

Federal Drug Discount and Compliance Monitor



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...BREAKING NEWS...

JANUARY 5, 2006

Grand Jury Indicts Director of Controversial Program Utilizing 340B Discounts

A federal grand jury in Pittsburgh, PA has issued an indictment charging the director of a controversial program affiliated with a 340B entity with illegally distributing 340B-discounted drugs without a wholesaler's license.

If found guilty, Physician Medicine Assist Program (PMAP) Director Dr. Joseph Rudolph could face up to ten years in jail or \$250,000 in fines, depending on the seriousness of the offense and prior criminal history, if any, of the defendant, according to the US Attorney's Office for the Western District of Pennsylvania.

The indictment, filed on January 3, specifically alleges that from January 2004 to August 2005, Dr. Rudolph purchased 340B-priced drugs from pharmaceutical manufacturers and illegally distributed these drugs through the PMAP program to oncology clinics around the country.

"Federal law prohibits the wholesale distribution of prescription medications without a license," the US Attorney said in a news release. "The indictment alleges that Dr. Rudolph was distributing these medications without such a license."

The indictment states that this behavior is a violation of Section 353(b) of Title 21 of the United States Code, which governs the marketing and distribution of prescription drugs in interstate commerce. This provision was established by Congress as part of the Prescription Drug Marketing Act.

Dr. Rudolph will now face a trial on the grand jury's charges.

"An indictment is only a charge and is not evidence of guilt," the US Attorney said in its statement. "A defendant is presumed innocent and is entitled to a fair trial at which the government must prove guilt beyond a reasonable doubt."

According to the indictment, the particular drugs in question include Procrit, Vidaza, Gemzar, Taxotere, Anzement, Epogen, Avastin, Herceptin, Rituxan, Aranesp, Neulasta, Neupogen, and Zometa.

The investigation that led to the indictment was jointly conducted by the Federal Bureau of Investigation (FBI), the Department of Health and Human Services Office of Inspector

General (OIG), and special agents of the Food and Drug Administration (FDA), according to the US Attorney.

The PMAP program was affiliated with Aliquippa Community Hospital (ACH) Oncology Centers, a disproportionate share hospital (DSH) site that was listed in the Office of Pharmacy Affairs (OPA) database as having entered the 340B program in January 2004.

As reported in *The Monitor*, this particular site was deemed ineligible for the program by OPA in September, and was removed from the list of participating covered entities maintained on the OPA website at that time. No official reason for its removal was given. (*The Monitor*, September 2005).

Neither Dr. Rudolph nor ACH CEO Anthony Puorro was available for comment by deadline.

More information will be available in the January 2006 issue of *The Monitor*.