DEPARTMENT OF VETERANS AFFAIRS
Office of General Counsel
PO Box 76
Hines IL 60141

March 31, 2004

In Reply Refer To:

RE: New Flu Vaccine Provisional FCP Policy – Update of March 17, 2003 Policy Letter

Dear Manufacturer of Flu Vaccine:

As a result of input from your industry and the Department of Veterans Affairs (VA) Pharmacy Benefits Management Strategic Healthcare Group, and after conferences with managers and contracting officers from the VA National Acquisition Center (NAC), VA's Public Law 102-585, Section 603, Policy Group has agreed to change the present requirements for calculation of provisional and temporary federal ceiling prices (FCPs) for flu vaccines.

All of the above parties start with the fully agreed proposition that flu vaccines are unlike other covered drugs or biologicals in that: 1) they are essentially a new product every year, manufactured to meet certain expected strains of flu, and 2) they are required at one time of the year in large quantities for the inoculation of large at-risk populations.

The current VA policy regarding the calculation of FCPs for new covered drug products is contained in the October, 2001, "Dear Manufacturer" letter issued by this office. To summarize the relevant portion of the letter, it specifies a three step FCP determination process. The first step is creation of a provisional FCP, usually set at wholesale acquisition cost (WAC) less the statutory 24% discount, less any other discounts given to wholesalers such as, but not limited to, prompt payment discounts. The provisional FCP is normally set at the time a new covered drug product is launched but before there is any significant sales history to support a statutory FCP calculation. After 30 days of wholesale sales (final or booked orders), a new drug's manufacturer is required to gather non-Federal average manufacturer price (Non-FAMP) data for the new product and submit it to VA 45 days from launch. This data yields a temporary FCP that is kept in place until either data is available from one full calendar quarter of sales experience or, in the case of drugs launched in the second or third quarters, sales from date of launch through September 30th are used to calculate a permanent FCP that is due by November 15.

Representatives of your industry have complained that the standard new drug FCP policy described above yields unfair results when applied to the unusual flu vaccine market. They have argued that flu vaccine orders in the largest quantities under committed contracts are normally taken by a

manufacturer in early spring before any of the product is ready for delivery, and the prices given to these "pre-booked orders" are normally the lowest of the year. Thus, taking 30 days of ordering data (beginning with the opening of the ordering process by the manufacturer) to figure temporary FCPs for flu vaccines yields artificially low temporary FCPs that then govern all Big Four committed vaccine orders until at least August.

Industry representatives have proposed that VA change the three step process for flu vaccines by essentially doing away with the temporary FCP requirement and maintaining a provisional ceiling price until a permanent one is calculated after a full quarter of ordering experience or on November 15 (depending on the timing of vaccine launch for each manufacturer). As stated in VA's October, 2001 letter, the permanent FCP would be prospective not retroactive. Industry apparently believes that a provisional FCP based on wholesale acquisition cost and set when ordering books are opened is a fairer, more realistic way to get statutory compliance for this unusual product and still allow the manufacturers to bid on huge VA and DOD contracts.

During their discussions of this proposal, VA representatives were concerned that giving up the temporary ceiling price calculation as a determiner of the maximum prices that VA and DOD would pay for their huge pre-booked vaccine orders would create a possibility that future industry managers might be tempted to set wholesale acquisition costs artificially high. If this occurred, even with the statutory discount, the Government would end up paying a higher price for its large orders than any commercial healthcare provider.

After reviewing the above proposals and comments, the Public Law Policy Group has agreed to the following changes to the calculation of flu vaccine FCPs:

(A) The provisional FCP for Flu vaccine shall be based on "wholesale acquisition cost" (WAC) ("list price" for manufacturers who do not sell through wholesalers), less the statutory 24% discount, less any other standard discount regularly given by the manufacturer to wholesalers (or to direct customers, if appropriate) such as, but not limited to the prompt payment discount. The provisional FCP shall be reported to VA's Pharmacy Benefits Management (PBM) Data Base Manager within seven calendar days of the date on which the vaccine is first marketed by establishing a commercial price list for pre-book orders for the up-coming flu season.

(B) The temporary FCP for Flu vaccine will be eliminated.

(C) To avoid WAC or price list manipulation, flu vaccine manufacturers shall, after the deadline for taking pre-booked orders and before any

Government orders are invoiced, review all pre-booked orders. Manufacturers shall then reduce the provisional FCP on the "Big Four" Government agencies' flu vaccine orders to whatever was the lowest pre-booked commercial price (if that price was lower than the provisional FCP described in paragraph (A) above). However, pre-booked orders placed against multi-year commercial contracts may be excluded from this process. Also, orders on a single year commercial contract with terms materially different from the Government's may be excluded if, after negotiations, the VA CO making flu vaccine procurements agrees. Within seven calendar days of completing their reviews, manufacturers shall report any required adjustment in the provisional FCP to VA's PBM Data Base Manager. On request, flu vaccine manufacturers shall make their pre-booked orders and related documents available to the VA Office of Inspector General for its independent review.

(D) The permanent FCP shall be derived from a Non-FAMP calculation that includes all pre-booked flu vaccine orders that are not withdrawn, as well as all available sales data from one full calendar quarter of sales experience after the product's launch date; in the case of flu vaccine launched into the public market place in the second or third calendar quarters, pre-booked orders and all sales data through September 30th will be used in the permanent Non-FAMP calculation due by November 15th. Permanent FCPs shall be in effect from the date of filing of the permanent Non-FAMP report or from November 15th, depending on the launch date, until that season's supply of vaccine is exhausted.

(E) Because flu vaccine is a seasonal product, a manufacturer does not have to establish an FSS tracking customer for the product.

This policy change is effective immediately and applies to 2004 flu vaccine pricing.

If you have any questions, please contact me at (708) 786-5167.

Sincerely,

M. A. Noel, Jr.

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Senior Contract Attorney