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Inspections, Compliance, Enforcement, and Criminal Investigations

February 16, 2012: Local Cancer Doctor Pleads Guilty to Receiving Misbranded Cancer Drugs Two Californians also Named in Indictment



Food and Drug Administration Office of Criminal Investigations

U.S. Department of Justice Press Release

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St. Louis, MO - The United States Attorney's Office announced today that Dr. Abid S. Nisar of Town and Country, MO, was indicted, along with two California residents, with charges of distributing and receiving misbranded and adulterated prescription drugs, including the cancer treatment drugs marketed in the United States as Neupogen®, Herceptin® and Rituxan®. After making his first appearance today, Dr. Nisar pled guilty to one misdemeanor count of misbranding drugs. His sentencing set for May 25, 2012.

According to his plea agreement, Nisar is a licensed medical doctor specializing in the treatment of cancer patients, with offices in Florissant, Missouri, and East St. Louis and Granite City, IL. As part of his chemotherapy treatment, Dr. Nisar purchased large amounts of assorted prescription drugs from businesses associated with co-defendants James Newcomb and Sandra Behe, prescribed and dispensed these prescription drugs to his patients and then sought reimbursement for the drugs from the Medicare and Medicaid programs.

Dr. Nisar's prescription drugs were not the U.S. version of these drugs that the U.S. Food and Drug Administration ("FDA") had approved for use in the United States, and their labeling did not contain National Drug Codes and other legally required information from the U.S. labeling for these drugs. Some of the drugs contained foreign language labeling, for example Turkish language instructions. Further, these prescription drugs did not come from manufacturing plants that were registered with or inspected by FDA. As such, these prescription drugs were "misbranded" and illegal to receive or provide to patients in the United States.

Dr. Nisar admitted with his plea that he ordered and used a prescription drug labeled "Mabthera" from businesses associated with co-defendants Newcomb and Behe. Generally, "Mabthera" does contain Rituximab, the same active ingredient found in the FDA-approved drug legally used and marketed in the United States called Rituxan®. However, the drug ordered by Dr. Nisar came from an unregistered drug establishment located in Switzerland that did not provide FDA with an annual list of any drugs manufactured there, and was distributed by another company in New Delhi, India. By contrast, Rituxan® is manufactured in a drug establishment located in Vacaville, California, that is registered with FDA that FDA can inspect.

According to his plea agreement, sometime in January 2010, a nurse employed by Dr. Nisar received a fax

transmission from a business associated with co-defendants Newcomb and Behe offering assorted prescription cancer treatment drugs at 14% – 60% off their average wholesale price in the United States.

Dr. Nisar began regularly purchasing these cheaper prescription drugs during February through December of 2010 and provided the drugs to his patients without informing them of their source. After Dr. Nisar provided the drugs to his patients, Nisar submitted claims for reimbursement to various health care benefit programs, including the Medicare and Medicaid programs, without informing the programs of the source of the drugs. Dr. Nisar received reimbursement from the health care programs and also collected co-payments from beneficiaries for the drugs. Ultimately, Dr. Nisar purchased approximately \$352,504 worth of prescription drugs from unlicensed foreign distributors through approximately 47 separate shipments containing 1,138 separate drug units.

The indictment alleges that co-defendants Newcomb and Behe were both employed at Ban Dune Marketing Inc. ("BDMI"), a business that was located in La Jolla, California. From January 1, 2008 through May 18, 2011, they caused the distribution of un-approved prescription drugs from foreign countries to physicians located in the United States, including Dr. Nisar, with the assistance of persons in Canada and the United Kingdom.

ABID S. NISAR, Town and Country, MO, pled guilty to one misdemeanor count of introducing misbranded prescription drugs into interstate commerce; **SANDRA L. BEHE**, La Jolla, CA, was indicted on one felony count of introducing adulterated prescription drugs into interstate commerce; and **JAMES R. NEWCOMB**, also of La Jolla, CA, was indicted on one count of conspiracy to cause the introduction of adulterated prescription drugs into interstate commerce. Newcomb is set to make his first appearance on February 21, 2012.

"This indictment reflects the commitment of the FDA's Office of Criminal Investigations to protect the American public from the harms inherent to misbranded and adulterated drugs. The public must have confidence that their health care providers are receiving and administering drugs that fully comply with U.S. laws," said Special Agent in Charge Patrick J. Holland of FDA's Office of Criminal Investigations, Kansas City Field Office. "We will aggressively pursue all those who seek to profit from the importation and distribution of misbranded and adulterated drugs."

If convicted, the conspiracy count carries a maximum penalty of five years in prison and/or fines up to \$250,000. The other two counts carry maximums between one and three years in prison and/or fines between \$100,000 to \$250,000. In determining the actual sentences, a Judge is required to consider the U.S. Sentencing Guidelines, which provide recommended sentencing ranges.

This case was investigated by the Office of Criminal Investigation for the United States Food and Drug Administration and the Office of Inspector General for the United States Department of Health and Human Services, with assistance from the Defense Criminal Investigative Service of the U.S. Department of Defense.

As is always the case, charges set forth in an indictment are merely accusations and do not constitute proof of guilt. The remaining defendants are presumed to be innocent unless and until proven guilty.

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