



# Influenza Vaccine Production & Distribution

MARKET BRIEF



HEALTH INDUSTRY DISTRIBUTORS ASSOCIATION

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# Executive Summary

This Market Brief presents key facts regarding influenza vaccine production, supply and allocation for the past several years through the 2000-2005 influenza seasons. It is intended to assist all stakeholders by providing a clear baseline of influenza vaccine production and distribution in the U.S. Market. Two key factors are impacting the influenza vaccine supply chain:

1. **Total Doses Manufactured:** Despite stated goals, increases in annual influenza vaccine production have proven difficult to sustain over the past five influenza seasons. Since 2000, annual average production for the U.S. market has continued to be 82.8 million doses.
2. **Timing of Provision to the Healthcare Provider:** In addition to the total produced, the question of when influenza vaccine doses actually reach the point of care is an important and often overlooked consideration. In several of the past influenza seasons, the total production numbers were achieved by year end. However, the supply was later than expected or arrived in several staggered shipments during the crucial August to November period of peak demand.

To cope with the realities of staggered supply, distributors have used proportional distribution—e.g. if the distributor receives 50% of their order, then each of their customers get 50% of their orders filled. While this is a fair and equitable method, the result is that every customer's orders are partially filled.

In addition, distributors are the preferred channel of influenza vaccine supply to physician offices in particular. While 36% of the total 2005 vaccine supply went to physicians, 80% of the supply allocated to distributors was sold to physician offices. In this way, disruptions or staggered supply to the distribution channel disproportionately impact physicians.

As an example, in 2004 Chiron was barred from shipping vaccine into the U.S. Since Chiron sends 100% of its supply through distribution, who in turn sell eight out of ten of their doses to doctors' offices, physicians were affected to a greater degree than others.

These dynamics result in dissatisfaction from healthcare providers who cannot reconcile their partial shipment with the appearance of a fully supplied flu shot clinic at a large retailer or other non-medical site.

Because of public relations efforts to show its ability to prevent illness, well informed and health-conscious consumers are driving new and sustained demand for their annual flu shot.

An open question is one of supply rather than demand. Can the public health benefits and goals for increases in the number of flu shots administered be achieved with current manufacturing capacity, an effective, but often fragile manufacturing process, and current reimbursement levels?

This report calls for government leadership in incentivizing growth in manufacturing capacity for the U.S. influenza vaccine market. Whether accomplished through liability protections, reimbursement increases, accelerated funding for development of new manufacturing processes or construction of new factories. These and other incentives are, are essential if the goal of a safe, reliable, plentiful supply of influenza vaccine is to be realized.

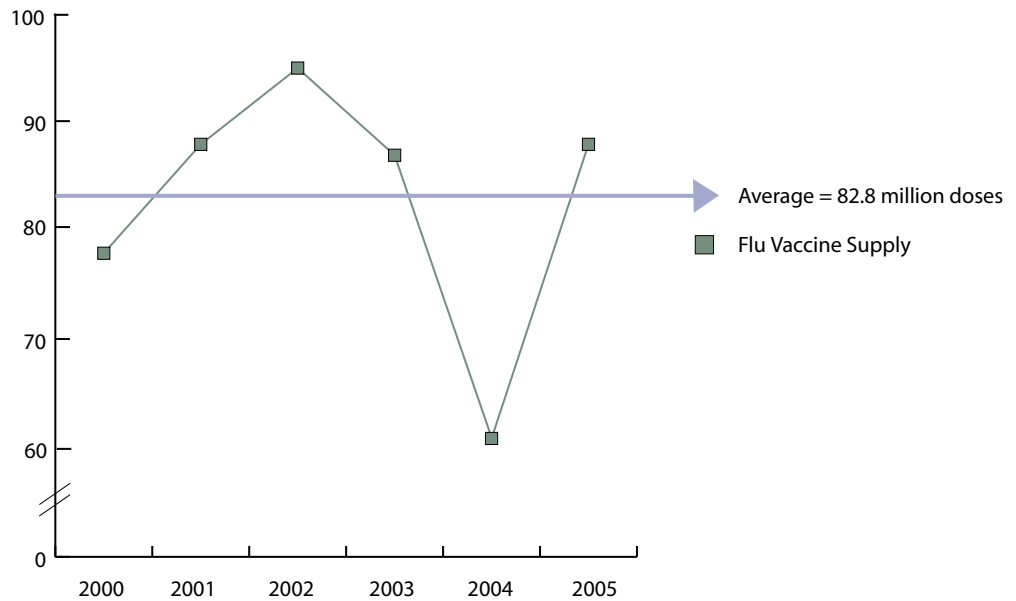
# Influenza Vaccine Production for the U.S. Market

## 2000-2005

Vaccine manufacturers serving the U.S. market have had difficulty sustaining consistent increases in production from year to year. Four manufacturers currently produce influenza vaccine for the U.S. market.

An average of 82.8 million doses has been produced each year since 2000. Had vaccine been produced at expected rates in 2004, the six-year average would have risen to 85.3 million (Figure 1).

Figure 1:



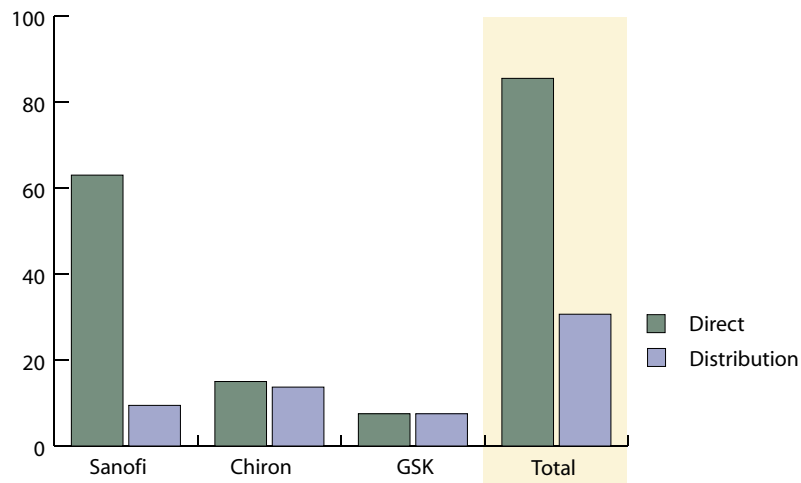
Source: U.S. Centers for Disease Control and Prevention (CDC) Data, 2006

**Note: If Chiron had produced its projected supply, total supply would have been 76 million in 2004.**

# 2005 Influenza Vaccine Production for the U.S. Market

In 2005 the U.S. market saw 85.5 million doses of inactive influenza vaccine produced. This amount was above the six-year average for all vaccine production (Figure 2).

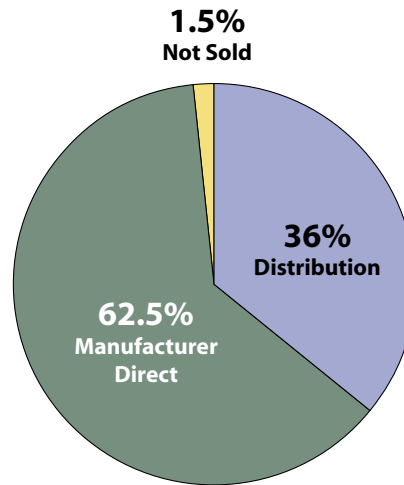
Figure 2:



Source: 2005 CDC/AMA Flu Summit Presentations

Each manufacturer employs the wholesale-distribution channel based on their individual market strategies to get vaccine to the end user. Of total vaccine doses produced, 36% were sold to wholesalers or distributors and 62.5% went directly from manufacturers to healthcare providers. (Figure 3)

Figure 3:



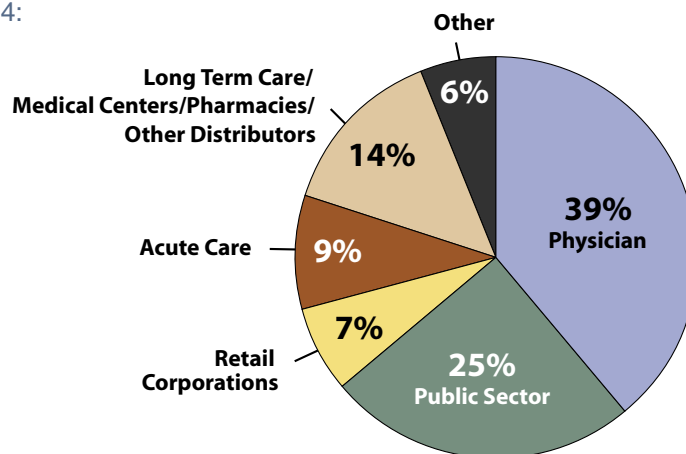
Source: U.S. Centers for Disease Control and Prevention (CDC) Data, 2006

## 2005 Influenza Vaccine Sold in the U.S. Market

### Direct and Distributed

Thirty-nine percent (39%) of all vaccine produced was sold to physician offices in 2005. A smaller amount (14%) went to a combination of long-term care facilities, medical centers, pharmacies, the public sector, and other distributors, which did not buy directly from the original manufacturers (Figure 4).

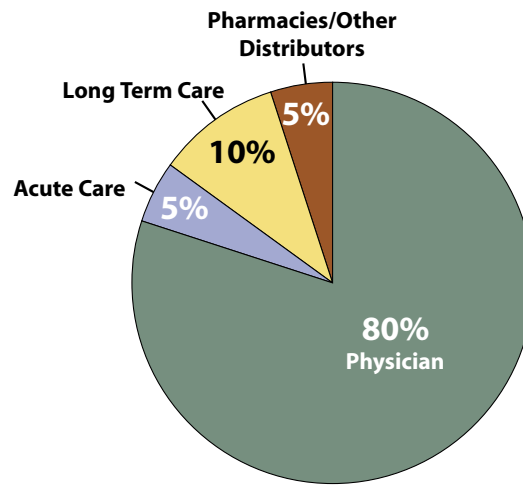
Figure 4:



Source: 2005 CDC/AMA Flu Summit Presentations

Distributors are the primary channel for delivering influenza vaccine to physician offices. While 36% of the total supply went to physicians, 80% of the supply allocated to distributors went to physician offices (Figure 5). Of the distributors' remaining supply, 10% went to nursing homes and other long-term care facilities (LTC), 5% went to acute care facilities (hospitals) and about 5% went to pharmacies and other distributors.

Figure 5:



Source: 2005 CDC/AMA Flu Summit Presentations

In addition to the total number of doses produced, an important underlying consideration is when those doses are shipped to the market. In the past several years, many customers, including distributors, received their pre-booked orders staggered over a number of separate shipments.

Having received a number of partial orders over several months in many of the past influenza seasons, distributors reported using proportional delivery when fulfilling their pre-booked orders as the most efficient and fair way to deal with staggered shipments from manufacturers. As distributors received vaccine in staggered smaller shipments, each distributor provided a proportional amount of vaccine to each customer. For example, if a distributor received 50% of its pre-booked order from manufacturers, it in turn shipped doses to each provider customer equal to one half of the providers' pre-booked order. In most cases, this meant that the distributor sent multiple shipments to the same customer over a period of time so that each customer received their fair, proportional share at the same time as other customers\* (Figure 6).

\*Source: HIDA 2006 member survey

Figure 6: Proportional Delivery to Large and Small Customers (Illustrative)

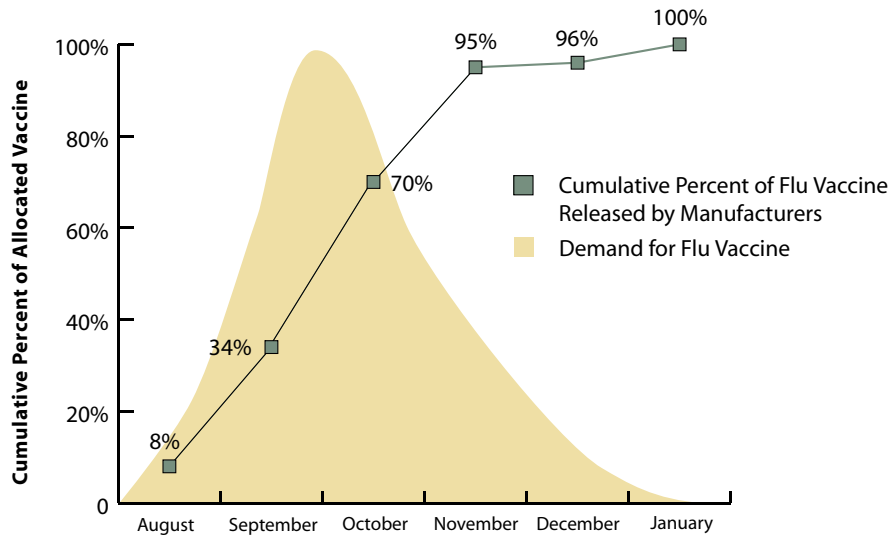
	Total Number of Doses Ordered	Percent of Allocation Rec'd by Distributor	Number of Doses Rec'd by Distributor	Number of Months Delivered <sup>1</sup>	(Approx.) Percent Allocation Per Month	Number of Doses Provided Per Month
Small Physician's Office (Full Allocation)	1,200	100%	1,200	6	16.67%	200
Large Retail Provider (Full Allocation)	120,000	100%	120,000	6	16.67%	20,000
Small Physician's Office (Reduced Allocation)	1,200	50%	600	6	16.67%	100
Large Retail Provider (Reduced Allocation)	120,000	50%	60,000	6	16.67%	10,000

<sup>1</sup> Assuming influenza vaccine is provided from August through January

# Influenza Vaccine Demand Peaked Before Supply

As reported at the recent Centers for Disease Control (CDC)/American Medical Association (AMA) Influenza Summit, demand for flu shots remains the highest in September and October despite the public campaign to stretch the flu shot “season” into December and January. In 2005, there was less inactive vaccine produced than expected. The delivery to distributors was staggered and many providers did not receive the balance of their influenza vaccine order until November.

Figure 7:



Source: U.S. Centers for Disease Control and Prevention (CDC) Data, 2006

**Note: The 100% noted in the chart includes the doses of vaccine that were allocated to the National Vaccine Stockpile.**

## Distribution’s Role in the Influenza Vaccine Process

### Wholesaler or Distributor

Influenza vaccine sold through “distribution” can be sold to wholesalers or distributors. Manufacturers use both kinds of “distribution” to sell their influenza vaccine to the U.S. market in addition to selling directly to the healthcare providers themselves.

For the purposes of this Market Brief, we use the terms wholesalers and distributors defined as they are used commonly in the healthcare supply chain. They both perform the distribution function – physically conveying a wide range of products and services to healthcare providers--but are usually focused on a different product mix for different types of customers. In the case of influenza vaccine, both types of organizations play a role in getting the product to the provider.

Since this report is focused only on influenza vaccine, we are using the term “wholesaler” or “drug wholesaler” to generally refer to the companies that engage in wholesale purchasing and reselling of pharmaceutical products to pharmacies of all types including those in hospitals, retail, and other institutional settings. Generally speaking, this usually means larger shipments to larger customers.

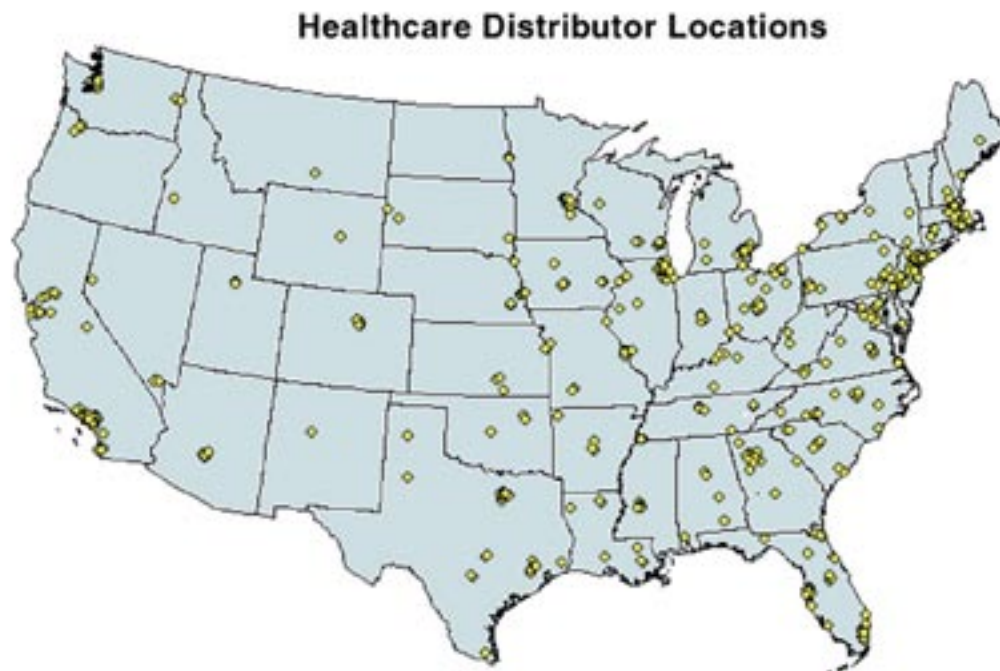
The term “distributor”, is used in this report to refer to a company whose business is to supply medical products and related services to providers in all care settings: hospital, physician office, nursing home or in-home settings. With influenza vaccine, these medical products distributors usually are able to accommodate smaller, customized orders from providers such as doctor’s offices and nursing homes.

# Distribution Speeds Vaccines to Physician Offices

There are more than 800 distribution centers across the U.S., operated by more than 600 distributors\* (see map below for locations). The distribution system is set up to handle a range of delivery volumes to a wide variety of customers; and is particularly adept at handling smaller, more frequent orders. This makes distribution a preferred channel for many smaller providers. With more than 12,000 medical practices in the United States consisting of 6 or fewer physicians (representing 62% of the U.S. medical practices overall), distribution is well-suited to provide influenza vaccine.\*\*

\*Source: HIDA 2005 Distribution Market Report

\*\*Source: HIDA 2006 Physician Market Report



## Pre-booking Enables Quantification of Demand

Distributors and manufacturers both use the pre-booking request process for influenza vaccine as a way to help prepare for the immunization season each year. This essential process provides an important and early pre-production assessment of the overall demand for projected influenza vaccine supply before manufacturing begins. Each company structures their pre-booking in a way that fits with their overall business plan.

## Influenza Vaccine Receives Priority Handling in Distribution Centers

Due to the handling and storage requirements and its seasonal nature, influenza vaccine does not typically “sit” in a distributors’ distribution center. Most distributors report receiving bulk shipments from manufacturers and re-shipping to their customers the same day.

The logo features the letters 'BIS' in a large, bold, black serif font. A small yellow triangle is positioned above the 'I'. To the right of 'BIS', the word 'HIDA' is written in a smaller, bold, italicized sans-serif font. Below 'HIDA', the words 'BUSINESS INTELLIGENCE SERVICE' are stacked vertically in a bold, black, sans-serif font. At the bottom, the words 'PARTNER PROGRAM' are written in a white, bold, sans-serif font inside a yellow rectangular box.

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