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PRESS RELEASE

AMGEN INC. PLEADS GUILTY TO FEDERAL CHARGE IN BROOKLYN AND PAYS $762 MILLION TO RESOLVE CRIMINAL LIABILITY AND CIVIL FRAUD ALLEGATIONS

Biotech Giant Pleads Guilty to Illegally Introducing Drug into Market for Uses that the FDA Declined to Approve; Will Pay $612 Million to Resolve False Claims Act Suits and $150 Million in Criminal Penalties and Forfeiture

AmerisourceBergen Corporation Subsidiary International Nephrology Network Also Agrees to Pay $15 Million to Resolve Related Qui Tam Action

BROOKLYN, NY – Earlier today, at the federal courthouse in Brooklyn, New York, U.S. District Judge Sterling Johnson, Jr. accepted a guilty plea by American biotechnology giant Amgen Inc. ("Amgen") for illegally introducing a misbranded drug into interstate commerce, and approved Amgen's global settlement with the United States in which Amgen agreed to pay $762 million to resolve criminal and civil liability arising from its sale and promotion of certain drugs. The settlement represents the single largest criminal and civil fraud settlement involving a biotechnology company in U.S. history.

The announcement was made by Marshall L. Miller, Acting U.S. Attorney for the Eastern District of New York; Stuart Delery, Principal Deputy Assistant Attorney General for the Civil Division of the Department of Justice; Jenny A. Durkan, U.S. Attorney for the Western District of Washington; Thomas O'Donnell, Special Agent in Charge, U.S. Department of Health and Human Services, Office of Inspector General (HHS-OIG), New York Regional Office; John Roth, Director, U.S. Food and Drug Administration (FDA), Office of Criminal Investigations; Eric Schneiderman, New York State Attorney General; and George Venizelos, Assistant Director in Charge of the FBI's New York Field Office; along with numerous law enforcement and regulatory partners.

As part of the plea agreement and criminal settlement, Amgen pled guilty to a criminal information (the "Information") charging the company with illegally introducing a misbranded drug, Aranesp, into interstate commerce. Under the Food, Drug and Cosmetics Act, it is illegal for drug companies to introduce into the marketplace drugs that the company intends will be used "off-label," i.e., for uses or at doses not approved by the FDA. Aranesp is an erythropoiesis-stimulating[1] agent ("ESA") that was approved by the FDA at calibrated doses for particular patient populations suffering from anemia. In order to increase sales of Aranesp and reap the resulting profits, Amgen illegally sold the drug with the intention that it be used at "off-label" doses that the FDA had specifically considered and rejected, and for an "off-label" treatment that the FDA had never approved. Under the terms of the criminal plea agreement, Amgen will pay a criminal fine of $136 million and criminal forfeiture in the amount of $14 million.

As part of the civil settlement, Amgen has agreed to pay $612 million ($587.2 million to the United States and $24.8 million to the states) to resolve claims that it caused false claims to be submitted to Medicare, Medicaid and other government insurance programs. The federal civil settlement agreement encompasses allegations that Amgen: (1) promoted Aranesp and two other drugs that it manufactured, Enbrel and Neulasta, for "off-label" uses and doses that were not approved by the FDA and not properly reimbursable by federal insurance programs; (2) offered illegal kickbacks to a wide range of entities in an effort to influence health care providers to select its products for use regardless of whether they were reimbursable by federal health care programs or were medically necessary; and (3) engaged in false price reporting practices involving several of its drugs. As part of the global settlement, Amgen has also agreed to enter into a Corporate Integrity Agreement (the "CIA") with HHS-OIG that will govern its conduct and ensure careful oversight of its branding and marketing practices.

"Instead of working to extend and enhance human lives, Amgen illegally pursued corporate profits while jeopardizing the safety of vulnerable consumers suffering from disease. Americans expect - and the law requires - much more. Today's guilty plea and $762 million global resolution demonstrate our vigilance in protecting America's healthcare consumers and pursuing any corporation that seeks to profit by violating U.S. law," said Acting United States Attorney Marshall L. Miller of the Eastern District of New York. "To all who might consider introducing misbranded drugs into the marketplace, you are on notice: we remain steadfastly committed to prosecuting such violations of law." Mr. Miller also expressed his appreciation to the Offices of Inspector General for the Department of Defense, the Office of Personnel Management and the Veterans Administration for their assistance.

"Today's resolution reinforces the Department of Justice's commitment to protecting the public safety and federal treasury from all forms of pharmaceutical fraud," said Stuart Delery, Principal Deputy Assistant Attorney General for the Civil Division of the Department of Justice.

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[1] Erythropoieses is the process by which the body produces red blood cells.

"We will continue to pursue those who improperly market pharmaceuticals and biologics at the expense of individual patients' well-being and the federal health care system as a whole."

"The public has been well served by this investigation, and the FDA commends the efforts of the U.S. Attorney's Office in the Eastern District of New York, the Department of Justice and the other law enforcement agencies that worked with us to vigorously pursue this matter," said John Roth, Director of the FDA's Office of Criminal Investigations. "Today's settlement demonstrates our continued scrutiny of any illegal practices used by pharmaceutical and biotechnology companies."

"We continue our two-pronged attack on alleged fraudulent corporate behavior," said Daniel R. Levinson, Inspector General of the U.S. Department of Health and Human Services. "Our investigations expose wrongdoing, and our Corporate Integrity Agreements monitor companies' compliance with controls designed to prevent future problems."

"Promoting drugs for unapproved purposes is beyond wrong; it jeopardizes the health and safety of the public," said FBI Assistant Director in Charge George Venizelos. "Preserving the integrity of the pharmaceutical industry is important work, and the FBI will continue working with our colleagues in law enforcement to investigate and charge those who inappropriately market drugs for scurrilous profits."

"This sends a powerful message to pharma companies: you must not put profits ahead of patients' health and doctors' trust. Drugs should be prescribed because they make people better, not because they make companies money," said U.S. Attorney Jenny A. Durkan, Western District of Washington. "The coordination by our office, the U.S. Attorney's Offices in the Eastern District of New York and Massachusetts and Main Justice also shows that there is no corner of the country where these actors can hide."

"Today's resolution is a testament to coordination and cooperation throughout the Department of Justice to ensure drug manufacturers are held to account and fraud is properly addressed," said Boston U.S. Attorney Carmen M. Ortiz. "The District of Massachusetts is proud to have played a role in the resolution of this matter, and in ensuring that drug manufacturers' claims regarding their products are truthful and properly supported."

"There are no excuses for illegally marketing off label drugs, offering kickbacks to health care professionals and ripping off the taxpayers by defrauding Medicaid and other programs," said Attorney General Schneiderman. "With this settlement the message we are sending is clear: biotechnology giants are not above the law, and my office will continue to ensure that prescriptions be written based on medical judgment - not profit motive."

The Criminal Plea Agreement

As alleged in the Information, beginning at the launch of Aranesp in 2002 and extending until 2007, Amgen illegally introduced Aranesp for uses and at dosage levels that the FDA had specifically declined to approve due to insufficient clinical evidence to establish their safety and efficacy. In particular, Amgen illegally introduced Aranesp into the oncology and nephrology[2] ESA markets, intending that it be used for patients suffering from anemia due to chronic kidney disease or chemotherapy at off-label, unapproved doses that were larger and less frequently administered than those approved by the FDA for these patient populations. Amgen also illegally introduced Aranesp into the oncology ESA market intending that it be used to treat anemia caused by cancer, irrespective of whether the patient had been prescribed chemotherapy - a use which the FDA had never approved and which the FDA subsequently determined caused an increased risk of death. In particular, in 2007, the FDA mandated that a "black box" label be added to Aranesp's label, warning that Aranesp "increased the risk of death . . . in patients with active malignant disease [cancer] receiving neither chemotherapy nor radiation." At approximately the time that the FDA issued the black box warning, Amgen ceased its promotion of Aranesp for the treatment of anemia caused by cancer rather than the cancer's treatment.

Amgen's internal sales and marketing materials made plain that Amgen's misbranding of Aranesp was the company's core business strategy to gain market share from its only ESA competitor, Procrit, sold by Johnson & Johnson. At the time of Aranesp's 2002 launch, doctors typically prescribed Procrit to treat the anemic patient populations for which Aranesp was approved. To compete with Procrit, Amgen built the Aranesp commercial strategy around the unapproved, off-label approach of a less frequent dosing schedule, which Amgen sales representatives argued was more convenient for patients and more profitable for doctors. Amgen implemented this illegal commercial effort through its promotion of off-label doses from two to four times larger than those approved by the FDA, administered far less frequently than approved by the FDA.

When this unapproved, "off-label" dosing effort proved commercially successful, Amgen sales and marketing executives determined that capturing the population of anemic cancer patients who were not undergoing chemotherapy was "the next big thing" and would give Amgen a "fifty-one percent [ESA] market share." Accordingly, the company set about capturing the off-label market of patients suffering from anemia caused by cancer itself, rather than anemia caused by chemotherapy, and its sales representatives began marketing the safety and efficacy of Aranesp in that population. Ultimately, in 2007, the FDA determined that Aranesp increased the risk of death in that very population.

Aware that its misbranding of Aranesp was illegal, Amgen instructed its sales representatives to promote off-label uses through the guise of "reactive marketing." This technique attempted to circumvent the law by inducing doctors to ask questions about an off-

[2] Nephrology is a medical specialty that concerns itself with the study of kidney function and kidney problems and treatment of kidney problems and renal replacement therapy (dialysis and kidney transplantation therapy).

label use, to serve as a smokescreen to hide Amgen's intentional effort to introduce the drug for unapproved, "off-label" uses. Amgen thus trained its sales representatives to intentionally elicit questions from doctors about off-label uses as legal cover to then provide the doctors with studies supporting the off-label use, thereby promoting the drug for that unapproved use. The studies Amgen provided to doctors to support off-label uses were often the very same studies that the FDA had rejected as insufficient to support the safety and efficacy of those off-label uses, when Amgen had applied to expand Aranesp's label to encompass them.

The Civil Settlement Agreement

The $612 million dollar civil settlement encompasses broader allegations by the United States against Amgen than those contained in the Information.[3] The civil settlement agreement resolves claims contained in ten lawsuits against Amgen that were brought under the *qui tam*, or whistle-blower provisions of the False Claims Act, which allow private citizens to bring civil actions on behalf of the United States and share in any recovery. Seven of these cases currently are pending in the Eastern District of New York; two are pending in the District of Massachusetts and one in the Western District of Washington.

Like the Information, the civil settlement contains allegations that Amgen illegally promoted Aranesp for off-label indications. More specifically, the United States contends that between September 2001 and September 2011, Amgen knowingly promoted the sale and use of Aranesp for dosing regimens and indications which were (a) not approved by the FDA, and (b) not medically accepted indications, including anemia caused by cancer, anemia caused by chronic disease, chronic anemia, and anemia caused by myelodysplastic syndrome. The United States further contends that Amgen used journal articles that were insufficient to support the safety and efficacy of the off-label uses at issue, and improperly obtained listings in medical compendia in an effort to establish that the off-label uses were medically accepted, and thereby eligible for coverage by federal health care programs. The United States contends that Amgen similarly promoted its drugs Enbrel and Neulasta for off-label indications that were not eligible for coverage by federal health care programs. The civil settlement agreement also covers claims that Amgen knowingly reported inaccurate pricing information such as Average Sales Prices, Best Prices, and Average Manufacturer Prices for several drugs.

In a separate civil settlement, International Nephrology Network (INN), renamed Integrated Nephrology Network, a subsidiary of AmerisourceBergen Corporation, has also agreed to pay $15 million to resolve civil liability arising from its role in the marketing of Aranesp. The agreement encompasses claims that INN offered illegal kickbacks to influence health care providers' selection of Aranesp for treatment of kidney disease and in so doing also caused false price reporting for Aranesp. This agreement resolves a single *qui tam* action.

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[3] The claims settled by the civil settlement agreement are allegations only, and there has been no determination of liability, except to the extent that Amgen has admitted facts in connection with its criminal plea.

The Corporate Integrity Agreement

In addition to the criminal and civil resolutions, Amgen also executed a CIA with HHS-OIG. The five-year CIA includes provisions designed to increase accountability of individuals and Board members, to increase transparency, and to strengthen Amgen's compliance program. The CIA requires that a committee of Amgen's board of directors annually review the effectiveness of the company's compliance program and that executives in key areas certify to compliance. It also requires that Amgen post on its company website information about payments to doctors. Under the CIA, Amgen must establish and maintain a centralized risk assessment and mitigation program and policies relating to research, publications, and Amgen's interactions with federal payors. Amgen is subject to exclusion from Federal health care programs for a material breach of the CIA and subject to monetary penalties for less significant breaches.

The government's multi-year joint criminal and civil investigation and the negotiation of the global settlement were conducted on the criminal side by Assistant U.S. Attorneys Roger Burlingame and Winston Paes and on the civil side by Assistant United States Attorneys Deborah B. Zwany, Paul Kaufman and Erin Argo, and Affirmative Civil Enforcement Auditor Emily Rosenthal from the Eastern District of New York. Assistant U.S. Attorney Zachary Cunha from the District of Massachusetts, Assistant U.S. Attorneys Harold Malkin and Peter Winn from the Western District of Washington, Trial Attorneys Jessica Champa, John Henebery and Doug Rosenthal from the Department of Justice's Commercial Litigation Branch assisted on the civil side. Assistant U.S. Attorney Susan Loitz of the United States Attorney's Office for the Western District of Washington and Trial Attorney Sondra Mills of the Department of Justice's Office of Consumer Litigation assisted on the criminal side. The Corporate Integrity Agreement was negotiated by Mary Riordan and Lisa Veigel from the Department of Health and Human Service's Office of Inspector General. The state civil settlement agreement was negotiated by Jay Speers, Carolyn Ellis, Christopher Miller, and Laura Meehan of the New York State Office of the Attorney General on behalf of the National Association of Medicaid Fraud Control Units.