

Federal Drug Discount and Compliance Monitor



www.DrugDiscountMonitor.com

...BREAKING NEWS...

MAY 8, 2006

Trial of Pittsburgh Doctor Accused of Drug Diversion Goes to the Jury

After two weeks of often rancorous testimony, the trial of Dr. Joseph Rudolph, a Pittsburgh-area physician charged with illegally distributing 340B-discounted medications, is now in the hands of a federal jury.

The federal government has charged Dr. Rudolph with illegally selling pharmaceuticals obtained through the 340B program to oncologists throughout the country, and is being tried under the Prescription Drug Marketing Act for allegedly running an unlicensed wholesale distribution operation. The trial is taking place before Judge Arthur Schwab of the United States District Court for the Western District of Pennsylvania.

Last week's proceedings included several hours of testimony by Dr. Rudolph concerning his dealings with the Aliquippa Community Hospital (ACH), a facility participating in the 340B program. The trial also focused on Rudolph's interaction with the Office of Pharmacy Affairs (OPA), the Food and Drug Administration (FDA) and the Federal Bureau of Investigation (FBI).

According to testimony elicited by the Rudolph defense team, ACH and Dr. Rudolph started to utilize 340B discounts under its Physician Medicine Assist Program (PMAP) in early 2004. During Aliquippa's initial participation in the 340B program, PMAP distributed a wide variety of pharmaceuticals to individuals seeking discounts in Pennsylvania and other states that paid a fee and received a pharmacological consultation. Those who were out of state could receive this consultation via telephone or videoconference.

OPA issued a cease-and-desist letter to Rudolph in May 2004, which Rudolph says led him to end the original program and focus on the ACH Oncology Center program. Under the oncology program, the ACH Oncology Center purchased 340B-discounted drugs through the hospital and sold them to oncologists whose patients underwent a drug interaction analysis. According to witnesses for Dr. Rudolph, participating doctors were also required to be credentialed as members of the ACH staff and were required to provide a specific amount of uncompensated care. The government contends that many of these oncologists were not affiliated with the hospital and therefore their patients were not eligible for 340B discounts.

Identifying the dividing line between Aliquippa's original use of the 340B program and the ACH Oncology Center Program has been an issue of contention between the government and defense. The defense used several diagrams to illustrate the distinctions between these programs; the government claims that they were facets of the same illegal distribution operation.

Throughout the trial, Dr. Rudolph maintained that concern for others led him to implement various 340B programs at ACH. Dr. Rudolph emphasized what he described as a need for reduced-fee drug programs, saying that he designed them for, "those who needed us – [the] uninsured, underinsured," and that this drove him to design and implement them.

Assistant United States Attorney Shaun Sweeney sought to persuade the jury that Dr. Rudolph was not being truthful about his motivations for implementing the drug distribution programs. Sweeney characterized Dr. Rudolph as beginning the programs to "make a boatload of money" and that greed was Dr. Rudolph's primary motivating factor. He also said that the government repeatedly warned Rudolph to stop the program.

The gradual souring of his relationships with federal regulatory agencies constituted another major theme during Dr. Rudolph's defense. Dr. Rudolph claimed that he used to look forward to FDA inspections as, "an excellent time to pick their [the government's] brains and find out if [he was] in compliance." However, the defense described his relationship with federal agencies as eventually deteriorating and accused the government of intimidating tactics including searching Dr. Rudolph's office and home.

Defense attorney Fred Thieman, a former U.S. attorney, expanded on the theme of government intimidation during his closing statement, comparing Dr. Rudolph to the protestors massacred by the People's Liberation Army in Tiananmen Square fifteen years ago. "We're much more civilized here in America. We don't use tanks. We use people in suits who write annual reports," he said.

Thieman also likened the Constitution to the body of Vladimir Lenin, as something kept preserved under glass as an example of a country's ideals. He reminded the five-woman, seven-man jury to honor that Constitution, and that the power granted them was to be used, not abused.

Assistant U.S. Attorney Sweeney compared Dr. Rudolph to an errant teenager who broke curfew repeatedly, despite warnings from his parents. He also equated the telehealth drug consultations to ordering fast food, saying it was like, "someone who's working at a fast food restaurant taking your order, typing it in and printing out a receipt."

While it is unclear how the jury will ultimately decide the case, the testimony by the government's final witness may end up harming the prosecution's case. Karyn Campbell, the assistant director for investigations for the FDA's Philadelphia office testified that she had not heard of Dr. Rudolph and had no contact with the physician. The prosecution hoped to use that testimony to counter the doctor's claim that he and Campbell had spoken by phone and that he had sent her a letter summarizing and

elaborating on their phone conversation in the spring of 2004. According to Dr. Rudolph, he sent the letter to query Campbell about whether ACH needed a wholesale license to operate the Oncology Center program.

Campbell's review of her phone records showed no evidence of such a call, she said. Similarly, she said her files did not include the spring 2004 letter.

Yet, when Thieman produced a February 2006 e-mail exchange between Campbell and Dr. Rudolph, the visibly surprised Campbell gasped and quickly revised her remarks, saying that her search of records touched only communications by phone and mail but not by e-mail. Dr. Rudolph's e-mail, which outlined the ACH Oncology Center program, asked whether he needed a wholesaler license to distribute drugs to facilities in other states. Campbell's response was that the law requiring a wholesale license did not apply to Dr. Rudolph's operation as long as the drugs were distributed to the hospital's patients.

As substantial amount of evidence was presented by both sides at trial on the question of whether drugs purchased by ACH under the 340B program were actually distributed to patients of the hospital; that evidence is part of what the jury will assess in determining whether Dr. Rudolph's actions constituted an illegal wholesale distribution scheme. If convicted, Dr. Rudolph could face up to ten years in jail or \$250,000 in fines.