota. The state of Texas can encourage and/or facilitate the creation of these arrangements by providers in Texas.

Support federal legislation. Provisions of the federal legislation that has been introduced (see page 17) may be advantageous to physicians in Texas. A legislative analysis was not conducted for this report, but the state of Texas may consider actively supporting provisions that are desirable.

Conclusion

A conflict exists between the concerns of physicians that they may not be able to vaccinate their patients against the flu and the public health goal of vaccinating as many people as possible, regardless of the venue. While physicians in the past have pushed for priority in distribution of the flu vaccine, public health officials are reluctant to give preference to any immunization provider over another.

While implementing a system that gives priority to physicians over retail establishments is an option for Texas, it may impact distribution to other immunizers, which could negatively impact the ability to achieve flu vaccination goals. Texas will need to weigh the administrative and financial costs of implementing any tool to enhance distribution to physicians with the most recent experience in the 2007/2008 flu season in which more flu vaccine was produced than ever before – 132 million doses, of which 118 million had been purchased by February 2008. Six pharmaceutical companies are now producing flu vaccine and production is expected to increase for the next flu season as more of the population is recommended to receive the vaccine. Increased production will prevent overall shortages, although temporary shortages may persist for individual providers, especially those receiving small shipments.

⁶⁸ CDC Influenza Vaccine Price List, <http://www.cdc.gov/vaccines/programs/vcf/cdc-vac-price-list.htm>, accessed 2/18/2008.

⁶⁹ GAO 08-27, pp. 30-33.

Appendix A: Interviews

Charles Alexander, Chief, Bureau of Immunization, Florida Department of Health
Dr. Howard Backer, Chief, Immunization Branch, California Department of Health Services
Tom Banning, Director of Policy, Texas Academy of Family Physicians
James Farrell, Director, Division of Immunization, Virginia State Department of Health
Mark Francesconi, Senior Public Health Specialist, Rhode Island Department of Health
Rick Gulla, Media Relations Manager, Massachusetts Medical Society
Greg Herzog, Associate Director, Division of Public Affairs, Texas Medical Association
Steve Kair, Director of National Accounts and Flu Program, ASD Healthcare
Sanford Kaufman, Director of Policy, Sanofi Pasteur, Inc.
Sarah Landry, Director of Vaccine Public Policy, GlaxoSmithKline
Gayle Love, Director of Public Health, Texas Medical Association
Andrew MacLean, Deputy Executive Vice President, Maine Medical Association
Kathleen Mahaleris, Comprehensive Health Planner I, Immunization Program, Maine Department of Health and Human Services
Eric Pennington, Vaccine Finance Manager, Nevada Department of Health and Human Services
Karen Reagan, Vice President Government Affairs and Executive Director, Texas Federation of Drug Stores
Gary Rinaldi, Vaccine Manager, Immunization Program, New York State Department of Health
Debbye Rosen, Adult Immunization Coordinator, Connecticut State Department of Public Health
Dr. Jeanne Santoli, Deputy Director, Immunization Services Division, National Center for Immunization and Respiratory Diseases, U.S. Centers for Disease Control and Prevention
Jack Sims, Immunization Branch Manager, Texas Department of State Health Services
Elizabeth Sjoberg, Associate General Counsel, Texas Hospital Association
Heather Stafford, Director, Division of Immunizations, Pennsylvania Department of Health
Dr. Litjen (L.J) Tan, Director, Infectious Disease, Immunology, and Molecular Medicine, American Medical Association
Andrew Van Ostrand, Director of Policy and Research, Health Industry Distributors Association
Bob Wardwell, Vice President, Regulatory and Public Affairs, Visiting Nurse Associations of America
Kristie Zamrazil, Senior Director of Public Affairs, Texas Pharmacy Association

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