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**JOHNSON & JOHNSON SUBSIDIARY, SCIOS, PLEADS GUILTY
TO MISBRANDING HEART FAILURE DRUG NATRECOR**

California-Based Company Will Pay \$85 Million Criminal Fine

SAN FRANCISCO – Scios Inc., a subsidiary of pharmaceutical giant Johnson & Johnson, pleaded guilty today to a misdemeanor violation of the Food, Drug and Cosmetic Act (FDCA) for introducing into interstate commerce its heart failure drug, Natrecor, for a use that was not approved by the Food and Drug Administration (FDA), the Justice Department announced. The district court also sentenced Scios, which is based in Fremont, Calif., to pay an \$85 million criminal fine in accordance with the plea agreement between Scios and the United States.

Under the FDCA, a company must specify the intended uses of a drug in its new drug application to the FDA. Before approval, the FDA must determine that the drug is safe and effective for the uses proposed by the company in its application. Once the drug is approved, if the manufacturer intends a different use and then introduces the drug into interstate commerce for that unapproved use, the drug becomes misbranded and the introduction into commerce is a criminal violation. The unapproved use is also known as an “off-label” use because it is not included in the drug’s FDA-approved labeling.

In 2001, FDA approved Natrecor for “the intravenous treatment of patients with acutely decompensated congestive heart failure [CHF] who have dyspnea [shortness of breath] at rest or with minimal activity.” The approved labeling for Natrecor did not list any other use, and the drug was not approved by FDA for any other use. Natrecor must be administered intravenously

to patients. It is a vasodilator and opens up the blood vessels, which reduces the heart's workload and may help to improve the acutely decompensated patient's shortness of breath.

As part of its plea today, Scios admitted that it intended Natrecor to be used off-label for infusing chronic (non-acute) CHF patients on a scheduled, serial basis and that it understood that this was not an approved use of the drug. Scios also admitted that the FDA-approved labeling for Natrecor did not contain any directions for this scheduled, serial use to treat chronic (non-acute) patients.

"Putting misbranded drugs into interstate commerce is serious because it undercuts the FDA's role in keeping our medicines safe and effective," said Tony West, Assistant Attorney General for the Civil Division of the Department of Justice. "This criminal plea by a major pharmaceutical company and the significant criminal fine imposed demonstrate the Justice Department's commitment to fighting health care fraud wherever we find it."

In addition to this criminal matter, the United States has sued Scios and Johnson & Johnson in an on-going related civil case under the False Claims Act in the Northern District of California (*U.S. ex rel. Strom v. Scios, Inc. and Johnson & Johnson, No. C 05-3004 CRB*). In that action, the United States alleges that the companies' promotion of the scheduled, serial use of Natrecor to treat non-acute heart failure patients caused false claims to be submitted to Medicare and other federal healthcare programs for this unapproved use of Natrecor because it was not a medically accepted and effective use of the drug.

The criminal case was prosecuted by the U.S. Attorney's Office for the Northern District of California, and the Justice Department's Civil Division, with the assistance of the FDA Office of Chief Counsel. The case was investigated by FDA's Office of Criminal Investigation, the FBI, the Office of Inspector General of the Department of Health and Human Services, the Department of Veterans Affairs, and the Office of Personnel Management.

Further Information:

Case #: CR 11-461 CRB

A copy of this press release may be found on the U.S. Attorney's Office's website at www.usdoj.gov/usao/can.

Electronic court filings and further procedural and docket information are available at <https://ecf.cand.uscourts.gov/cgi-bin/login.pl>.

Judges' calendars with schedules for upcoming court hearings can be viewed on the court's website at www.cand.uscourts.gov.

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