

**No. 11-1085**

---

---

In the  
Supreme Court of the United States

---

**AMGEN, INC., ET AL.,**  
*Petitioners,*

v.

**CONNECTICUT RETIREMENT PLANS  
AND TRUST FUNDS,**  
*Respondent.*

---

**On Writ of Certiorari  
to the United States Court of Appeals  
for the Ninth Circuit**

---

**BRIEF OF *AMICUS CURIAE*  
PUBLIC JUSTICE, P.C.  
IN SUPPORT OF RESPONDENT**

---

---

Arthur H. Bryant  
PUBLIC JUSTICE, P.C.  
555 12<sup>th</sup> St., Suite 1230  
Oakland, CA 94607  
(510) 622-8150

Earl Landers Vickery  
3007 Dancy  
AUSTIN, TX 78722  
(512) 435-6666  
*Counsel of Record*

September 27, 2012

Add'l Counsel:

William H. Narwold  
MOTLEY RICE LLC  
One Corporate Center  
20 Church St., 17<sup>th</sup> Floor  
Hartford, CT 06103  
(860) 882-1681

Ann K. Ritter  
MOTLEY RICE LLC  
28 Bridgeside Boulevard  
Mt. Pleasant, SC 29464  
(843) 216-9000

**TABLE OF CONTENTS**

	<b>Page</b>
INDEX OF AUTHORITIES .....	ii
INTEREST OF THE <i>AMICUS CURIAE</i> .....	1
SUMMARY OF THE ARGUMENT .....	1
ARGUMENT .....	4
I. A MULTITUDE OF CASES ILLUSTRATE THE SYSTEMIC FRAUD IN THE PHARMACEUTICAL INDUSTRY .....	4
II. AMGEN'S ACTIONS WITH RESPECT TO EPOGEN AND ARANESP MIRROR THE SAME INDUSTRY-WIDE PROBLEMS IDENTIFIED ABOVE .....	27
CONCLUSION .....	42

## INDEX OF AUTHORITIES

<b>Cases</b>	<b>Page(s)</b>
<i>New York v. Amgen, Inc.</i> , 652 F.3d 103 (1st Cir. 2011), <i>cert. dismissed</i> , 132 S.Ct. 993 (2011) . . . . .	40
<i>Washington Legal Foundation v. Friedman</i> , 13 F. Supp. 2d 51 (D.D.C. 1998), <i>vacated as moot by</i> <i>Washington Legal Foundation v. Henney</i> , 202 F.3d 331 (D.C. Cir. 2000) . . . . .	5
<b>Statutes, Regulations and Rules</b>	<b>Page(s)</b>
31 U.S.C. § 3729 . . . . .	4
21 C.F.R. § 201.1(e)(4)(i)(a) . . . . .	5
21 C.F.R. § 201.51(g) . . . . .	39
21 C.F.R. § 201.80(e) . . . . .	37
Sup. Ct. R. 37.6 . . . . .	1
<b>Press Releases</b>	<b>Page(s)</b>
Press Release, Department of Justice, TAP Pharmaceutical Products Inc. and Seven Others Charged with Health Care Crimes; Company Agrees to Pay \$875 Million to Settle Charges (Oct. 3, 2001) .	23

Press Release, Department of Justice, Drug Giant Pfizer & Two Subsidiaries to Pay \$49 Million for Defrauding Drug Medicaid Rebate Program (Oct. 28, 2002) .....	23
Press Release, Department of Justice, AstraZeneca Pharmaceuticals LP Pleads Guilty to Healthcare Crime; Company Agrees to Pay \$355 Million to Settle Charges (June 20, 2003) .....	24
Press Release, Department of Justice, Warner-Lambert to Pay \$430 Million to Resolve Criminal & Civil Health Care Liability Relating to Off-Label Promotion (May 13, 2004) .....	7
Press Release, Department of Justice, Schering-Plough to Pay \$345 Million to Resolve Criminal and Civil Liabilities for Illegal Marketing of Claritin (July 30, 2004) .....	18
Press Release, Department of Justice, GlaxoSmithKline Pays \$150 Million to Settle Drug Pricing Fraud Case (Sept. 20, 2005) .....	24
Press Release, Department of Justice, Serono to Pay \$704 Million for the Illegal Marketing of AIDS Drug (Oct. 17, 2005) .....	19
Press Release, Department of Justice, King Pharmaceuticals to Pay U.S. \$124 Million for Medicaid Rebate Underpayments & Overcharging for Drug Products (Nov. 1, 2005) .....	24

Press Release, Department of Justice, Eli Lilly and Company to Pay U.S. \$36 Million Relating to Off-Label Promotion (Dec. 21, 2005) . . . . .	8
Press Release, Department of Justice, Medco to Pay U.S. \$155 Million to Settle False Claims Act Cases (Oct. 23, 2006) . . . . .	19
Press Release, Department of Justice, Biopharmaceutical Firm Intermune to Pay U.S. Over \$36 Million for Illegal Promotion and Marketing of Drug Actimmune (Oct. 26, 2006) . . . . .	9
Press Release, Department of Justice, Medicis Pharmaceutical to Pay U.S. \$9.8 Million to Resolve False Claims Allegations (May 8, 2007) . . . . .	9
Press Release, Department of Justice, Merck to Pay More than \$650 Million to Resolve Claims of Fraudulent Price Reporting and Kickbacks (Feb. 7, 2008) . . . . .	20
Press Release, Department of Justice, Aventis Pays More than \$190 Million to Settle Drug Pricing Fraud Matters (Sept. 10, 2007) . . . . .	25
Press Release, Department of Justice, Pharmaceutical Company Cephalon to Pay \$425 Million for Off-Label Drug Marketing (Sept. 29, 2008) . . . . .	10
Press Release, Department of Justice, Pharmaceutical Company Eli Lilly to Pay Record \$1.415 Billion for Off-Label Drug Marketing (Jan. 15, 2009) . . . . .	10

Press Release, Department of Justice, Aventis  
Pharmaceutical to Pay U.S. \$95.5 Million to Settle  
False Claims Act Allegations (May 28, 2009) . . . . 25

Press Release, Department of Justice, Justice  
Department Announces Largest Health Care Fraud  
Settlement in Its History (Sept. 2, 2009) . . . . . 8

Press Release, Department of Justice, Four  
Pharmaceutical Companies Pay \$124 Million for  
Submission of False Claims to Medicaid (Oct. 19, 2009)  
. . . . . 26

Press Release, Department of Justice, Alparma to Pay  
\$42.5 Million to Resolve False Claims Act Allegations  
in Connection with Promotion of Drug Kadian (Mar.  
16, 2010) . . . . . 20

Press Release, Department of Justice, Pharmaceutical  
Giant AstraZeneca to Pay \$520 Million for Off-Label  
Drug Marketing (Apr. 27, 2010) . . . . . 11

Press Release, Department of Justice, Two Johnson &  
Johnson Subsidiaries to Pay Over \$81 Million to  
Resolve Allegations of Off-Label Promotion of Topamax  
(Apr. 29, 2010) . . . . . 12

Press Release, Department of Justice, Drug Maker  
Forest Pleads Guilty; to Pay More Than \$313 Million  
to Resolve Criminal Charges and False Claims Act  
Allegations (Sept. 15, 2010) . . . . . 21

Press Release, Department of Justice, GlaxoSmithKline to Plead Guilty & Pay \$750 Million to Resolve Criminal and Civil Liability Regarding Manufacturing Deficiencies at Puerto Rico Plant (Oct. 26, 2010) .....	12
Press Release, Department of Justice, Pharmaceutical Manufacturers to Pay \$421.2 Million to Settle False Claims Act Cases (Dec. 7, 2010) .....	22
Press Release, Department of Justice, Pharmaceutical Companies to Pay \$214.5 Million to Resolve Allegations of Off-Label Promotion of Zonegran (Dec. 15, 2010) .....	13
Press Release, Public Citizen, Pharmaceutical Industry Is Biggest Defrauder of the Federal Government Under the False Claims Act, New Public Citizen Study Finds (Dec. 16, 2010) .....	3
Press Release, Department of Justice, Pharmaceutical Manufacturer to Pay \$280 Million to Settle False Claims Act Case (Dec. 20, 2010) .....	26
Press Release, Department of Justice, Serono to Pay \$44.3 Million to Resolve False Claims Act Allegations in Connection with Promotion of Drug Rebif (May 4, 2011) .....	21
Press Release, Department of Justice, Danish Pharmaceutical Novo Nordisk to Pay \$25 Million to Resolve Allegations of Off-Label Promotion of Novoseven (June 10, 2011) .....	15



Press Release, Department of Justice, Pfizer to Pay \$14.5 Million for Illegal Marketing of Drug Detrol (Oct. 21, 2011) . . . . . 13

News Release Detail, Amgen, Amgen’s Third Quarter 2011 Revenue and Adjusted Earnings Per Share (EPS) Each Increased 3 Percent to \$3.9 Billion and \$1.40 (Oct. 24, 2011) . . . . . 41

Press Release, Department of Justice, U.S. Pharmaceutical Company Merck Sharp & Dohme Sentenced in Connection with Unlawful Promotion of Vioxx (Apr. 19, 2012) . . . . . 14

Press Release, Department of Justice, Abbott Labs to Pay \$1.5 Billion to Resolve Criminal & Civil Investigations of Off-label Promotion of Depakote (May 7, 2012) . . . . . 14

Press Release, Department of Justice, GlaxoSmithKline to Plead Guilty and Pay \$3 Billion to Resolve Fraud Allegations and Failure to Report Safety Data (July 2, 2012) . . . . . 15

**FDA Materials** **Page(s)**

*FDA, Good Reprint Practices for the Distribution of Medical Journal Articles and Medical or Scientific Reference Publications on Unapproved New Uses of Approved Drugs and Approved or Cleared Medical Devices* (Jan. 2009) . . . . . 6

FDA Briefing Document, *Continuing Reassessment of the Risks of Erythropoiesis-Stimulating Agents (ESAs) Administered for the Treatment of Anemia associated with Cancer Chemotherapy for May 10, 2007 Meeting of Oncologic Drugs Advisory Committee, FDA . . . .* 27

Food & Drug Admin., Drugs@FDA: FDA Approved Drug Products (PROCRIT/EPOGEN – Label Information (Apr. 1, 1993)) . . . . . 28

Food & Drug Admin., Drugs@FDA: FDA Approved Drug Products (EPOGEN – Label Information (July 26, 1999)) . . . . . 28

Food & Drug Admin., Drugs@FDA: FDA Approved Drug Products (EPOGEN/PROCRIT – Label Information (Dec. 17, 2007)) . . . . . 36

Food & Drug Admin., Drugs@FDA: FDA Approved Drug Products (EPOGEN – Highlights of Prescribing Information (June 24, 2011)) . . . . . 29

**Other Sources** **Page(s)**

Alexander Gaffney, *Reports: Johnson & Johnson to Pay \$2.2 Billion to Settle Risperdal Marketing Probe, Regulatory Affairs Prof'ls Soc'y* (June 11, 2012) . . 18

<i>An Act Making Appropriations for the Departments of Labor, Health and Human Services, and Education, and Related Agencies, for the Fiscal Year Ending September 30, 1999, and for Other Purposes: Hearings on H.R. 4274 / S. 2440 Before a Subcommittee of the Committee on Appropriations, United States Senate, 105th Cong., 2nd Sess. (Mar. 5, 1998)</i> . . . . .	32
Anatole Besarab et al., <i>The Effects of Normal as Compared with Low Hematocrit Values in Patients with Cardiac Disease Who Are Receiving Hemodialysis and Epoetin</i> , 339 <i>New. Eng. J. Med.</i> 584 (1998) . . .	34
Andrew Pollack, <i>Amgen to Pay \$780 Million to Settle Suits on Its Sales</i> , <i>N.Y. Times</i> (Oct. 24, 2011) . . . . .	4
Antonia F. Giuliana, Esq., <i>FCA Alert</i> (Mar. 2, 2011) . . . . .	7
Ashley Wazana, <i>Physicians and the Pharmaceutical Industry : Is a Gift Ever Just a Gift?</i> , 283 <i>JAMA</i> 373 (2000) . . . . .	17
Carl Elliott, <i>White Coat, Black Hat: Adventures on the Dark Side of Medicine</i> (Beacon Press 2010) . . . . .	16
Catherine Larkin, <i>Allergan Will Pay Fine, Plead Guilty to Misdemeanor</i> , <i>Bloomberg</i> (Sept. 1, 2010) . . . . .	12

Daniel W. Coyne, *Opinion: Misleading Drug Trials Amgen's Incomplete Report on an Early Major Trial of Epoetin Misled the Medical Community About the Anemia Drug's Risks and Benefits—and Helped Make Amgen Rich*, *The Scientist* (May 14, 2012) . . . *passim*

Daniel W. Coyne, *The Health-Related Quality of Life was Not Improved by Targeting Higher Hemoglobin in the Normal Hematocrit Trial*, 82 *Kidney Int'l* 235 (2012) . . . . . *passim*

David C. Radley et al., *Off-label Prescribing Among Office-Based Physicians*, 166 *Archives Internal Med.* 1021 (2006) . . . . . 6

David Evans, *Pfizer Broke the Law by Promoting Drugs for Unapproved Uses*, *Bloomberg* (Nov. 9, 2009) . . . 7

Eric G. Campbell et al., *A National Survey of Physician-Industry Relationships*, 356 *N. Eng. J. Med.* 1742 (Apr. 2007) . . . . . 16

James P. Orłowski & Leon Wateska, *The Effects of Pharmaceutical Firm Enticements on Physician Prescribing Patterns: There's No Such Thing as a Free Lunch*, 102 *Chest* 270 (1992) . . . . . 16

Jim Edwards, *5 Amgen Execs Plead the Fifth on Alleged Kickbacks Described in Spreadsheet*, *CBS Money Watch*, Mar. 2, 2011 . . . . . 40

Jim Edwards, <i>Lesson From Pfizer: Don't Describe Your Product as "Snake Oil" in Internal Email</i> (Mar. 26, 2010) .....	11
John M. Grohol, <i>Johnson &amp; Johnson Settles 3rd Risperdal Lawsuit for \$158M</i> , PsychCentral (Jan. 25, 2012) .....	17
Kathleen Sharp, <i>Blood Feud: The Man Who Blew the Whistle on One of the Deadliest Prescription Drugs Ever</i> (Penguin Books 2011) .....	42
Katie Thomas, <i>J&amp;J Fined \$1.2 Billion in Drug Case</i> , N.Y. Times (Apr. 11, 2012) .....	18
Kevin Loughlin & Joyce Generali, <i>The Guide to Off-Label Prescription Drugs: New Uses for FDA-Approved Prescription Drugs</i> (2006) .....	6
OpenSecrets.org, Lobbying: Pharmaceuticals/Health Products – Industry Profile, 1998 .....	31
OpenSecrets.org, Lobbying: Pharmaceuticals/Health Products – Industry Profile, 2011 .....	31
Peter Whoriskey, <i>Anemia Drugs Made Billions, But at What Cost?</i> , Wash. Post, July 19, 2012 .....	<i>passim</i>
<i>State ex rel. Jones v. Janssen LP</i> , No. D-1-GV-04-001288, Tr. of Alexander Miller & Steven Shon (Tex. Dist. Travis Co. Jan. 11, 2012) .....	17

*US Jury's Neurontin Ruling to Cost Pfizer \$141 Mln,*  
Reuters (Mar. 25, 2010) ..... 10

## **INTEREST OF THE *AMICUS CURIAE*<sup>1</sup>**

Public Justice, P.C. (“Public Justice”) is a national public interest law firm dedicated to pursuing justice for the victims of corporate and government abuses. Public Justice specializes in precedent-setting and socially significant individual and class action litigation designed to advance civil rights and civil liberties, consumer and victims’ rights, workers’ rights, the preservation of the civil justice system and the protection of the poor and powerless. Public Justice regularly represents consumers and employees in class actions, and our experience is that the class action device often represents the only meaningful way that individuals can vindicate important legal rights. Public Justice is gravely concerned that the arguments advanced by Petitioners in this case would, if adopted, erode the only remedy available for large numbers of victims of corporate misconduct.

## **SUMMARY OF THE ARGUMENT**

In their joint amicus brief filed on behalf of Petitioners, the Chamber of Commerce, PhRMA and BIO suggest that class action securities litigation unfairly targets the pharmaceutical industry with frivolous litigation. They claim that the resolution for

---

<sup>1</sup> Pursuant to Sup. Ct. R. 37.6, *amici* affirm that no counsel for a party authored this brief in whole or in part and that no person other than *amici*, their members, and their counsel made a monetary contribution to its preparation or submission. The parties have consented to the filing of this brief.

which Petitioners argue is not merely practical, but indeed “safeguards the productivity of the U.S. economy,” Chamber Br. 27, noting that the percentage of large health care companies “targeted in securities class actions” doubled in 2010, *id.* PhRMA pleads its case in a more self-interested way, *id.* at 2 (“The issues in this case are especially significant to PhRMA members because many of them have borne the expense and burden of defending against securities-fraud class actions in recent years, which raise the already substantial cost and risks of developing new medicines.”).

As Respondents observe, Congress has already considered and addressed these policy arguments. *See* Resp. Br. 38-41. Rather than requiring that courts answer common questions at class certification – which would undermine the very purpose of class actions – Congress has implemented procedural protections to “raise the bar” for plaintiffs asserting securities fraud actions. *Id.* at 39. Given the response by Congress, the Court should refuse to re-weigh the same policy arguments.

But there is a substantive response to these arguments that is at least as compelling. Any increased “targeting” of pharmaceutical companies in securities litigation does not reflect a problem with the securities laws or the rules of class certification, but results directly from the cancer of fraud that has spread throughout the modern pharmaceutical industry. Indeed, the pharmaceutical industry has now surpassed the defense industry as the largest



defrauder of the federal government, measured by payments made for violations of the False Claims Act.<sup>2</sup> The trend is accelerating: of the almost \$20 billion in such payments between 1991 and 2010, three-quarters came in the last five years.<sup>3</sup> Promotion of drugs for uses not approved by the U.S. Food and Drug Administration (“FDA”), concealing and misrepresenting safety information, exploiting improper relationships with prescribing physicians and manipulating the reimbursement system of governmental insurers such as Medicare and Medicaid -- all to induce more and more prescriptions in higher and higher doses -- have become far too common courses of conduct. Despite billions of dollars in payments for False Claims Act (“FCA”) violations, moreover, these practices continue. In Section I, Public Justice illustrates the scope of the problem by identifying representative examples of health care fraud in the last decade.

Petitioner Amgen has been a willing participant in these activities, including with respect to the drugs at issue in this litigation. Amgen extensively promoted Epogen and Aranesp in doses exceeding FDA’s approved targets; manipulated the reporting of scientific studies to hide safety risks; marketed the

---

<sup>2</sup> Press Release, Public Citizen, *Pharmaceutical Industry Is Biggest Defrauder of the Federal Government Under the False Claims Act, New Public Citizen Study Finds* (Dec. 16, 2010), <http://www.citizen.org/pressroom/pressroomredirect.cfm?ID=3239>.

<sup>3</sup> *Id.*

drugs based on improvement of “quality of life,” a claim for which there has never been scientific support; supplied to physicians and clinics significantly more of the drugs than necessary, urging them to bill the excess to Medicare or Medicaid; and instructed prescribing physicians how to make their offices profit centers for the sale of these drugs, thereby inducing more and more prescriptions. The result was a period of more than two decades in which Amgen realized billions in profits from drugs for which it greatly overstated the benefits, but largely hid the risks. One year ago, Amgen finally agreed to pay \$780 million to address federal criminal and civil investigations and to settle the False Claims Act charges resulting from its conduct.<sup>4</sup> This was merely a nod to an incidental cost of doing business in the pharmaceutical industry.

## ARGUMENT

### I. A MULTITUDE OF CASES ILLUSTRATE THE SYSTEMIC FRAUD IN THE PHARMACEUTICAL INDUSTRY.

The False Claims Act, 31 U.S.C. § 3729 *et seq.* (“FCA”) prohibits submitting false or fraudulent claims for payment to the United States. Despite billions of dollars paid for violations of the Act, the prospect of profits far in excess of potential fines and settlements

---

<sup>4</sup> Andrew Pollack, *Amgen to Pay \$780 Million to Settle Suits on Its Sales*, N.Y. Times (Oct. 24, 2011) (“Pollack”), [http://www.nytimes.com/2011/10/25/health/25amgen.html?\\_r=0](http://www.nytimes.com/2011/10/25/health/25amgen.html?_r=0).

has led numerous pharmaceutical companies to engage in enormous health care fraud.

1. Marketing drugs for uses beyond those approved by FDA provides a significant economic opportunity. The use of a drug for an indication approved by FDA, in accordance with the parameters of that approval, is termed “on-label” use. Once FDA approves a drug for *any* indication, however, a physician may prescribe the drug for any *other* indication or for use in a manner beyond the parameters of FDA approval. Such use of a drug is termed “off-label.” While FDA regulations prohibit the promotion of drugs for off-label use, *see* 21 C.F.R. § 201.1(e)(4)(i)(a), drug companies, spearheaded by Petitioners’ *amicus* the Washington Legal Foundation, have successfully asserted that a First Amendment right to disseminate truthful information about even unapproved uses and benefits of their drugs forecloses FDA’s efforts to prohibit such promotion. *See, e.g., Wash. Legal Found. v. Friedman*, 13 F. Supp. 2d 51, 62 (D.D.C. 1998), *vacated as moot by Wash. Legal Found. v. Henney*, 202 F.3d 331, 337 & n.7 (D.C. Cir. 2000).<sup>5</sup> This has relegated FDA to attempt

---

<sup>5</sup> Paradoxically, drug companies deny any corresponding ability to disseminate truthful information about the *safety risks* of their drugs. *E.g.*, Brief of Petitioner, *Wyeth v. Levine*, No. 06-1249, at 27 (“Wyeth was not permitted to depart from FDA’s conclusion [regarding labeling of the risks and benefits of the drug] — as state law would have required—without violating the FDCA and FDA’s regulations.”).

damage control by enacting voluntary guidelines governing dissemination of such material.<sup>6</sup>

In this regulatory climate, the opportunity to maintain and expand market share by promoting off-label uses has proven irresistible, and the drug industry's circumvention of regulation in this sphere has been remarkably successful. One of every four drugs currently dispensed in this country is prescribed for uses not approved by FDA.<sup>7</sup> This is true even though a 2006 study found that almost three-fourths of off-label prescriptions are for uses that "lack[] evidence of clinical efficiency," while barely one-fourth "were supported by strong scientific evidence."<sup>8</sup>

Promotion of drugs for unapproved uses teems with the opportunity for abuse. Between 2004 and 2010, the United States resolved at least 21 significant off-label marketing cases and collected nearly \$8 billion in criminal fines and civil settlements. Manufacturers

---

<sup>6</sup> FDA, *Good Reprint Practices for the Distribution of Medical Journal Articles and Medical or Scientific Reference Publications on Unapproved New Uses of Approved Drugs and Approved or Cleared Medical Devices* (Jan. 2009), available at <http://www.fda.gov/RegulatoryInformation/Guidances/ucm125126.htm>.

<sup>7</sup> Kevin Loughlin & Joyce Generali, *Preface to The Guide to Off-Label Prescription Drugs: New Uses for FDA-Approved Prescription Drugs* (2006).

<sup>8</sup> David C. Radley et al., *Off-label Prescribing Among Office-Based Physicians*, 166 *Archives Internal Med.* 1021, 1023 (2006), <http://archinte.jamanetwork.com/article.aspx?articleid=410250>.

entered criminal guilty pleas in 15 of those cases.<sup>9</sup> Of those cases, 95% of the investigations were initiated by a *qui tam* complaint filed pursuant to the FCA.<sup>10</sup> Despite guilty pleas and billions of dollars, however, violations continue to escalate.

In May 2004, Warner-Lambert (a subsidiary of Pfizer) pled guilty and agreed to pay \$430 million to resolve criminal charges and civil liabilities in connection with illegal and fraudulent promotion of unapproved uses for its drug, Neurontin.<sup>11</sup> In 2009, Pfizer pled guilty to off-label marketing of another drug, Bextra, and agreed to pay a \$1.19 billion criminal fine plus \$1 billion in civil settlements relating to the off-label promotion of Bextra and three other drugs.<sup>12</sup> “Pfizer promoted the sale of Bextra for several uses

---

<sup>9</sup> See Antonia F. Giuliana, Esq., FCA Alert (Mar. 2, 2011), available at <http://www.fcaalert.com/2011/03/articles/settlements-1/statistics-for-off-label-marketing-settlements-involving-prescription-drugs/>.

<sup>10</sup> *Id.*

<sup>11</sup> Press Release, Department of Justice, Warner-Lambert to Pay \$430 Million to Resolve Criminal & Civil Health Care Liability Relating to Off-Label Promotion (May 13, 2004), [http://www.justice.gov/opa/pr/2004/May/04\\_civ\\_322.htm](http://www.justice.gov/opa/pr/2004/May/04_civ_322.htm); hereinafter, citations to Press Releases by the Department of Justice (“DOJ”) will take the form “DOJ Press Release.”

<sup>12</sup> See David Evans, *Pfizer Broke the Law by Promoting Drugs for Unapproved Uses*, Bloomberg (Nov. 9, 2009), <http://www.bloomberg.com/apps/news?pid=newsarchive&sid=a4yV1nYxCGoA>.

and dosages that the FDA specifically declined to approve due to safety concerns,” and “paid kickbacks to health care providers to induce them to prescribe these, as well as other, drugs.”<sup>13</sup> The Assistant United States Attorney from the Neurontin prosecution summarized Pfizer’s indifference, observing that, “[a]t the very same time Pfizer was in our office negotiating and resolving the allegations of criminal conduct in 2004, Pfizer was itself in its other operations violating those very same laws.”<sup>14</sup>

Other examples of fraudulent off-label marketing abound:

- ▶ Eli Lilly and Company “agreed to plead guilty and to pay \$36 million in connection with its illegal promotion of its pharmaceutical drug Evista” in December 2005. Among other allegations, Lilly had trained its sales representatives to use scientific articles to promote unapproved uses while hiding pages disclosing that “[a]ll of the authors were either employees or paid consultants of Eli Lilly at the time this article was written.”<sup>15</sup>

---

<sup>13</sup> DOJ Press Release, Justice Department Announces Largest Health Care Fraud Settlement in Its History (Sept. 2, 2009), <http://www.justice.gov/opa/pr/2009/September/09-civ-900.html>.

<sup>14</sup> *Id.*

<sup>15</sup> DOJ Press Release, Eli Lilly and Company to Pay U.S. \$36 Million Relating to Off-Label Promotion (Dec. 21, 2005), [http://www.justice.gov/opa/pr/2005/December/05\\_civ\\_685.html](http://www.justice.gov/opa/pr/2005/December/05_civ_685.html).

- ▶ InterMune agreed in October 2006 to pay more than \$36.9 million to address its criminal and civil liability relating to its drug Actimmune. The company promoted the drug for an unapproved use, mischaracterizing its clinical trials as having demonstrated a benefit when none had been shown.<sup>16</sup>
- ▶ In May 2007, Medicis Pharmaceutical Corporation agreed to pay \$9.8 million to settle claims that it had marketed its drug Loprox to children under ten, a patient population that FDA had not approved.<sup>17</sup>
- ▶ In September 2008, Cephalon agreed to pay \$425 million to settle criminal and civil allegations relating to the off-label marketing of three of its drugs, and to plead guilty to a criminal information. FDA had approved one of the drugs, Actiq (which is manufactured as a lollipop) for use in cancer patients for whom morphine no longer was effective. But “[u]sing the mantra ‘pain is pain,’” Cephalon instructed its sales representatives “to focus on physicians other than oncologists,” and to promote the “highly addictive narcotic . . . for noncancer patients to use for such maladies as migraines,

---

<sup>16</sup> DOJ Press Release, Biopharmaceutical Firm Intermune to Pay U.S. Over \$36 Million for Illegal Promotion and Marketing of Drug Actimmune (Oct. 26, 2006), [http://www.justice.gov/opa/pr/2006/October/06\\_civ\\_728.html](http://www.justice.gov/opa/pr/2006/October/06_civ_728.html).

<sup>17</sup> DOJ Press Release, Medicis Pharmaceutical to Pay U.S. \$9.8 Million to Resolve False Claims Allegations (May 8, 2007), [http://www.justice.gov/opa/pr/2007/May/07\\_civ\\_336.html](http://www.justice.gov/opa/pr/2007/May/07_civ_336.html).

sickle-cell pain crises, injuries, and in anticipation of changing wound dressings or radiation therapy.”<sup>18</sup>

- ▶ In January 2009, Eli Lilly agreed to a settlement of \$1.415 billion to resolve criminal and civil allegations related to the off-label marketing of its anti-psychotic drug Zyprexa. Among other actions, Lilly trained its sales representatives to promote Zyprexa to physicians caring for the elderly for such afflictions are “Alzheimer’s, agitation, aggression, hostility, depression, and generalized sleep disorder,” none of which were approved uses. Lilly subsequently instituted the “Viva Zyprexa” campaign to make Zyprexa an “everyday agent in primary care” even though primary care physicians do not typically treat either of the conditions for which FDA *had* approved the drug.<sup>19</sup>
- ▶ In March 2010, Pfizer was ordered to pay \$47 million (trebled to \$141 million because of the violation of the federal RICO law) for its improper promotion of Neurontin.<sup>20</sup> In that case, a Pfizer

---

<sup>18</sup> DOJ Press Release, Pharmaceutical Company Cephalon to Pay \$425 Million for Off-Label Drug Marketing (Sept. 29, 2008), <http://www.justice.gov/civil/cpb/cases/cases/Cephalon/Cephalon%20Press%20Release.pdf>.

<sup>19</sup> DOJ Press Release, Pharmaceutical Company Eli Lilly to Pay Record \$1.415 Billion for Off-Label Drug Marketing (Jan. 15, 2009), <http://www.justice.gov/usao/pae/News/Pr/2009/jan/lillyrelease.pdf>.

<sup>20</sup> See *US Jury’s Neurontin Ruling to Cost Pfizer \$141 Mln*, Reuters (Mar. 25, 2010),



executive had written an e-mail calling Neurontin “the ‘snake oil’ of the twentieth century.”<sup>21</sup>

- ▶ In April 2010, Astra Zeneca agreed to pay \$520 million to resolve allegations that it illegally marketed Seroquel, an anti-psychotic drug, for uses not approved as safe or effective by the FDA. Approximately \$302 million went to the federal government for false claims to agencies such as Medicare, with the remainder going to states for false claims submitted to state Medicaid programs.<sup>22</sup>
- ▶ Also in April, 2010, Ortho-McNeil Pharmaceutical & Ortho-McNeil-Janssen Pharmaceuticals, both subsidiaries of Johnson & Johnson, agreed to pay more than \$81 million to resolve criminal and civil liability arising from the illegal promotion of the epilepsy drug Topamax. Ortho-McNeil Pharmaceutical, which pled guilty to criminal charges, sponsored a "Doctor-for-a-Day" program, in which it “hired outside physicians to join sales representatives in their visits to the offices of health

---

<http://www.reuters.com/article/2010/03/25/pfizer-neurontin-idUSN259778920100325>.

<sup>21</sup> Jim Edwards, *Lesson From Pfizer: Don't Describe Your Product as "Snake Oil" in Internal Email* (Mar. 26, 2010), [http://www.cbsnews.com/8301-505123\\_162-42844492/lesson-from-pfizer-dont-describe-your-product-as-snake-oil-in-internal-email/](http://www.cbsnews.com/8301-505123_162-42844492/lesson-from-pfizer-dont-describe-your-product-as-snake-oil-in-internal-email/).

<sup>22</sup> DOJ Press Release, *Pharmaceutical Giant AstraZeneca to Pay \$520 Million for Off-Label Drug Marketing* (Apr. 27, 2010), <http://www.justice.gov/opa/pr/2010/April/10-civ-487.html>.

care providers and to speak at meetings and dinners about prescribing Topamax for unapproved uses and doses.”<sup>23</sup>

- ▶ In 2010, Allergan pled guilty and agreed to pay \$600 million for marketing its drug Botox between 2000 and 2005 for such unapproved uses as “headache, pain, muscle stiffness and juvenile cerebral palsy.”<sup>24</sup>
- ▶ In October 2010, GlaxoSmithKline pled guilty to felony and misdemeanor charges of manufacturing and distributing adulterated drugs made at its now-closed facility in Puerto Rico. The company agreed to pay a \$150 million in criminal fine and forfeiture, plus \$600 million to settle the civil claims. The manufacturing defects caused the drugs to fall outside the parameters of their FDA approvals.<sup>25</sup>

---

<sup>23</sup> DOJ Press Release, Two Johnson & Johnson Subsidiaries to Pay Over \$81 Million to Resolve Allegations of Off-Label Promotion of Topamax (Apr. 29, 2010), <http://www.justice.gov/opa/pr/2010/April/10-civ-500.html>.

<sup>24</sup> Catherine Larkin, *Allergan Will Pay Fine, Plead Guilty to Misdemeanor*, Bloomberg (Sept. 1, 2010), <http://www.bloomberg.com/news/2010-09-01/allergan-will-pay-600-million-plead-guilty-to-misdemeanor-in-botox-probe.html>.

<sup>25</sup> DOJ Press Release, GlaxoSmithKline to Plead Guilty & Pay \$750 Million to Resolve Criminal and Civil Liability Regarding Manufacturing Deficiencies at Puerto Rico Plant (Oct. 26, 2010), <http://www.justice.gov/opa/pr/2010/October/10-civ-1205.html>.

- ▶ In December 2010, Elan agreed to pay more than \$203 million to resolve criminal and civil charges under the FCA for the illegal promotion of the epilepsy drug Zonegran. Elan promoted Zonegran for “a wide variety of improper off-label uses including mood stabilization for mania and bipolar disorder, migraine headaches, chronic daily headaches, eating disorders, obesity/weight loss and seizures in children under the age of 16. Elan’s off-label marketing efforts targeted non-epilepsy prescribers and the company paid illegal kickbacks to physicians in an effort to persuade them to prescribe Zonegran for these off-label uses.”<sup>26</sup>
  
- ▶ In October 2011, Pfizer agreed to pay \$14.5 million to resolve FCA allegations that it had marketed its drug Detrol for uses not approved by FDA.<sup>27</sup>
  
- ▶ In April 2012, a district court imposed a \$321 million criminal fine on Merck for promoting an off-label use of its drug Vioxx, even after FDA had warned the company not to do so. This followed a civil settlement five months earlier, in which Merck agreed to pay more than \$628 million to resolve allegations of making “inaccurate, unsupported, or

---

<sup>26</sup> DOJ Press Release, Pharmaceutical Companies to Pay \$214.5 Million to Resolve Allegations of Off-Label Promotion of Zonegran (Dec. 15, 2010), <http://www.justice.gov/opa/pr/2010/December/10-civ-1444.html>.

<sup>27</sup> DOJ Press Release, Pfizer to Pay \$14.5 Million for Illegal Marketing of Drug Detrol (Oct. 21, 2011), <http://www.justice.gov/opa/pr/2011/October/11-civ-1389.html>.

misleading statements” regarding the safety of the drug, as well as allegations of off-label promotion.<sup>28</sup>

- ▶ In May, 2012, Abbot Laboratories agreed to pay \$1.5 billion for its criminal and civil liability with respect to the off-label promotion of its drug Depakote, significantly to elderly patients. “In an agreed statement of facts filed in the criminal action, Abbott admit[ted] that from 1998 through 2006, the company maintained a specialized sales force trained to market Depakote in nursing homes for the control of agitation and aggression in elderly dementia patients, despite the absence of credible scientific evidence that Depakote was safe and effective for that use.” Abbott also waited almost two years to notify its sales representatives who were promoting Depakote off-label to treat schizophrenia that the studies it had funded showed no benefit for that condition.<sup>29</sup>
  
- ▶ In the largest health care fraud settlement in U.S. history to date, GlaxoSmithKline pled guilty in July 2012, and agreed to pay \$1 billion in criminal fines, plus another \$2 billion for its civil liabilities related

---

<sup>28</sup> DOJ Press Release, U.S. Pharmaceutical Company Merck Sharp & Dohme Sentenced in Connection with Unlawful Promotion of Vioxx (Apr. 19, 2012), <http://www.justice.gov/opa/pr/2012/April/12-civ-497.html>.

<sup>29</sup> DOJ Press Release, *Abbott Labs to Pay \$1.5 Billion to Resolve Criminal & Civil Investigations of Off-label Promotion of Depakote* (May 7, 2012), <http://www.justice.gov/opa/pr/2012/May/12-civ-585.html>.

to several of its drugs. GSK promoted off-label uses of its drugs, including by marketing unapproved uses for children, and paid kickbacks to health care professionals to induce them to prescribe its drugs. It also failed to report relevant safety data to FDA.<sup>30</sup>

Both the financial and public health consequences of this conduct are extremely detrimental. As an Assistant Attorney General commented with respect to Novo Nordisk's agreement to pay \$25 million for illegal promotion of its hemostasis management drug, NovoSeven, in June 2011, "[t]he off-label promotion alleged here not only wasted taxpayer dollars, but also undermined the FDA's important role in ensuring that drugs are properly marketed to government agencies and members of the public."<sup>31</sup> Sadly, this has become a common practice.

2. The influence of pharmaceutical companies on the practice of medicine is staggering. According to a 2004 study of the 15 largest drug companies in the United States, the industry spent just under a third of its total budget for marketing on payments to

---

<sup>30</sup> DOJ Press Release, GlaxoSmithKline to Plead Guilty and Pay \$3 Billion to Resolve Fraud Allegations and Failure to Report Safety Data (July 2, 2012), <http://www.justice.gov/opa/pr/2012/July/12-civ-842.html>.

<sup>31</sup> DOJ Press Release, Danish Pharmaceutical Novo Nordisk to Pay \$25 Million to Resolve Allegations of Off-Label Promotion of Novoseven (June 10, 2011), <http://www.justice.gov/opa/pr/2011/June/11-civ-764.html>.

physicians.<sup>32</sup> These payments have produced results. According to a national survey published in *The New England Journal of Medicine* in 2007, 94% of physicians had some sort of financial relationship with a pharmaceutical company.<sup>33</sup>

The drug industry has long understood the benefits of its financial relationships with physicians. In a landmark 1992 study, researchers at the Cleveland Clinic in Ohio tracked the prescribing habits of physicians who attended drug companies' "all-expenses-paid trips to popular . . . vacation sites to attend symposia."<sup>34</sup> The researchers looked at each physician's prescribing habits for two intravenous drugs (an antibiotic and a heart medication) for the 22 months prior to the trip and the 17 months afterward. Prescriptions written for the antibiotic initially increased tenfold after the trip, then leveled off to a rate that was more than three times higher than previous levels. Prescriptions for the heart medication increased to four and a half times their pre-trip levels. Research also shows that physicians who receive

---

<sup>32</sup> Carl Elliott, *White Coat, Black Hat: Adventures on the Dark Side of Medicine* 78 n.3 (Beacon Press 2010).

<sup>33</sup> Eric G. Campbell et al., *A National Survey of Physician-Industry Relationships*, 356 N. Eng. J. Med. 1742, 1746 & 1746 tbl.2 (Apr. 2007).

<sup>34</sup> James P. Orlowski & Leon Wateska, *The Effects of Pharmaceutical Firm Enticements on Physician Prescribing Patterns: There's No Such Thing as a Free Lunch*, 102 Chest 270, 270 (1992).

payments and perks from a pharmaceutical company are more likely to ask that hospitals, practice groups, and insurers use that company's drugs.<sup>35</sup>

This influence leads to tangible financial benefits. In a Texas case against Janssen Pharmaceuticals for its fraudulent marketing of the drug Risperdal, the evidence showed that the state's medical algorithm favored Risperdal as a first-line drug. Tellingly, physicians involved in developing the algorithm testified that they had received thousands of dollars in payments from Janssen, including funding of trips to other states to promote the Texas system.<sup>36</sup> When Texas subsequently sued Janssen for Medicaid fraud based, *inter alia*, on its "improperly influencing officials and doctors to push the drug," Janssen settled for \$158 million, an amount which, in the words of one commentator, "will barely blink their corporate eyeballs as they make out the check."<sup>37</sup> Janssen and its parent, Johnson & Johnson, subsequently paid fines or settlements of \$1.2 billion in Arkansas, \$327 million in South Carolina and \$258 million in Louisiana for its

---

<sup>35</sup> Ashley Wazana, *Physicians and the Pharmaceutical Industry: Is a Gift Ever Just a Gift?*, 283 JAMA 373, 376 (2000).

<sup>36</sup> See *State ex rel. Jones v. Janssen LP*, No. D-1-GV-04-001288, Tr. of Alexander Miller & Steven Shon (Tex. Dist. Travis Co. Jan. 11, 2012).

<sup>37</sup> John M. Grohol, *Johnson & Johnson Settles 3rd Risperdal Lawsuit for \$158M*, PsychCentral (Jan. 25, 2012), <http://psychcentral.com/blog/archives/2012/01/25/johnson-johnson-settles-3rd-risperdal-lawsuit-for-158m/>.

fraudulent marketing of Risperdal.<sup>38</sup> It expect to settle similar claims with the Justice Department for \$2.2 billion.<sup>39</sup>

Other cases also illustrate the industry's improper influence on the practice of medicine.

- ▶ In July 2004, Schering-Plough agreed to pay \$345 million to resolve criminal and civil liabilities for its illegal marketing of Claritin. Claritin was much more expensive than Allegra, another allergy medication, but Schering paid an HMO a \$1.8 million kickback to keep Claritin on its formulary. The U.S. Attorney who negotiated the guilty plea observed that “[t]his wasn’t a mistake. It was a marketing strategy. The result was that programs created to provide healthcare to the poorest among us were actually paying more for drugs than those who have private health insurance.”<sup>40</sup>

---

<sup>38</sup> Katie Thomas, *J&J Fined \$1.2 Billion in Drug Case*, N.Y. Times (Apr. 11, 2012), <http://www.nytimes.com/2012/04/12/business/drug-giant-is-fined-1-2-billion-in-arkansas.html>.

<sup>39</sup> Alexander Gaffney, *Reports: Johnson & Johnson to Pay \$2.2 Billion to Settle Risperdal Marketing Probe*, Regulatory Affairs Prof'ls Soc'y (June 11, 2012), <http://www.raps.org/focus-online/news/news-article-view/article/1702/reports-johnson-johnson-to-pay-22-billion-to-settle-risperdal-marketing-probe.aspx>.

<sup>40</sup> DOJ Press Release, *Schering-Plough to Pay \$345 Million to Resolve Criminal and Civil Liabilities for Illegal Marketing of Claritin* (July 30, 2004), [http://www.justice.gov/opa/pr/2004/July/04\\_civ\\_523.htm](http://www.justice.gov/opa/pr/2004/July/04_civ_523.htm).



- ▶ In October 2005, Serono agreed to pay \$704 million to address its criminal and civil liability for promoting its drug Serotism.” As part of the agreement, “Serono Labs agreed to plead guilty to offering physicians an all expense-paid trip to a medical conference in Cannes, France in return for the doctors writing up to 30 new prescriptions of Serotism, which cost \$21,000 per course of treatment, for a total value of \$630,000 per doctor.”<sup>41</sup>
  
- ▶ Medco Health Solutions, the nation’s second largest pharmacy benefit management company, agreed in October 2006 to pay \$155 million to settle allegations that the company “submitted false claims to the government, solicited and accepted kickbacks from pharmaceutical manufacturers to favor their drugs, and paid kickbacks to health plans to obtain business.”<sup>42</sup>
  
- ▶ Merck agreed to pay more than \$650 million in February 2008 to settle allegations that it defrauded Medicaid and other government health care programs. Allegations of kickbacks figured prominently in the prosecution: “Merck had approximately fifteen different programs used by its sales representatives to induce physicians to use its

---

<sup>41</sup> DOJ Press Release, Serono to Pay \$704 Million for the Illegal Marketing of AIDS Drug (Oct. 17, 2005), [http://www.justice.gov/opa/pr/2005/October/05\\_civ\\_545.html](http://www.justice.gov/opa/pr/2005/October/05_civ_545.html).

<sup>42</sup> DOJ Press Release, Medco to Pay U.S. \$155 Million to Settle False Claims Act Cases (Oct. 23, 2006), [http://www.justice.gov/opa/pr/2006/October/06\\_civ\\_722.html](http://www.justice.gov/opa/pr/2006/October/06_civ_722.html).

many products. These programs primarily consisted of excess payments to physicians that were disguised as fees paid to them for training, 'consultation' or 'market research.'"<sup>43</sup>

- ▶ In March 2010, Alpharma Inc. "agreed to pay \$42.5 million to resolve FCA allegations in connection with the marketing of the morphine-based drug, Kadian." Alpharma allegedly paid health care providers to induce them to prescribe Kadian and made misrepresentations about the safety and efficacy of the drug.<sup>44</sup>
  
- ▶ Forest Laboratories pled guilty in September 2010 to a criminal felony count of obstructing justice and criminal misdemeanor charges of off-label promotion and distributing misbranded drugs. Although FDA had approved certain drugs for use only in adult patients, Forest promoted them for use by children, using "illegal kickbacks." The total payment was more than \$313 million.<sup>45</sup>

---

<sup>43</sup> DOJ Press Release, Merck to Pay More than \$650 Million to Resolve Claims of Fraudulent Price Reporting and Kickbacks (Feb. 7, 2008), [http://www.justice.gov/opa/pr/2008/February/08\\_civ\\_094.html](http://www.justice.gov/opa/pr/2008/February/08_civ_094.html).

<sup>44</sup> DOJ Press Release, Alpharma to Pay \$42.5 Million to Resolve False Claims Act Allegations in Connection with Promotion of Drug Kadian (Mar. 16, 2010), <http://www.justice.gov/opa/pr/2010/March/10-civ-269.html>.

<sup>45</sup> DOJ Press Release, Drug Maker Forest Pleads Guilty; to Pay More Than \$313 Million to Resolve Criminal Charges and False

- ▶ In May 2011, Serono Laboratories “agreed to pay \$44.3 million to resolve FCA allegations in connection with the marketing of the drug Rebif. The settlement resolves allegations that, [for eight years], Serono paid health care providers to induce them to promote or prescribe Rebif.” A U.S. Attorney involved in the prosecution emphasized that “[h]ealth care decisions must be based solely upon what is best for the individual patient and not on which pharmaceutical company is paying the doctor the biggest kickback.”<sup>46</sup>

3. The manner in which government programs such as Medicare and Medicaid reimburse health care practitioners for drugs they dispense also provides a recipe for more and more drugs, at higher and higher prices. Government healthcare programs set their reimbursement rates by the prices that drug companies report. But if a drug company actually sells the drug to a health care provider for less than the price it reported, the reimbursement for the drug itself becomes a profit center for the provider. “The difference between the resulting inflated government payments and the actual price paid by healthcare

---

Claims Act Allegations (Sept. 15, 2010), <http://www.justice.gov/opa/pr/2010/September/10-civ-1028.html>.

<sup>46</sup> DOJ Press Release, Serono to Pay \$44.3 Million to Resolve False Claims Act Allegations in Connection with Promotion of Drug Rebif (May 4, 2011), [http://www.justice.gov/usao/md/PublicAffairs/press\\_releases/press08/SeronotoPay44.3MilliontoResolveFalseClaimsActAllegations.html](http://www.justice.gov/usao/md/PublicAffairs/press_releases/press08/SeronotoPay44.3MilliontoResolveFalseClaimsActAllegations.html).

providers for a drug is referred to as the ‘spread.’ The larger the spread on a drug, the larger the profit for the health care provider or pharmacist who gets reimbursed by the government.”<sup>47</sup> The incentive is clear: the more prescriptions a physician writes, the more money he will make.

In December 2010, three drug companies agreed to pay a total of \$421 million to settle FCA allegations that they had manipulated the spread with respect to numerous drugs. As the U.S. Attorney observed, “[s]ome pharmaceutical manufacturers have asserted that a culture within the industry gave them license to manipulate the system to suit their interests. This is not the case.”<sup>48</sup> Again, this was not an isolated event.

- ▶ In 2001, a federal grand jury indicted TAP Pharmaceutical Products, six of its managers and a physician, charging a conspiracy to pay kickbacks to physicians, as well as other Medicaid pricing crimes. In October of that year, TAP agreed to pay \$875 million to address its criminal and civil liability. The U.S. Attorney prosecuting the case explained that “[i]n all instances where the kickbacks worked to ensure the prescription of TAP's product Lupron, the Medicare Program and the elderly Americans suffering from prostate cancer paid more for their

---

<sup>47</sup> DOJ Press Release, Pharmaceutical Manufacturers to Pay \$421.2 Million to Settle False Claims Act Cases (Dec. 7, 2010), <http://www.justice.gov/opa/pr/2010/December/10-civ-1398.html>.

<sup>48</sup> *Id.*

care than if the doctor had prescribed the competitor's product."<sup>49</sup>

- ▶ In October 2002, Pfizer and its subsidiaries, Warner-Lambert and Parke-Davis, agreed to pay \$49 million to settle allegations of violations of the FCA. Allegations include that “the defendants fraudulently avoided paying fully the rebates owed to the state and federal governments under the national drug Medicaid Rebate program for the cholesterol-lowering drug Lipitor.”<sup>50</sup>
- ▶ In June 2003, AstraZeneca pled guilty to various health care pricing crimes and agreed to pay a total of \$355 million to resolve its criminal and civil liabilities. In addition to manipulating the spread by setting prices of its drug Zoladex in excess of the actual prices it charged to providers, AstraZeneca induced over-prescription of Zoladex by liberally providing free samples (which it knew the providers could then bill to Medicare and Medicaid) and by promising “unrestricted educational grants, business assistance grants and services, travel and

---

<sup>49</sup> DOJ Press Release, TAP Pharmaceutical Products Inc. and Seven Others Charged with Health Care Crimes; Company Agrees to Pay \$875 Million to Settle Charges (Oct. 3, 2001), <http://www.justice.gov/opa/pr/2001/October/513civ.htm>.

<sup>50</sup> DOJ Press Release, Drug Giant Pfizer & Two Subsidiaries to Pay \$49 Million for Defrauding Drug Medicaid Rebate Program (Oct. 28, 2002), [http://www.justice.gov/opa/pr/2002/October/02\\_civ\\_622.htm](http://www.justice.gov/opa/pr/2002/October/02_civ_622.htm).

entertainment, consulting services, and honoraria.”<sup>51</sup>

- ▶ In September 2005, GlaxoSmithKline paid more than \$150 million to settle FCA allegations that it had manipulated the spread of its drugs Zofran and Kytril. With respect to Kytril, the government alleged that “the drug company engaged in a ‘double dipping’ billing scheme by encouraging customers to pool leftover vials of Kytril to create an extra dose, which then would be administered to a patient and re-billed to Medicare and other federal healthcare programs.”<sup>52</sup>
- ▶ In November 2005, King Pharmaceuticals agreed to pay more than \$124 million plus interest to resolve charges that it misrepresented the prices of its drugs to Medicaid during an eight-year period.<sup>53</sup>
- ▶ In September 2007, Aventis Pharmaceuticals paid more than \$190 million to resolve allegations that it had manipulated the spread to inflate governmental

---

<sup>51</sup> DOJ Press Release, AstraZeneca Pharmaceuticals LP Pleads Guilty to Healthcare Crime; Company Agrees to Pay \$355 Million to Settle Charges (June 20, 2003), [http://www.justice.gov/opa/pr/2003/June/03\\_civ\\_371.htm](http://www.justice.gov/opa/pr/2003/June/03_civ_371.htm).

<sup>52</sup> DOJ Press Release, GlaxoSmithKline Pays \$150 Million to Settle Drug Pricing Fraud Case (Sept. 20, 2005), [http://www.justice.gov/opa/pr/2005/September/05\\_civ\\_489.html](http://www.justice.gov/opa/pr/2005/September/05_civ_489.html).

<sup>53</sup> DOJ Press Release, King Pharmaceuticals to Pay U.S. \$124 Million for Medicaid Rebate Underpayments & Overcharging for Drug Products (Nov. 1, 2005), [http://www.justice.gov/opa/pr/2005/November/05\\_civ\\_581.html](http://www.justice.gov/opa/pr/2005/November/05_civ_581.html).

reimbursements in order to induct physicians to prescribe more of its drug, Anzemet.<sup>54</sup>

- ▶ Aventis Pharmaceutical Inc. agreed to pay \$95.5 million in May 2009 to settle allegations that it had misreported the prices of its drugs to avoid paying Medicaid based on the actual prices it charged for its drugs. “In order to avoid triggering a new best price that would obligate it to pay millions of dollars in additional drug rebates to Medicaid, Aventis entered into ‘private label’ agreements with the HMO Kaiser Permanente that simply repackaged Aventis’s drugs under a new label.”<sup>55</sup>
  
- ▶ In October 2009, four pharmaceutical companies – Mylan Pharmaceuticals, UDL Laboratories, AstraZeneca and Ortho McNeil – agreed to pay a total of \$124 million to settle claims that they had intentionally classified drugs as other drugs to significantly decrease their rebate payments to Medicaid.<sup>56</sup>

---

<sup>54</sup> DOJ Press Release, *Aventis Pays More than \$190 Million to Settle Drug Pricing Fraud Matters* (Sept. 10, 2007), [http://www.justice.gov/opa/pr/2007/September/07\\_civ\\_694.html](http://www.justice.gov/opa/pr/2007/September/07_civ_694.html).

<sup>55</sup> DOJ Press Release, *Aventis Pharmaceutical to Pay U.S. \$95.5 Million to Settle False Claims Act Allegations* (May 28, 2009), <http://www.justice.gov/opa/pr/2009/May/09-civ-520.html>.

<sup>56</sup> DOJ Press Release, *Four Pharmaceutical Companies Pay \$124 Million for Submission of False Claims to Medicaid* (Oct. 19, 2009), <http://www.justice.gov/opa/pr/2009/October/09-civ-1120.html>.

- ▶ Dey Inc. agreed in December 2010 to pay \$280 million to settle FCA allegations that it had “created artificially inflated spreads to market, promote and sell the drugs to existing and potential customers.” The Assistant Attorney General emphasized that “[t]axpayer-funded kickback schemes like this not only cost federal health care programs millions of dollars, they threaten to undermine the integrity of the choices health care providers make for their patients.”<sup>57</sup>

The Health and Human Services Inspector General underscored the practical effect of the continuing violations in connection with GSK’s 2005 settlement: “Any pharmaceutical company that intentionally inflates the cost of prescription drugs with elaborate pricing schemes robs states and beneficiaries nationwide of millions of Medicare and Medicaid dollars. We will not tolerate any company abusing programs intended to benefit our most vulnerable citizens.”<sup>58</sup> Despite the government’s best efforts, however, health care fraud has become entrenched in the industry.

## **II AMGEN’S ACTIONS WITH RESPECT TO ARANESP AND EPOGEN MIRROR THE SAME**

---

<sup>57</sup> DOJ Press Release, Pharmaceutical Manufacturer to Pay \$280 Million to Settle False Claims Act Case (Dec. 20, 2010), <http://www.justice.gov/opa/pr/2010/December/10-civ-1464.html>.

<sup>58</sup> See DOJ Press Release, *supra* note 52.



## INDUSTRY-WIDE PROBLEMS IDENTIFIED ABOVE.

Amgen's actions with respect to the drugs at issue in this case reveal the same cancer that has spread throughout the industry.

1. Epogen and Aranesp are in a drug class known as erythropoiesis-stimulating agents ("ESAs"). ESAs stimulate the production of red blood cells, thereby increasing a patient's red blood cell count ("hematocrit"), and FDA initially approved both Epogen (1989) and Aranesp (2001) for treatment of anemia associated with chronic renal failure.<sup>59</sup> In healthy individuals, red blood cells comprise 40 percent or more of their blood. In individuals with severe anemia, however, hematocrit can dip below 25 percent, causing significant health complications.<sup>60</sup> Although blood transfusions address severe anemia, they can boost the hematocrit in severely anemic patients only

---

<sup>59</sup> FDA Briefing Document, *Continuing Reassessment of the Risks of Erythropoiesis-Stimulating Agents (ESAs) Administered for the Treatment of Anemia associated with Cancer Chemotherapy for May 10, 2007 Meeting of Oncologic Drugs Advisory Committee*, FDA, at 10 ("2007 Briefing Document"), available at <http://www.fda.gov/ohrms/dockets/ac/07/briefing/2007-4301b2-02-FDA.pdf>.

<sup>60</sup> See Daniel W. Coyne, *Opinion: Misleading Drug Trials Amgen's Incomplete Report on an Early Major Trial of Epoetin Misled the Medical Community About the Anemia Drug's Risks and Benefits—and Helped Make Amgen Rich*, *The Scientist* (May 14, 2012) ("Coyne, Scientist"), <http://the-scientist.com/2012/05/14/opinion-misleading-drug-trials/>.

to 30 percent or so, far short of “normal.” Thus, the development of ESAs, offering the prospect of increasing hematocrit without the significant risks posed by blood transfusions, sparked great optimism. It also sparked a great marketing opportunity.

When FDA first approved Epogen, it approved a hematocrit target range of 30%-33%, close to the level that could be reached in a transfusion.<sup>61</sup> In 1995, at Amgen’s suggestion, FDA raised the upper end of the target to 36%.<sup>62</sup> This change had “huge financial implications” for Amgen, as achieving this three percent increase required “about 40 percent more of the drug, a jump that would push the amount consumed from \$7,000 to \$10,000 annually.”<sup>63</sup> The upper end of the FDA-approved target range would remain at 36% until 2011, when FDA directed that

---

<sup>61</sup> Food & Drug Admin., Drugs@FDA: FDA Approved Drug Products at cols. 1, 6 (PROCRIT/EPOGEN – Label Information (Apr. 1, 1993)) (“1993 Label”), *available at* [http://www.accessdata.fda.gov/drugsatfda\\_docs/label/pre96/103234s1015\\_LBL.pdf](http://www.accessdata.fda.gov/drugsatfda_docs/label/pre96/103234s1015_LBL.pdf).

<sup>62</sup> Food & Drug Admin., Drugs@FDA: FDA Approved Drug Products at 2 (EPOGEN – Label Information (July 26, 1999)) (“1999 Label”), *available at* [http://www.accessdata.fda.gov/drugsatfda\\_docs/label/2000/epoamg072699lb.pdf](http://www.accessdata.fda.gov/drugsatfda_docs/label/2000/epoamg072699lb.pdf).

<sup>63</sup> Peter Whoriskey, *Anemia Drugs Made Billions, But at What Cost?*, Wash. Post, July 19, 2012 (“Whoriskey”), *available at* [http://www.washingtonpost.com/business/economy/anemia-drug-made-billions-but-at-what-cost/2012/07/19/gJQAX5yqwW\\_story.html](http://www.washingtonpost.com/business/economy/anemia-drug-made-billions-but-at-what-cost/2012/07/19/gJQAX5yqwW_story.html).

“[u]sing ESAs to target a hemoglobin level of greater than [33%]<sup>64</sup> increases the risk of serious adverse cardiovascular reactions and has not been shown to provide additional benefits.”<sup>65</sup>

Even the 16-year reign of a dangerously inflated hematocrit target did not satisfy Amgen. Every incremental increase in the hematocrit target meant a corresponding increase in profits, and there was still a gap between the approved upper end of 36% and a “normal” hematocrit, several points higher. Amgen sought to close this gap by promoting the ability of ESAs to improve general “quality of life.” While earlier labels mentioned “quality of life,”<sup>66</sup> Amgen greatly expanded this alleged benefit in subsequent labels, touting the results of its clinical trials in glowing terms: “Once the target hematocrit (32% to 38%) was

---

<sup>64</sup> The actual text defines the target as “11 g/dL.” “Hematocrit [is] calculated by multiplying the measured hemoglobin (Hgb) level by three.” See Daniel W. Coyne, *The Health-Related Quality of Life was Not Improved by Targeting Higher Hemoglobin in the Normal Hematocrit Trial*, 82 *Kidney Int'l* 235, 235 (2012) (“Coyne”), <http://www.nature.com/ki/journal/v82/n2/full/ki201276a.html>].

<sup>65</sup> Food & Drug Admin., Drugs@FDA: FDA Approved Drug Products at 1 (EPOGEN – Highlights of Prescribing Information (June 24, 2011)) (“2011 Label”), available at [http://www.accessdata.fda.gov/drugsatfda\\_docs/label/2011/103234Orig1s5166\\_103234Orig1s5266lbl.pdf](http://www.accessdata.fda.gov/drugsatfda_docs/label/2011/103234Orig1s5166_103234Orig1s5266lbl.pdf).

<sup>66</sup> *E.g.*, 1993 Label, col. 7 (“As the hematocrit increases and patients experience an improved sense of well-being and quality of life, . . .”).

achieved, statistically significant improvements were demonstrated for most quality of life parameters measured, including energy and activity level, functional ability, sleep and eating behavior, health status, satisfaction with health, sex life, well-being, psychological effect, life satisfaction, and happiness.”<sup>67</sup> The idea that “higher doses could make patients feel better” became “[t]he key to their marketing claim,” forming the “basis of television and print advertising campaigns, pitched to people with potentially fatal illnesses”<sup>68</sup>

Amgen also marketed the idea to physicians and hospitals that hematocrit levels closer to “normal” equated to a better quality of life.<sup>69</sup> “They’d bring lunch in, or they’d have presentations at conferences, and they’d always have the same message: A little was good, more is better,” said Steven Bander, formerly chief medical officer with Gambro, one of the nation’s largest dialysis chains. “They would quote all these studies about quality of life. They never talked about the negative data.”<sup>70</sup> The campaign was wildly successful. In the years following FDA’s initial approvals, Amgen’s ESAs became blockbuster drugs. “Very quickly, the market included nearly all dialysis patients, not just the roughly 16 percent who required

---

<sup>67</sup> 1999 Label at 5.

<sup>68</sup> Whoriskey.

<sup>69</sup> Whoriskey.

<sup>70</sup> Whoriskey.

blood transfusions. The size of average doses would more than triple. And during the next five years, the FDA would approve it to treat anemia in patients with cancer and AIDS, as well as those getting hip and knee surgery.”<sup>71</sup>

To convince physicians to keep increasing dosages, it was important to maintain governmental reimbursement of the higher doses. Lobbying became critical.<sup>72</sup> In response to the Health Care Financing Administration’s (“HCFA”) announced policy to limit Medicare reimbursement to a hematocrit level consistent with the FDA-approved target range, there was a Congressional hearing in March 1998. At that hearing, Congressional members castigated the HCFA Administrator for the new policy, asserting that reimbursement in excess of the upper limit of the FDA-approved target range, and up to 37.5 percent, was

---

<sup>71</sup> Whoriskey.

<sup>72</sup> According to the Center for Responsive Politics, in 1998, the pharmaceutical/health products industry spent almost \$70 million on lobbying, with \$2.36 million coming from Amgen. OpenSecrets.org, Lobbying: Pharmaceuticals/Health Products – Industry Profile, 1998, at <http://www.opensecrets.org/lobby/indusclient.php?id=H04&year=1998> (last visited Sept. 25, 2012). By 2011, its lobbying expenditures exceeded \$240 million— more than any other industry – with Amgen contributing \$10 million of that total. *Id.* at <http://www.opensecrets.org/lobby/indusclient.php?id=H04&year=2011>. *See also* Whoriskey.

necessary.<sup>73</sup> The increase “could have raised by 20 percent the amount of Epogen that doctors could freely prescribe in an average patient, adding a cost of \$2,000 or more.”<sup>74</sup> Faced with such hostility from Congress, the regulators ultimately backed off the proposed limitation on reimbursement and agreed to the higher limits, effectively sanctioning a use of Amgen’s ESAs that FDA had not approved. “On the day the agency raised the maximum level, Amgen shares spiked 6 percent.”<sup>75</sup>

As the Washington Post observed, “[t]he doses kept rising. By 2006, about half of all dialysis patients were getting so much of the drugs that their hematocrits were rising beyond the FDA-recommended ceiling of 36 percent. More than 80 percent were getting more than the level now deemed advisable.”<sup>76</sup> The profits transformed Amgen from a small firm into a Fortune 500 company, with “[a]s much as a third of [those

---

<sup>73</sup> *An Act Making Appropriations for the Departments of Labor, Health and Human Services, and Education, and Related Agencies, for the Fiscal Year Ending September 30, 1999, and for Other Purposes: Hearings on H.R. 4274 / S. 2440 Before a Subcomm. of the Committee on Appropriations, United States Senate, 105th Cong., 2nd Sess. at 69-70 (Mar. 5, 1998), available at <http://www.gpo.gov/fdsys/pkg/CHRG-105shrg46105/html/CHRG-105shrg46105.htm>.*

<sup>74</sup> Whoriskey.

<sup>75</sup> Whoriskey.

<sup>76</sup> Whoriskey.

profits] coming from reimbursements funded by U.S. taxpayers.”<sup>77</sup>

2. In the mid-1990s, Amgen funded the Normal Hematocrit Trial (“NHT”), the largest trial of ESAs ever done, in an attempt to justify using ESAs to boost hematocrit levels to “normal” levels. Approximately half of the 1,265 participants were given doses to raise hematocrit levels to around 30 percent, the level that could be obtained in a blood transfusion. The others were given doses to raise hematocrit levels to 42, percent, close to the level in a normal, healthy person.<sup>78</sup> The hypothesis was that “higher [hematocrit levels] would reduce mortality, and improve survival and quality of life.”<sup>79</sup> In May 1996, however, the study was terminated after 29 months because patients in the “normal level” group were dying and suffering heart attacks more frequently than the other group. “These results were not a complete surprise to [Amgen:] a rationale for the trial was an ‘increased risk of mortality [as] the potential adverse effect[] of full correction of anemia in dialysis patients’.”<sup>80</sup> In its 1996 clinical trial report, Amgen noted that patients in the 42 percent group had experienced “significantly more ‘other thrombotic events’” than patients in the 30

---

<sup>77</sup> Whoriskey.

<sup>78</sup> See Coyne Scientist.

<sup>79</sup> Coyne at 235.

<sup>80</sup> Coyne at 237.

percent group, but that “[t]here were no statistically significant changes in quality-of-life scores between groups or over time.”<sup>81</sup> These results presented “the first major evidence of safety problems with the use of ESAs.”<sup>82</sup>

When the results were presented to the public, however, the interpretation of the data had changed. *The New England Journal of Medicine* published the results of the NHT in 1998.<sup>83</sup> Four of the authors were Amgen employees who undoubtedly had access to Amgen’s clinical trial report,<sup>84</sup> yet the published article did not contain the unadjusted statistical results. Instead, the data were adjusted to present the risk of “other thrombotic events” between the two groups as “insignificantly different.” “Therefore the trial results were reported as showing only a trend toward—and

---

<sup>81</sup> Coyne at 237. *See also* Coyne, Scientist, (“The results I found in the Amgen report, filed with the FDA in 1996, showed that bigger epoetin doses to target higher hematocrit did not improve the physical function quality of life component at all, and had significantly increased the risk of death, heart attack, other thrombotic events, and hospitalizations.”).

<sup>82</sup> Coyne at 239.

<sup>83</sup> Anatole Besarab et al., *The Effects of Normal as Compared with Low Hematocrit Values in Patients with Cardiac Disease Who Are Receiving Hemodialysis and Epoetin*, 339 *New. Eng. J. Med.* 584 (1998).

<sup>84</sup> Coyne at 240. Although two of the other authors were consultants to Amgen, the extent to which the four non-Amgen employee authors had access is unknown. *Id.*



not solid evidence for—increased harm.”<sup>85</sup> With respect to quality of life, the published report provided that “an increase in the hematocrit from 30 percent to 42 percent was associated with a clinically meaningful increase of 7.2 points in the score on the physical-function scale.”<sup>86</sup> Although the published article did discourage targeting hematocrit to “normal” levels, it failed to convey the great risk in increasing the hematocrit level significantly in excess of the “transfusion” level.<sup>87</sup>

The perception that there was no significant risk, combined with “quality of life” message, drove clinical practice. Understatement of the risks posed by ESAs continued for nine years after the 1998 publication, and three years after the May 2004 meeting of FDA’s Oncologic Drugs Advisory Committee (“ODAC”), the lead-up to which defines the beginning of the class period in this case. In the briefing document prepared for the May 2007 meeting of that committee, however, FDA finally recognized what Amgen had known *for 11 years*: “as demonstrated in the ‘Normal Hematocrit’ and CHOIR studies, the incidence of serious thrombotic events are increased with treatment strategies intended to maintain hemoglobin levels above [36 percent],” an increased risk that “ha[d] been consistently observed across multiple patient

---

<sup>85</sup> Coyne, Scientist.

<sup>86</sup> Coyne at 237.

<sup>87</sup> See Coyne, Scientist.

populations.”<sup>88</sup> Significantly, FDA also observed that after years of study, the data were still inconclusive about the safety risks posed by ESAs when used *on-label* to treat cancer patients: “[t]here are insufficient data to characterize the effects of ESAs on survival or on tumor promotion when ESAs are administered in accordance with recommended dosing in product labeling.”<sup>89</sup>

Later in 2007, FDA instructed that ESA labels contain a boxed warning providing, *inter alia*, that “[p]atients experienced greater risks for death and serious cardiovascular events when administered [ESAs] to target higher versus lower hemoglobin levels . . . in two clinical studies.”<sup>90</sup> A boxed warning is the strongest warning FDA regulations allow, short of contraindicating the use altogether. *See* 21 C.F.R. § 201.80(e). With respect to cancer patients, the boxed warning cautions that ESAs “shortened overall survival and/or increased the risk of tumor progression

---

<sup>88</sup> 2007 Briefing Document at 9.

<sup>89</sup> *Id.* at 52. In the May 2004 ODAC meeting, Amgen had identified additional studies that might “further investigate the risk of ESAs.” *Id.* at 19. At the May 2007 meeting three years later, FDA had received primary data from only three of the 16 studies identified. These three had “design limitations” that limited additional clarification of risks. *Id.* at 21.

<sup>90</sup> Food & Drug Admin., Drugs@FDA: FDA Approved Drug Products at 1 (EPOGEN/PROCRIIT – Label Information (Dec. 17, 2007)) (“2007 Label”), *available at* [http://www.accessdata.fda.gov/drugsatfda\\_docs/label/2007/103234s5163lbl.pdf](http://www.accessdata.fda.gov/drugsatfda_docs/label/2007/103234s5163lbl.pdf)

or recurrence . . . .”<sup>91</sup> The December 2007 label also eliminated the “quality of life” claims, emphasizing that Epogen “has not been demonstrated in controlled clinical trials to improve symptoms of anemia, quality of life, fatigue, or patient well-being.”<sup>92</sup>

In 2011, FDA finally eliminated the 36 percent hematocrit target, acknowledging that “[n]o trial has identified a hemoglobin level, ESA dose, or dosing strategy that does not increase the[] risks” of death and “serious adverse cardiovascular reactions.”<sup>93</sup> The current boxed warning instructs physicians to “[u]se the lowest Epogen dose sufficient to reduce the need for red blood cell (RBC) transfusions.”<sup>94</sup> The current label also reports the NHT’s “hazard ratio and confidence intervals for death and heart attack and all-cause death as significantly higher in the higher hematocrit arm,”<sup>95</sup> finally acknowledging the risks set forth in Amgen’s 1996 clinical trial report, but hidden in the 1998 publication of its results.<sup>96</sup>

---

<sup>91</sup> 2007 Label at 1.

<sup>92</sup> *Id.* at 4, 8.

<sup>93</sup> 2011 Label at 1.

<sup>94</sup> *Id.*

<sup>95</sup> Coyne, Scientist.

<sup>96</sup> *See* Coyne at 236.

The eventual disclosure does not rectify the intervening years. As Dr. Daniel Coyne, a professor at Washington University School of Medicine and a former paid speaker for Amgen who became a critic after the dangers posed by ESAs surfaced, summarized:

[T]he effect was to force experts to say targeting hematocrit to about 42 percent using higher epoetin doses improved quality of life and reduced transfusions, and prevented them from saying such management significantly increased deaths, cardiac events, thrombotic events, and hospitalizations. Amgen controlled the debate, and by 2012 had made \$37 billion from epoetin sales in the United States alone.<sup>97</sup>

**3.** While Amgen worked the congressional, regulatory and scientific fronts, it also took direct measures with prescribing physicians. In contrast to prescription pills that may be taken at home, ESAs must be injected in a clinical setting. As explained in section I.3, this situation allowed Amgen to exploit the “spread” between the amount paid by the provider and the amount reimbursed by insurers. The spread between the amount that health care providers charge and the amount reimbursed to them by the governmental insurers “led the Office of the Inspector General to issue at least seven reports recommending either that the reimbursement price be reduced or the incentives changed. The Government Accountability

---

<sup>97</sup> Coyne, Scientist.

Office and the Medicare Payment Advisory Commission made similar recommendations.”<sup>98</sup> The measures did not pass, and Amgen’s profits remained robust. With respect to Amgen’s ESAs, “[t]he markup that doctors, clinics and hospitals received on the drugs given to Medicare patients reached as high as 30 percent, according to the Medicare Payment Advisory Commission . . . .”<sup>99</sup> Even “[a]s late as 2009, dialysis clinics were getting a markup of 9 to 17 percent on the drugs, according to an inspector general’s audit.”<sup>100</sup>

In addition to the spread, Amgen induced even more ESA prescriptions by supplying physicians and clinics with much more of the drug than necessary to treat patients. Federal regulations allow vials of injectable drugs to contain enough excess to insure that the physician will be able to withdraw a full dose, but caution that “[v]ariations from stated quantity of contents shall not be unreasonably large.” 21 C.F.R. § 201.51(g). With respect to its ESAs, however, Amgen has admitted that the “overfill” of Aranesp was almost double the recommended amount between 2001 and 2008.<sup>101</sup> Combining the spread in prices and the overfill in vials, Amgen was able to make the provision of its ESAs a spectacular profit center for health care

---

<sup>98</sup> Whoriskey.

<sup>99</sup> Whoriskey.

<sup>100</sup> Whoriskey.

<sup>101</sup> *New York v. Amgen, Inc.*, 652 F.3d 103, 107 (1st Cir. 2011), *cert. dismissed*, 132 S.Ct. 993 (2011).

providers. This of course induced even more prescriptions.

According to a former Amgen pharmacist, Amgen actually provided spread sheets to physicians to illustrate how they could profit by billing the overfill amount to Medicaid or Medicare.<sup>102</sup> The pharmacist eventually filed a *qui tam* action under the FCA on behalf of herself, the United States, 17 individual states and the District of Columbia.<sup>103</sup> At their depositions in that litigation, five former Amgen executives refused to answer questions about the spread sheets, invoking their Fifth Amendment rights.<sup>104</sup> In October 2011, Amgen agreed to settle pending litigation involving its sales and marketing practices with respect to Epogen and Aranesp, and to address pending criminal and civil investigations, for \$780 million.<sup>105</sup>

---

<sup>102</sup> See 652 F.3d at 105. See also Jim Edwards, *5 Amgen Execs Plead the Fifth on Alleged Kickbacks Described in Spreadsheet*, CBS Money Watch, Mar. 2, 2011 (“5 Amgen Execs”), [http://www.cbsnews.com/8301-505123\\_162-42847582/5-amgen-exec-p](http://www.cbsnews.com/8301-505123_162-42847582/5-amgen-exec-p).

<sup>103</sup> 652 F.3d at 106.

<sup>104</sup> *5 Amgen Execs*, *supra*.

<sup>105</sup> News Release Detail, Amgen, *Amgen's Third Quarter 2011 Revenue and Adjusted Earnings Per Share (EPS) Each Increased 3 Percent to \$3.9 Billion and \$1.40*, Oct. 24, 2011, [http://www.amgen.com/media/media\\_pr\\_detail.jsp?releaseID=1620695](http://www.amgen.com/media/media_pr_detail.jsp?releaseID=1620695). See also Pollack, *supra*.

As discussed in part I, conduct resulting in payments of this sort has spread throughout the pharmaceutical industry. Despite the size of the payment, moreover, it made no discernible dent in the profits that Amgen realized with respect to Epogen and Aranesp. As the Washington Post summarized:

The trouble, as a growing body of research has shown, is that for about two decades, the benefits of the drug — including “life satisfaction and happiness” according to the FDA-approved label — were wildly overstated, and potentially lethal side effects, such as cancer and strokes, were overlooked.

Last year, Medicare researchers issued an 84-page study declaring that among most kidney patients, the original and largest market for the drugs, there was no solid evidence that they made people feel better, improved their survival or had any “clinical benefit” besides elevating a statistic for red blood cell count.

It was a remarkable finding of futility: While drugmakers had seen billions in profits for more than 22 years, and much of it from taxpayers, millions of patients had been subjected to dangerous doses that might have had little advantage.<sup>106</sup>

---

<sup>106</sup> Whoriskey. See also Kathleen Sharp, *Blood Feud: The Man Who Blew the Whistle on One of the Deadliest Prescription Drugs Ever* (Penguin Books 2011).

**CONCLUSION**

The judgment of the court of appeals should be affirmed.

Respectfully submitted,

Arthur H. Bryant  
PUBLIC JUSTICE, P.C.  
555 12<sup>th</sup> St., Suite 1230  
Oakland, CA 94607  
(510) 622-8150

Earl Landers Vickery  
3007 Dancy  
AUSTIN, TX 78722  
(512) 435-6666  
*Counsel of Record*

William H. Narwold  
MOTLEY RICE LLC  
One Corporate Center  
20 Church St., 17<sup>th</sup> Floor  
Hartford, CT 06103  
(860) 882-1681

Ann K. Ritter  
MOTLEY RICE LLC  
28 Bridgeside Boulevard  
Mt. Pleasant, SC 29464  
(843) 216-9000

September 27, 2012