



Department of Justice

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FOUR DEFENDANTS, "HI-TECH PHARMACEUTICALS" PLEAD GUILTY TO IMPORTING AND DISTRIBUTING "KNOCK-OFF" PRESCRIPTION DRUGS

Newnan, GA -- JARED ROBERT WHEAT, 36, of Alpharetta, Georgia; STEPHEN DOUGLAS SMITH, 40, of Duluth, Georgia; TOMASZ HOLDA, 45, of Duluth, Georgia; SERGIO OLIVEIRA, 48, of Hoschton, Georgia; and "HI-TECH PHARMACEUTICALS, INC.," a company based in Norcross, Georgia, pleaded guilty today to conspiring to import and distribute adulterated, mislabeled and unapproved new drugs, and to commit mail and wire fraud.

United States Attorney David E. Nahmias said of the pleas, "These defendants set up an offshore manufacturing facility where, in unsanitary conditions, they reproduced leading pharmaceutical products for importation into the United States, all without FDA approval or licensing from the rightful patent holders. Their motive in flouting the law, violating patents and exposing their customers to unknown health risks was greed, pure and simple. I commend the FDA and the DEA for their thorough investigation in this case. The Department of Justice and these agencies will continue to work hard to protect American consumers from such fraudsters."

Rodney G. Benson, Special Agent in Charge of the DEA Atlanta Field Division said, "The diversion of pharmaceutical products over the internet continues to be a major concern. Rogue internet sites are in the business to make millions in illegal sales, not to benefit the public. Today's guilty pleas illustrate how DEA and our local, state and federal law enforcement counterparts are committed to eradicating this problem."

FDA Office of Criminal Investigations Special Agent In Charge David Bourne said, "As in this conviction, the FDA's Office of Criminal Investigations actively pursues those who deceive the public by manufacturing and selling unapproved and unregulated medications which may pose risks to the health of consumers. We are committed to investigating and preventing those who use trickery and deceit to illegally and unscrupulously sell medications over the internet at the expense of the public health."

According to Nahmias and the information presented in court: The defendants in this case, in furtherance of their conspiracy, established a manufacturing facility in a small office park in rural Belize. Inside what was essentially a four-room home, the defendants produced unauthorized generic versions of such popular prescription pharmaceuticals as Xanax, Valium, Ambien, Vioxx, Zoloft, Viagra, and Cialis. The manufacturing processes complied with none of the sanitary, hygienic, or quality-control regulations issued by the FDA, nor had the defendants obtained approval from the FDA or licenses from the patent-holders to make such drugs. Nonetheless, the defendants made the drugs and marketed them, primarily via the internet, to customers in the United States and elsewhere. The drugs were made available without prescription and also without disclosure of the unsanitary manufacturing conditions. The defendants realized millions of dollars of sales before the scheme was initially disrupted by Belizean authorities and ultimately ended by U.S. authorities.

United States District Court Judge Jack T. Camp accepted today's guilty pleas in federal court in Newnan. All defendants pleaded to conspiring to violate federal prohibitions against mail and wire fraud and the importation and distribution of adulterated, unapproved, and mislabeled drugs. This conspiracy offense carries a maximum penalty of five years in prison and a maximum fine of \$250,000 (maximum of five years on probation and a fine of the greater of \$500,000 or double the fraud amount for the corporate defendant). Sentencing for the defendants is now set for October 21, 2008, before Judge Camp. In determining the actual sentence, the Court will consider the United States Sentencing Guidelines, which are not binding but provide appropriate sentencing ranges for most offenders.

This case was investigated by the agents of the Drug Enforcement Administration (DEA), and the U.S. Food and Drug Administration (FDA) with overseas assistance from Belizean law enforcement authorities.

Assistant United States Attorneys Randy Chartash, Douglas Gilfillan, and Robert McBurney prosecuted the case.

For further information please contact David E. Nahmias, United States Attorney, or Charysse L. Alexander, Executive Assistant United States Attorney, through Patrick Crosby, Public Affairs Officer, U.S. Attorney's Office, at (404) 581-6016. The Internet address for the HomePage for the U.S. Attorney's Office for the Northern District of Georgia is www.usdoj.gov/usao/gan.