NEWS RELEASE

OFFICE OF THE UNITED STATES ATTORNEY
SOUTHERN DISTRICT OF CALIFORNIA
San Diego, California

United States Attorney
Laura E. Duffy

For Further Information, Contact:

Assistant U.S. Attorney Melanie Pierson (619) 546-7976

For Immediate Release

LA JOLLA ONCOLOGIST AND MEDICAL PRACTICE PLEAD GUILTY TO DISPENSING UNAPPROVED DRUGS

NEWS RELEASE SUMMARY – January 23, 2013

SAN DIEGO - A prominent La Jolla oncologist and his corporate medical practice have pleaded guilty in connection with a scheme to import unapproved foreign cancer drugs at a deep discount, dispense them to unwitting patients, bill Medicare as if the drugs were legitimate, and pocket the profits.

In a hearing before U.S. Magistrate Judge Bernard Skomal on January 15, Dr. Joel I. Bernstein entered a guilty plea to a single count of introducing an unapproved drug into interstate commerce – in this case, a cancer drug called "Mabthera" intended for market in Turkey - and administering it to patients. The approved U.S. drug with the same active ingredient is Rituxan, which is used to treat lymphomas and leukemias such as non-Hodgkin lymphoma and chronic lymphocytic leukemia. Bernstein was released pending sentencing, which is scheduled for April 16 at 1:30 p.m. before Judge Skomal.

In addition, his medical practice, Dr. Joel I. Bernstein, M.D., Inc., also pleaded guilty at a hearing today before U.S. District Judge Cathy Ann Bencivengo to one count of Health Care fraud. According to the plea agreement with the corporation, employees of Dr. Joel I. Bernstein, M.D., Inc. purchased $3.4 million of foreign cancer drugs, knowing they had not been approved by the U.S. Food and Drug Administration for use in the United States. From 2007 to 2011, Bernstein's office purchased these drugs for significantly less than market value in the U.S., and then submitted claims to Medicare at the full

reimbursement price. To conceal the scheme, the office fraudulently used Medicare reimbursement codes for approved cancer drugs, as Medicare does not pay for unapproved drugs.

The plea agreement for the corporation also calls for $1.7 million in restitution to Medicare, plus forfeiture of $1.2 million in profits. The corporate medical practice is scheduled to be sentenced on May 17, 2013, before Unites States District Judge Cathy Ann Bencivengo.

In addition, the government has also filed a False Claims Act lawsuit in District Court against Dr. Bernstein and his medical corporation for submitting false claims to the Medicare Program for these unapproved drugs. According to this civil complaint, the Medicare Program was defrauded of over $1.7 million, and under the False Claims Act, the United States can recover triple the amount of damages plus monetary penalties.

The cases involving Dr. Bernstein and his practice are the latest example of an alarming nationwide trend that potentially puts patients at risk by exposing them to foreign drugs – particularly injectable chemotherapy drugs - that are not vetted by the FDA. Agency officials have described the trend as an "epidemic of unapproved and counterfeit drugs."

The FDA's Office of Criminal Investigations (OCI) currently has over 200 investigations nationwide involving schemes in which medical practices purchase foreign, unapproved drugs and dispense them to unsuspecting patients for personal financial gain.

This practice is particularly disturbing because, unlike traditional prescription drugs which are dispensed to the patient by a pharmacy, oncology drugs are typically infused into a patient without the patient ever seeing the box it came in, or any of the related labeling.

"This isn't just about the greed of one doctor, but about the welfare of many patients," said U.S. Attorney Laura Duffy. "In a worst-case scenario, chemotherapy drugs that have not been approved by the FDA may be fake, ineffective, unsafe and dangerous. This is what motivates the Department of Justice and the FDA to be more aggressive in stopping those who would corrupt the integrity of the pharmaceutical supply chain with no regard for the well-being of patients."

John Roth, director of the FDA's Office of Criminal Investigations, the lead agency on the case, said, "When medical professionals decide that patient safety is less important than finding a great deal on pharmaceutical products from foreign countries and unknown suppliers our nation's pharmaceutical supply chain is at risk and patients are vulnerable. FDA's Office of Criminal Investigations will continue to investigate these cases and work closely with our regulatory counterparts in FDA and our law enforcement partners who share the same commitment to address this problem. We hope this message is heard loud and clear within the medical community-you will face criminal prosecution if you engage in this type of illegal activity."

Daphne Hearn, Special Agent in Charge of the San Diego FBI, said, "Health care fraud costs the country billions of dollars each year and undermines the security of the Medicare program. The FBI will continue to work with our law enforcement partners and prosecutors to ensure the safety of the public and ensure the Medicare program will be there for those who need it most."

Derek Benner, Special Agent in Charge of Immigration and Customs Enforcement's Homeland Security Investigations, said, "As part of this case, HSI agents and our law enforcement partners uncovered an intricate network involved in the illicit distribution and importation of unapproved drugs that were sold to doctors in the U.S. It's disturbing to see licensed, trusted medical professionals who are willing to put their own financial gain over public health and safety. We owe it to consumers to aggressively pursue pharmaceutical fraud given the significant risk to public health."

According to the corporation's plea agreement, Bernstein's employees knowingly purchased foreign drugs containing the same active ingredient as drugs sold in the United States as Abraxane, Alimta, Aloxi, Boniva, Eloxatin, Gemzar, Neulasta, Rituxan, Taxotere, Venofer and Zometa, but were intended for use in markets outside the United States and had not been approved for sale in the United States.

The medical practice, in pleading guilty, admitted that it was aware that the drugs were not approved by the FDA in part because the practice had received a Notice from the FDA in October, 2008, that a shipment of drugs had been detained because the drugs were not approved for use in the United States by the FDA. Despite this warning, Bernstein's medical practice continued to purchase unapproved cancer drugs and inject them into patients.

The FDA regulates the introduction of pharmaceuticals into commerce. This regulation helps ensure that drugs are safely manufactured, made from appropriate ingredients and properly labeled. The approval process addresses the chemical composition of the drug, the drug's safety and effectiveness, and the elements of the drug's distribution, such as the methods used in the manufacture, processing and packing of the drug, as well as the labeling to be used for the drug.

Only drugs that comply with vigorous U.S. standards should be given to patients in this country. Drugs manufactured outside the United States which are not intended for use in the United States do not go through this approval process and are considered unapproved, and therefore potentially unsafe.

In the Bernstein case, investigators found no evidence the illegal drugs involved were counterfeit. The unapproved foreign medications that were seized during the investigation were tested and found to contain the appropriate level of active ingredients. Although it's difficult to determine whether a decline in a patient's health should be attributed to unapproved drugs or to cancer, the investigation uncovered no evidence to indicate that Bernstein's patients were harmed by the foreign drugs he administered.

There have been numerous similar cases of illegal importation and distribution of foreign unapproved drugs in San Diego and around the United States in recent years.

In cases related to Bernstein, a Florida-based cancer-drug supplier, Martin Paul Bean III, was indicted by a federal grand jury in San Diego in September 2012 for allegedly selling more than $7 million of misbranded and unapproved prescription oncology drugs to U.S. doctors. Please see 12-cr-03734-WQH USA.

The indictment alleged that from 2005 to 2011, Bean, doing business as GlobalRxStore, ordered the misbranded and unapproved drugs from foreign countries, including Turkey, India and Pakistan, and sold

them to the doctors throughout the U.S. at substantially discounted prices via a wholesale pharmacy in San Diego.

That pharmacy - Oberlin Medical Supply and Service Corp. - was owned and operated by Maher Idriss, who pleaded guilty March 8, 2012, to conspiring with Bean to supply the unapproved drugs. Idriss acknowledged that U.S. doctors paid him over $7 million for foreign-sourced unapproved oncology drugs from May 2006 to May 2011. Idriss faces up to five years in prison and restitution and has already forfeited approximately $54,000 of profits. He is scheduled for sentencing May 20, 2013. Please see 12-cr-01775-WQH.

According to the plea agreement for the Bernstein medical practice, employees ordered drugs from Oberlin, among other suppliers.

Idriss admitted that after receiving payments from the doctors, he transferred the funds to the foreign suppliers and to the GlobalRXStore owner's bank account in Canada, keeping a portion for himself.

In another related case with a San Diego connection, James Newcomb of La Jolla was sentenced in August 2012 to 24 months in prison for conspiring to distribute adulterated prescription drugs to physicians in the United States. Newcomb admitted that he distributed unapproved prescription drugs from foreign countries to physicians located in the United States, with the assistance of persons in Canada and the United Kingdom. Please see 12-cr-00009-RWS-1.

Newcomb and others marketed these illegal drugs to U.S. doctors by offering them at up to 60% off the average wholesale price of the legitimate drugs in the United States.

According to the plea agreement of Bernstein’s medical practice, employees of his office purchased unapproved oncology drugs from Newcomb’s businesses, which included Medication Brokers, Pricing Logix, Richard’s Services, Ban Dune Marketing and Warwick Healthcare Solutions. Newcomb based his operations in offices in La Jolla. La Jolla resident Sandra Behe and Dr. Abid Nisar of St. Louis, Missouri, were also convicted in the same investigation.

Elsewhere in the country, doctors, office staff and drug suppliers in Maryland, Missouri, Tennessee and California were indicted in similar schemes in 2011 and 2012. They were accused of importing misbranded cancer drugs at significantly cheaper prices, providing them to patients without disclosing the source of the drugs, and then submitting claims for reimbursement from healthcare programs.

It was the FDA’s discovery of two counterfeit drugs - Avastin, the approved blockbuster cancer drug for treatment of colorectal, lung, kidney and brain cancer, and Altuzan, the unapproved Turkish version of Avastin - that brought national media attention to the problem. The Altuzan was found to contain no active ingredient at all, and thus would provide no benefit whatsoever to patients.

The FDA, recognizing the seriousness of this illegal activity and the discovery of the counterfeit Avastin and Altuzan, took the unprecedented regulatory action of issuing letters to numerous medical practices and physicians around the country, including many that purchased unapproved cancer drugs. To date over 500 letters have been issued.

Dr. Bernstein was among those who received a letter from the FDA prior to being charged with federal crimes.

The letter to Bernstein said, in part: “Purchasing prescription drug products, such as injectable cancer medications, from foreign or unlicensed suppliers puts patients at risk of exposure to drugs that may be fake, contaminated, improperly stored and transported, ineffective, and dangerous. In virtually all cases, purchasing unapproved prescription drugs from foreign sources violates the Federal Food, Drug, and Cosmetic Act and is illegal.”

The letter warned of the risks of purchasing medications from foreign, unfamiliar or unlicensed suppliers and selling unapproved versions of injectable cancer medications, noting that “patients were unknowingly placed at risk when they received medications of uncertain purity, storage, handling, identity and sourcing.”

The letter also noted that importing these medications from foreign sources is a violation of the Federal Food, Drug and Cosmetic Act.

“In an effort to protect the health of patients, health care providers should use only FDA-approved versions of these cancer medications,” the letter said. “Health care providers should be aware that purchasing medications from direct-to-clinic promotions that are from non-verified sources might increase the risk of receiving a potentially unsafe and ineffective product, since the products offered for sale may be unapproved, not manufactured with the quality attributes of FDA-approved products, or counterfeit.”

DEFENDANT **Criminal Case No. 13cr0120-BGS**

Joel I. Bernstein

SUMMARY OF CHARGES

Title 21, United States Code, Section 331(d), 333(a) (1) and 355(a), a misdemeanor – Introducing or causing to be introduced into interstate commerce an unapproved new drug

MAXIMUM PENALTIES

One year in prison; $100,000 fine, one year supervised release; restitution.

DEFENDANT **Criminal Case No. 13cr0119-CAB**

Dr. Joel I. Bernstein, M.D., Inc.

SUMMARY OF CHARGES

Title 18, United States Code, Section 1347 – Medicare Fraud

MAXIMUM PENALTIES

Five years' supervised release; $500,000 fine; mandatory restitution.

INVESTIGATING AGENCIES

The U.S. Food and Drug Administration's Office of Criminal Investigations was the lead investigative agency in this case. Other agencies involved were the Federal Bureau of Investigation and Immigration and Customs Enforcement's Homeland Security Investigations. The lead prosecutor is Melanie Pierson.