January 29, 2013

Attorney General Eric Holder
Office of the Attorney General of the U.S.
Department of Justice
Room 4400
950 Pennsylvania Ave, N.W.
Washington, DC 20530-0001

Dear Attorney General Holder:

I support Professor Robert Fellmeth's request that you investigate the Amgen affair which resulted in passage of a $500 million bonanza.

This corporate maneuver was led by named legislators who received substantial contributions from Amgen.

The intricacy of interactions by the parties and intermediaries are probative of an exchange, a deal that might cross the line from gift to payoff.

See the attached articles and editorial from *The New York Times*.

Sincerely,

Ralph Nader

P.O. Box 19312
Washington, DC 20036

Enclosed: NYTimes Editorial, article

January 28, 2013

Eric Holder
Attorney General of the United States
U.S. Justice Department
Washington, D.C. 20036

Dear Mr. Attorney General,

As you may be aware, the recent "fiscal cliff" legislation has apparently included an extraordinary benefit to the pharmaceutical for-profit company Amgen – allowing it to perhaps collect up to $500 million in revenues from MediCare appropriations that prior law would limit as to its "Sensibar" product. Amgen reportedly defended its second two-year extension of a waiver to allow higher prices as follows:

"Including oral-only medications in the payment system at the same time that the bundle is being rebased would have been disruptive to quality patient care. Further, a Government Accountability Office report recognized that it would not be in the best interest of patients to include oral-only medications into the Medicare bundle for dialysis patients because of unreliable data systems and a lack of quality metrics." (Amgen spokeswoman Kelley Davenport).

This explanation that a medicine is "oral" and hence will disrupt or compromise dialysis treatment unless it can be provided at a much higher price from MediCare funds is hardly a *bona fide* explanation. It is disappointing that a multibillion dollar corporation such as Amgen cannot come up with some justification that at least sounds plausible.

While Congressional "pork" to benefit a local business or serve local constituents is not uncommon in Washington D.C., an assessment to benefit a national corporation of up to $500 million over two years from a MediCare fund that already involves unprecedented unfunded liability for our children is rather exceptional. Why would selected members of Congress spearhead such a measure? What were they told by Amgen? What were they promised? What have they received or will they receive?

As a former Assistant U.S. Attorney, and the co-author of *California White Collar Crime* (Tower, 20011, 20013) and other publications in the field, I understand that federal bribery law requires a *quid pro quo* element. But one cannot imagine why this proposal would be written and arranged for any other motive. Certainly not for the rationale advanced to date. You will not learn of the promises made and the understandings reached without examining the staffs and principals involved. If there is a better example warranting a grand jury inquiry into Congressional corruption, where would it be?

Very Sincerely,

Robert C. Fellmeth
Price Professor of Public Interest Law
University of San Diego School of Law

cc: Ralph Nader

The New York Times

January 22, 2013

Amgen Gets a Gift From Congress

For a disheartening example of how intense lobbying and financial contributions can distort the legislative process in Washington, consider what happened to the "fiscal cliff" bill approved three weeks ago by Congress.

Senators who play a major role in federal health care financing were happy to help Amgen, the world's largest biotechnology company, evade Medicare cost-cutting controls by delaying price restraints on a class of drugs used by kidney dialysis patients, including Sensipar, a drug made by Amgen. That provision was inserted into the final fiscal bill by Senate aides. Many members of Congress did not know it was in the bill until just hours before it was approved.

Although other companies will benefit financially from that delay, Amgen, which has 74 lobbyists in Washington, was the only company to lobby aggressively for the provision. The delay will cost the Medicare program up to $500 million over a two-year period.

The disturbing details were revealed in a report by Eric Lipton and Kevin Sack of The Times on Sunday. The maneuvering to exempt these drugs undercuts a five-year effort to change the incentives used to pay for kidney dialysis care. Previously, Medicare had paid providers separately for the drugs and for administering dialysis treatment, a system that often encouraged overprescribing.

But, in 2008, Congress reversed the incentives by requiring Medicare to pay a single, bundled rate for a patient's dialysis treatment and related medications, starting in 2011. But certain oral drugs, including Sensipar, were given a two-year reprieve, to expire in 2014, from being included in that more cost-effective bundled system. The fiscal bill has now extended that exclusion for an additional two years.

Supporters of the delay — notably, Senator Max Baucus, a Democrat of Montana, who leads the Senate Finance Committee, and Orrin Hatch, of Utah, the ranking Republican on that committee — say it is needed to give the Medicare system and dialysis providers time to absorb other complicated changes in federal reimbursements for kidney care. But there is good reason to suspect other factors were involved as well. Both senators have political and financial ties to Amgen, as does Mitch McConnell, the Senate minority leader, who exerted great influence over the fiscal negotiations and praised the Medicare provisions.

A top aide to Mr. Hatch, who was involved in negotiating the dialysis delay, previously worked as a health policy analyst for Amgen. The current lobbyists for Amgen include former chiefs of staff for both Mr. Baucus and Mr. McConnell. And the three senators have received substantial contributions from Amgen's employees and its political action committee since 2007 — almost $68,000 to Senator Baucus, $59,000 to Senator Hatch, and $73,000 to Senator McConnell.

Amgen's strong influence prevailed even though it had pleaded guilty just weeks ago to marketing an anti-anemia drug illegally and agreed to pay criminal and civil penalties of $762 million, a record settlement for a biotechnology company.

This dreadful episode is a classic example of the power of special interests to shape legislation and shows how hard it may be to carry out the reforms needed to cut health care costs.

http://www.nytimes.com/2013/01/23/opinion/amgen-gets-a-gift-from-congress.html

The New York Times

January 19, 2013

Fiscal Footnote: Big Senate Gift to Drug Maker

By ERIC LIPTON and KEVIN SACK

WASHINGTON — Just two weeks after pleading guilty in a major federal fraud case, Amgen, the world's largest biotechnology firm, scored a largely unnoticed coup on Capitol Hill: Lawmakers inserted a paragraph into the "fiscal cliff" bill that did not mention the company by name but strongly favored one of its drugs.

The language buried in Section 632 of the law delays a set of Medicare price restraints on a class of drugs that includes Sensipar, a lucrative Amgen pill used by kidney dialysis patients.

The provision gives Amgen an additional two years to sell Sensipar without government controls. The news was so welcome that the company's chief executive quickly relayed it to investment analysts. But it is projected to cost Medicare up to $500 million over that period.

Amgen, which has a small army of 74 lobbyists in the capital, was the only company to argue aggressively for the delay, according to several Congressional aides of both parties.

Supporters of the delay, primarily leaders of the Senate Finance Committee who have long benefited from Amgen's political largess, said it was necessary to allow regulators to prepare properly for the pricing change.

But critics, including several Congressional aides who were stunned to find the measure in the final bill, pointed out that Amgen had already won a previous two-year delay, and they depicted a second one as an unnecessary giveaway.

"That is why we are in the trouble we are in," said Dennis J. Cotter, a health policy researcher who studies the cost and efficacy of dialysis drugs.

“Everybody is carving out their own turf and getting it protected, and we pass the bill on to the taxpayer.”

The provision’s inclusion in the legislation to avert the tax increases and spending cuts that made up the so-called fiscal cliff shows the enduring power of special interests in Washington, even as Congress faces a critical test of its ability to balance the budget.

Amgen has deep financial and political ties to lawmakers like Senate Minority Leader Mitch McConnell, Republican of Kentucky, and Senators Max Baucus, Democrat of Montana, and Orrin G. Hatch, Republican of Utah, who hold heavy sway over Medicare payment policy as the leaders of the Finance Committee.

It also has worked hard to build close ties with the Obama administration, with its lobbyists showing up more than a dozen times since 2009 on logs of visits to the White House, although a company official said Saturday that it had not appealed to the administration during the debate over the fiscal legislation.

Aides to Mr. Hatch and Mr. Baucus, and a spokeswoman for Amgen, said the delay would give the Medicare system and medical providers the time they needed to accommodate other complicated changes in how federal reimbursements for kidney care were determined.

“Sometimes when you try to do too much and too quickly, you screw up,” said Antonia Ferrier, a spokeswoman for Mr. Hatch. The goal, an Amgen spokeswoman said in a written statement, is “to ensure that quality of care is not compromised for dialysis patients.”

But the measure runs counter to a five-year effort in Washington to control the enormous expense of dialysis for the Medicare program by reversing incentives to overprescribe medication.

Amgen’s success also shows that even a significant federal criminal investigation may pose little threat to a company’s influence on Capitol Hill. On Dec. 19, as Congressional negotiations over the fiscal bill reached a frenzy, Amgen pleaded guilty to marketing one of its anti-anemia drugs, Aranesp, illegally. It agreed to pay criminal and civil penalties totaling $762 million, a record settlement for a biotechnology company, according to the Justice Department.

Amgen, whose headquarters is near Los Angeles and which had $15.6 billion in revenue in 2011, has a deep bench of Washington lobbyists that includes Jeff Forbes, the former chief of staff to Mr. Baucus; Hunter Bates, the former chief of staff for Mr. McConnell; and Tony Podesta, whose fast-growing lobbying firm has unusually close ties to the White House.

Amgen's employees and political action committee have distributed nearly $5 million in contributions to political candidates and committees since 2007, including $67,750 to Mr. Baucus, the Finance Committee chairman, and $59,000 to Mr. Hatch, the committee's ranking Republican. They gave an additional $73,000 to Mr. McConnell, some of it at a fund-raising event for him that it helped sponsor in December while the debate over the fiscal legislation was under way. More than $141,000 has also gone from Amgen employees to President Obama's campaigns.

What distinguishes the company's efforts in Washington is the diversity and intensity of its public policy campaigns. Amgen and its foundation have directed hundreds of thousands of dollars in charitable contributions to influential groups like the Congressional Black Caucus and to lesser-known groups like the Utah Families Foundation, which was founded by Mr. Hatch and brings the senator positive coverage in his state's news media.

Amgen has sent large donations to Glacier PAC, sponsored by Mr. Baucus in Montana, and OrrinPAC, a political action committee controlled by Mr. Hatch in Utah.

And when Mr. Hatch faced a rare primary challenge last year, a nonprofit group calling itself Freedom Path sponsored advertisements in Utah that attacked his opponent, an effort that tax records released in November show was financed in large part by the Pharmaceutical Research and Manufacturers of America, a trade group that includes Amgen.

In some cases, the company's former employees have found important posts inside the Capitol. They include Dan Todd, one of Mr. Hatch's top Finance Committee staff members on health and Medicare policy, who worked as a health policy analyst for Amgen's government affairs office from 2005 to 2009. Mr. Todd, who joined Mr. Hatch's staff in 2011, was directly involved in negotiating the dialysis components of the fiscal bill, and he met with "all the stakeholders," Mr. Hatch's spokeswoman said, not disputing when asked that this included Amgen lobbyists.

For years, Amgen used its clout in Washington to lobby for generous Medicare payments for its blockbuster drug, Epogen, which fends off anemia in dialysis patients.

The Medicare program covers most costs associated with treating severe renal disease, regardless of a patient's age, and the dialysis market continues to grow steadily. In 2010, the government's kidney program was spending $1.9 billion on injectable anti-anemia drugs like Epogen.

But nearly a decade ago, evidence started to surface that questioned the effectiveness and safety of Epogen at the levels being used.

Researchers found that Medicare's practice of reimbursing providers with separate payments for the drugs and for dialysis treatments encouraged overprescription because the providers made healthy profits with each dose. They also found that high doses posed cardiovascular risks to patients.

Congress reversed the incentive in 2008 by requiring Medicare to pay a single, bundled rate for a dialysis treatment and related medications starting in 2011. With providers potentially profiting more by prescribing less Epogen, use of dialysis drugs dropped by nearly 25 percent.

But the blow was softened for Amgen and other kidney care companies with a few favors from Congress. Among them was a two-year delay in the inclusion of certain oral drugs, Sensipar among them, in the new bundled payment system. That meant demand for Sensipar would not decline and Amgen would maintain control over pricing.

With that two-year exclusion set to expire in 2014, Amgen's lobbyists began making rounds again on Capitol Hill last fall. In private meetings with staff members of the House Ways and Means and Senate Finance Committees, they argued for another two-year delay, several Congressional aides said.

Committee staff members had been meeting regularly in Room S-124 of the Capitol to negotiate a package of Medicare cuts needed to prevent a large scheduled reduction in doctors' fees. The kidney program was on the table because a new report by the Government Accountability Office had found that Medicare had overpaid for dialysis by up to $880 million in 2011.

The discussions about cutting dialysis reimbursement began late last fall with little focus on a delay for oral drugs, but it was eventually endorsed by leading staff members for Mr. Baucus and Mr. Hatch, Congressional aides said.

Aides to the senators said the delay made sense because the Government Accountability Office had warned in early 2011 that federal regulators should take care in setting compensation levels for the drugs.

But others on Capitol Hill saw no justification for further delay.

"It is disappointing," said a Democratic Congressional aide who declined to be named because of the issue's sensitivity, "since the status quo encourages prescribing of oral drugs based on financial incentives rather than on best clinical practices."

Mr. Hatch's spokeswoman, Ms. Ferrier, said the involvement of Mr. Todd, the former Amgen employee, had not been inappropriate and that dozens of staff members on Capitol Hill handled matters that might benefit former employers.

"They have to leave their previous lives behind," Ms. Ferrier said. "And Dan has done just that."

After the House was sidelined late in the fiscal negotiations, the Senate gained control of the final bill-writing process, and the provision requested by Amgen was inserted into the legislation by Senate staff members.

Aides to Mr. Baucus and Mr. Hatch emphasized that the White House and Senate leadership, including Mr. McConnell, had the final word on the bill.

A spokesman for Mr. McConnell praised the parts of the legislation related to Medicare, while a White House spokesman declined to comment, saying the matter was decided by players on Capitol Hill.

Many lobbyists and Congressional aides said they first learned of the language when the final bill was posted publicly, only hours before being approved. It called for cutting $4.9 billion over 10 years by lowering Medicare payments for dialysis, but left hundreds of millions on the table by extending the oral drug delay.

At this point, opponents had no way to challenge the provision, as there was a single vote on the entire fiscal package. Mr. Baucus and Mr. Hatch voted in favor.

Aides to the senators said some heavy donors had won and others had lost in the Medicare negotiations — proof that the legislative outcome was based on the merits. "What is the best policy for Montanans and people across the country lies at the heart of every decision Chairman Baucus makes," said Meaghan Smith, a spokeswoman for Mr. Baucus. "It's as simple as that."

Eric Lipton reported from Washington, and Kevin Sack from Atlanta.

http://www.nytimes.com/2013/01/20/us/medicare-pricing-delay-is-political-win-for-amgen-drug-maker.html?pagewanted=all