

# *Federal Drug Discount and Compliance Monitor*



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**...BREAKING NEWS...**

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## **Pittsburgh Doctor Stands Trial for Alleged Drug Diversion**

After more than three years of inquiries and investigations by the federal government, Dr. Joseph Rudolph stood trial this week to face allegations that he illegally distributed 340B medications to individuals who were not patients of either his practice or Aliquippa Community Hospital (ACH), a disproportionate share hospital that contracted with Dr. Rudolph to develop its 340B program.

The trial, which is currently in recess until May 2, was brought by the government before Judge Arthur Schwab of the United States District Court for the Western District of Pennsylvania in Pittsburgh on April 24. If convicted by the jury, Dr. Rudolph could face up to ten years in jail or \$250,000 in fines.

According to the indictment issued by a federal grand jury on January 3, the government contends that Dr. Rudolph violated the Prescription Drug Marketing Act (PDMA) by selling cancer medications to oncology clinics around the country without a wholesale distribution license, which is required of physicians, pharmacies, hospitals, and other persons in order to transfer prescription drugs to individuals who are not their own patients.

Under the program in question—which was one of four proposed to the government by ACH in April 2004—Dr. Rudolph purchased 340B-discounted drugs through ACH and sold them to various oncology clinics with a 4% price markup that was allegedly shared by ACH and Dr. Rudolph.

According to the contract between ACH and participating oncologists, the doctors were subject to audit by Dr. Rudolph and his staff and were required to perform a specific amount of uncompensated care in order to participate.

For their part, ACH developed “drug interaction reports”—which were created by a non-professional member of Dr. Rudolph’s staff and faxed to the clinics after a short phone and video conferencing consultation—for all patients enrolled in the program and required that the participating doctors be “credentialed” as members of the ACH staff. According to Rudolph’s attorney, Rudolph believed that these procedures qualified the centers as clinics of ACH and the individuals as patients of ACH under the guidelines of the 340B program.

During his opening statement, Assistant United States District Attorney Sean Sweeney argued that Dr. Rudolph willfully exploited the 340B program by profiting from the sale of these discounted drugs, referring to the trial as “a case about greed and abuse.”

“The purpose of the 340B program is not to provide an opportunity for practitioners in private practice to make money,” said Sweeney, adding that Dr. Rudolph himself made “hundreds of thousands of dollars” through ACH’s 340B programs over a two year period.

Sweeney also said that the Office of Pharmacy Affairs (OPA) repeatedly requested information on the ACH program and eventually issued two “cease and desist” letters encouraging the hospital to end it, both of which failed to prevent Dr. Rudolph from continuing the program.

According to Sweeney, the government’s objections were based on their belief that Dr. Rudolph’s relationship with the patients that received the discounted drugs was not sufficient to meet the threshold required under the 340B program or PDMA. He later questioned four oncology doctors that participated in the program, each of whom testified that Dr. Rudolph played no role in the care of their patients beyond the drug interaction reports and that the patients did not know who Dr. Rudolph was.

Fred Thieman, Dr. Rudolph’s attorney and a former prosecutor himself, argued that his client developed his program in good faith and that he consulted regularly with both the government and his own legal counsel in the formation of the program.

“He believed not only that it was lawful, but that it was right,” said Thieman. “He told the government exactly what he was doing and when the government said to make changes, he made changes.”

Furthermore, Thieman questioned the investigation process by arguing that the case was compromised by the FBI—which at one point contacted Dr. Rudolph under the guise of an oncology clinic interested in participating in the program—and that it was only granted attention after the government began receiving complaints from pharmaceutical manufacturers about potential diversion.

The central issue in the case, as it relates to both PDMA and the 340B program, is whether the patients of these oncology doctors were in fact patients of Dr. Rudolph and ACH. Sweeney argued that the government believed this was clearly not the case and that Dr. Rudolph was made aware of their position on numerous occasions.

To that end, OPA Director Jim Mitchell testified that his office asked Dr. Rudolph for more information on his program upon learning of it and later asked twice that he “cease and desist” from selling 340B medications to “non-affiliated” physicians. Mitchell also said that he never received a response from Dr. Rudolph as to whether the oncology clinics with which he was partnered appeared as reimbursable on ACH’s Medicare cost report, a requirement for being added to the 340B database.

In his cross examination, Thieman called into question the clarity of the 340B program guidelines, even calling for dismissal of the trial due to the ambiguities in the definition of “patient.”

He also attempted to prove that Mitchell and his office did not specifically address or criticize ACH’s oncology program in its correspondence, nor did it respond to Dr. Rudolph’s requests for further guidance in a timely manner. Specifically, he argued that ACH voluntarily ended its Physician Medicine Assist Program (PMAP)—another 340B program—at the request of the government, but that the oncology program was never addressed by OPA.

Mitchell responded that he believed his letter asking ACH to end PMAP was sufficient to cover all of ACH’s 340B programs.

Thieman also raised questions about the government’s investigation of the matter, implying that OPA did not refer the case to the HHS Office of Inspector General (OIG) until it received specific complaints from pharmaceutical manufacturers and phone calls from the FBI.

Mitchell said that the OIG referral had nothing to do with these allegations and that he nonetheless remained committed to working with ACH to determine whether they were obeying the law.

The prosecution rested its case on April 27, and the defense is expected to begin calling witnesses on May 2. *The Monitor* will continue to provide updates on the latest developments in the case as it progresses.