**GlaxoSmithKline to Plead Guilty and Pay $3 Billion to Resolve Fraud Allegations and Failure to Report Safety Data**

*Largest Health Care Fraud Settlement in U.S. History*

Global health care giant GlaxoSmithKline LLC (GSK) agreed to plead guilty and to pay $3 billion to resolve its criminal and civil liability arising from the company’s unlawful promotion of certain prescription drugs, its failure to report certain safety data, and its civil liability for alleged false price reporting practices, the Justice Department announced today.  The resolution is the largest health care fraud settlement in U.S. history and the largest payment ever by a drug company.

GSK agreed to plead guilty to a three-count criminal information, including two counts of introducing misbranded drugs, Paxil and Wellbutrin, into interstate commerce and one count of failing to report safety data about the drug Avandia to the Food and Drug Administration (FDA).  Under the terms of the plea agreement, GSK will pay a total of $1 billion, including a criminal fine of $956,814,400 and forfeiture in the amount of $43,185,600.  The criminal plea agreement also includes certain non-monetary compliance commitments and certifications by GSK’s U.S. president and board of directors.  GSK’s guilty plea and sentence is not final until accepted by the U.S. District Court.

GSK will also pay $2 billion to resolve its civil liabilities with the federal government under the False Claims Act, as well as the states.  The civil settlement resolves claims relating to Paxil, Wellbutrin and Avandia, as well as additional drugs, and also resolves pricing fraud allegations.

“Today’s multi-billion dollar settlement is unprecedented in both size and scope. It underscores the Administration’s firm commitment to protecting the American people and holding accountable those who commit health care fraud,” said James M. Cole, Deputy Attorney General.  “At every level, we are determined to stop practices that jeopardize patients’ health, harm taxpayers, and violate the public trust – and this historic action is a clear warning to any company that chooses to break the law.”

“Today’s historic settlement is a major milestone in our efforts to stamp out health care fraud,” said Bill Corr, Deputy Secretary of the Department of Health and Human Services (HHS). “For a long time, our health care system had been a target for cheaters who thought they could make an easy profit at the expense of public safety, taxpayers, and the millions of Americans who depend on programs like Medicare and Medicaid. But thanks to strong enforcement actions like those we have announced today, that equation is rapidly changing.”

This resolution marks the culmination of an extensive investigation by special agents from HHS-OIG, FDA and FBI, along with law enforcement partners across the federal government. Moving forward, GSK will be subject to stringent requirements under its corporate integrity agreement with HHS-OIG; this agreement is designed to increase accountability and transparency and prevent future fraud and abuse. Effective law enforcement partnerships and fraud prevention are hallmarks of the Health Care Fraud Prevention and Enforcement Action Team (HEAT) initiative, which fosters government collaboration to fight fraud.

**Criminal Plea Agreement**

Under the provisions of the Food, Drug and Cosmetic Act, a company in its application to the FDA must specify each intended use of a drug.  After the FDA approves the product as safe and effective for a specified use, a company’s promotional activities must be limited to the intended uses that FDA approved.  In fact, promotion by the manufacturer for other uses – known as “off-label uses” – renders the product “misbranded.”

**Paxil:** In the criminal information, the government alleges that, from April 1998 to August 2003, GSK unlawfully promoted Paxil for treating depression in patients under age 18, even though the FDA has never approved it for pediatric use.  The United States alleges that, among other things, GSK participated in preparing, publishing and distributing a misleading medical journal article that misreported that a clinical trial of Paxil demonstrated efficacy in the treatment of depression in patients under age 18, when the study failed to demonstrate efficacy.  At the same time, the United States alleges, GSK did not make available data from two other studies in which Paxil also failed to demonstrate efficacy in treating depression in patients under 18.  The United States further alleges that GSK sponsored dinner programs, lunch programs, spa programs and similar activities to promote the use of Paxil in children and adolescents.  GSK paid a speaker to talk to an audience of doctors and paid for the meal or spa treatment for the doctors who attended. Since 2004, Paxil, like other antidepressants, included on its label a “black box warning” stating that antidepressants may increase the risk of suicidal thinking and behavior in short-term studies in patients under age 18. GSK agreed to plead guilty to misbranding Paxil in that its labeling was false and misleading regarding the use of Paxil for patients under 18.

**Wellbutrin:**  The United States also alleges that, from January 1999 to December 2003, GSK promoted Wellbutrin, approved at that time only for Major Depressive Disorder, for weight loss, the treatment of sexual dysfunction, substance addictions and Attention Deficit Hyperactivity Disorder, among other off-label uses. The United States contends that GSK paid millions of dollars to doctors to speak at and attend meetings, sometimes at lavish resorts, at which the off-label uses of Wellbutrin were routinely promoted and also used sales representatives, sham advisory boards, and supposedly independent Continuing Medical Education (CME) programs to promote Wllbutrin for these unapproved uses. GSK has agreed to plead guilty to misbranding Wellbutrin in that its labeling did not bear adequate directions for these off-label uses. For the Paxil and Wellbutrin misbranding offenses, GSK has agreed to pay a criminal fine and forfeiture of $757,387,200.

**Avandia:**   The United States alleges that, between 2001 and 2007, GSK failed to include certain safety data about Avandia, a diabetes drug, in reports to the FDA that are meant to allow the FDA to determine if a drug continues to be safe for its approved indications and to spot drug safety trends.  The missing information included data regarding certain post-marketing studies, as well as data regarding two studies undertaken in response to European regulators’ concerns about the cardiovascular safety of Avandia.  Since 2007, the FDA has added two black box warnings to the Avandia label to alert physicians about the potential increased risk of (1) congestive heart failure, and (2) myocardial infarction (heart attack).  GSK has agreed to plead guilty to failing to report data to the FDA and has agreed to pay a criminal fine in the amount of $242,612,800 for its unlawful conduct concerning Avandia.

“This case demonstrates our continuing commitment to ensuring that the messages provided by drug manufacturers to physicians and patients are true and accurate and that decisions as to what drugs are prescribed to sick patients are based on best medical judgments, not false and misleading claims or improper financial inducements,” said Carmen Ortiz, U.S. Attorney for the District of Massachusetts.

“Patients rely on their physicians to prescribe the drugs they need,” said John Walsh, U.S. Attorney for Colorado. “The pharmaceutical industries’ drive for profits can distort the information provided to physicians concerning drugs.  This case will help to ensure that your physician will make prescribing decisions based on good science and not on misinformation, money or favors provided by the pharmaceutical industry.”

**Civil Settlement Agreement**

As part of this global resolution, GSK has agreed to resolve its civil liability for the following alleged conduct:  (1) promoting the drugs Paxil, Wellbutrin, Advair, Lamictal and Zofran for off-label, non-covered uses and paying kickbacks to physicians to prescribe those drugs as well as the drugs Imitrex, Lotronex, Flovent and Valtrex; (2) making false and misleading statements concerning the safety of Avandia; and (3) reporting false best prices and underpaying rebates owed under the Medicaid Drug Rebate Program.

**Off-Label Promotion and Kickbacks:**The civil settlement resolves claims set forth in a complaint filed by the United States alleging that, in addition to promoting the drugs Paxil and Wellbutrin for unapproved, non-covered uses, GSK also promoted its asthma drug, Advair, for first-line therapy for mild asthma patients even though it was not approved or medically appropriate under these circumstances. GSK also promoted Advair for chronic obstructive pulmonary disease with misleading claims as to the relevant treatment guidelines. The civil settlement also resolves allegations that GSK promoted Lamictal, an anti-epileptic medication, for off-label, non-covered psychiatric uses, neuropathic pain and pain management.  It further resolves allegations that GSK promoted certain forms of Zofran, approved only for post-operative nausea, for the treatment of morning sickness in pregnant women. It also includes allegations that GSK paid kickbacks to health care professionals to induce them to promote and prescribe these drugs as well as the drugs Imitrex, Lotronex, Flovent and Valtrex.  The United States alleges that this conduct caused false claims to be submitted to federal health care programs.

GSK has agreed to pay $1.043 billion relating to false claims arising from this alleged conduct. The federal share of this settlement is $832 million and the state share is $210 million.

This off-label civil settlement resolves four lawsuits pending in federal court in the District of Massachusetts under the *qui tam*, or whistleblower, provisions of the False Claims Act, which allow private citizens to bring civil actions on behalf of the United States and share in any recovery.

**Avandia:**In its civil settlement agreement, the United States alleges that GSK promoted Avandia to physicians and other health care providers with false and misleading representations about Avandia’s safety profile, causing false claims to be submitted to federal health care programs. Specifically, the United States alleges that GSK stated that Avandia had a positive cholesterol profile despite having no well-controlled studies to support that message. The United States also alleges that the company sponsored programs suggesting cardiovascular benefits from Avandia therapy despite warnings on the FDA-approved label regarding cardiovascular risks.  GSK has agreed to pay $657 million relating to false claims arising from misrepresentations about Avandia. The federal share of this settlement is $508 million and the state share is $149 million.

**Price Reporting:**  GSK is also resolving allegations that, between 1994 and 2003, GSK and its corporate predecessors reported false drug prices, which resulted in GSK’s underpaying rebates owed under the Medicaid Drug Rebate Program. By law, GSK was required to report the lowest, or “best” price that it charged its customers and to pay quarterly rebates to the states based on those reported prices. When drugs are sold to purchasers in contingent arrangements known as “bundles,” the discounts offered for the bundled drugs must be reallocated across all products in the bundle proportionate to the dollar value of the units sold. The United States alleges that GSK had bundled sales arrangements that included steep discounts known as “nominal” pricing and yet failed to take such contingent arrangements into account when calculating and reporting its best prices to the Department of Health and Human Services. Had it done so, the effective prices on certain drugs would have been different, and, in some instances, triggered a new, lower best price than what GSK reported. As a result, GSK underpaid rebates due to Medicaid and overcharged certain Public Health Service entities for its drugs, the United States contends. GSK has agreed to pay $300 million to resolve these allegations, including $160,972,069 to the federal government, $118,792,931 to the states, and $20,235,000 to certain Public Health Service entities who paid inflated prices for the drugs at issue.

Except to the extent that GSK has agreed to plead guilty to the three-count criminal information, the claims settled by these agreements are allegations only, and there has been no determination of liability.

“This landmark settlement demonstrates the Department’s commitment to protecting the American public against illegal conduct and fraud by pharmaceutical companies,” said Stuart F. Delery, Acting Assistant Attorney General for the Justice Department’s Civil Division. “Doctors need truthful, fair, balanced information when deciding whether the benefits of a drug outweigh its safety risks.  By the same token, the FDA needs all necessary safety-related information to identify safety trends and to determine whether a drug is safe and effective.  Unlawful promotion of drugs for unapproved uses and failing to report adverse drug experiences to the FDA can tip the balance of those important decisions, and the Justice Department will not tolerate attempts by those who seek to corrupt our health care system in this way.”

**Non-monetary Provisions and Corporate Integrity Agreement**

In addition to the criminal and civil resolutions, GSK has executed a five-year Corporate Integrity Agreement (CIA) with the Department of Health and Human Services, Office of Inspector General (HHS-OIG).  The plea agreement and CIA include novel provisions that require that GSK implement and/or maintain major changes to the way it does business, including changing the way its sales force is compensated to remove compensation based on sales goals for territories, one of the driving forces behind much of the conduct at issue in this matter. Under the CIA, GSK is required to change its executive compensation program to permit the company to recoup annual bonuses and long-term incentives from covered executives if they, or their subordinates, engage in significant misconduct. GSK may recoup monies from executives who are current employees and those who have left the company.  Among other things, the CIA also requires GSK to implement and maintain transparency in its research practices and publication policies and to follow specified policies in its contracts with various health care payors.

“Our five-year integrity agreement with GlaxoSmithKline requires individual accountability of its board and executives,” said Daniel R. Levinson, Inspector General of the U.S. Department of Health and Human Services. “For example, company executives may have to forfeit annual bonuses if they or their subordinates engage in significant misconduct, and sales agents are now being paid based on quality of service rather than sales targets.”

“The FDA Office of Criminal Investigations will aggressively pursue pharmaceutical companies that choose to put profits before the public’s health,” said Deborah M. Autor, Esq., Deputy Commissioner for Global Regulatory Operations and Policy, U.S. Food and Drug Administration. “We will continue to work with the Justice Department and our law enforcement counterparts to target companies that disregard the protections of the drug approval process by promoting drugs for uses when they have not been proven to be safe and effective for those uses, and that fail to report required drug safety information to the FDA.”

“The record settlement obtained by the multi-agency investigative team shows not only the importance of working with our partners, but also the importance of the public providing their knowledge of suspect schemes to the government,” said Kevin Perkins, Acting Executive Assistant Director of the FBI’s Criminal, Cyber, Response and Services Branch. “Together, we will continue to bring to justice those engaged in illegal schemes that threaten the safety of prescription drugs and other critical elements of our nation’s healthcare system.”

“ Federal employees deserve health care providers and suppliers, including drug manufacturers, that meet the highest standards of ethical and professional behavior,” said Patrick E. McFarland, Inspector General of the U.S. Office of Personnel Management. “Today’s settlement reminds the pharmaceutical industry that they must observe those standards and reflects the commitment of Federal law enforcement organizations to pursue improper and illegal conduct that places health care consumers at risk.”

“Today’s announcement illustrates the efforts of VA OIG and its law enforcement partners in ensuring the integrity of the medical care provided our nation’s veterans by the Department of Veterans Affairs,” said George J. Opfer, Inspector General of the Department of Veterans Affairs. “The monetary recoveries realized by VA in this settlement will directly benefit VA healthcare programs that provide for veterans’ continued care.”

“This settlement sends a clear message that taking advantage of federal health care programs has substantial consequences for those who try,”  said Rafael A. Medina, Special Agent in Charge of the Northeast Area Office of Inspector General for the U.S. Postal Service. “The U.S. Postal Service pays more than one billion dollars a year in workers' compensation benefits and our office is committed to pursuing those individuals or entities whose fraudulent acts continue to unfairly add to that cost.”

**A Multilateral Effort**

The criminal case is being prosecuted by the U.S. Attorney’s Office for the District of Massachusetts and the Civil Division’s Consumer Protection Branch. The civil settlement was reached by the U.S. Attorney’s Office for the District of Massachusetts, the U.S. Attorney’s Office for the District of Colorado and the Civil Division’s Commercial Litigation Branch.  Assistance was provided by the HHS Office of Counsel to the Inspector General, Office of the General Counsel-CMS Division and FDA’s Office of Chief Counsel as well as the National Association of Medicaid Fraud Control Units.

This matter was investigated by agents from the HHS-OIG; the FDA’s Office of Criminal Investigations; the Defense Criminal Investigative Service of the Department of Defense; the Office of the Inspector General for the Office of Personnel Management; the Department of Veterans Affairs; the Department of Labor; TRICARE Program Integrity; the Office of Inspector General for the U.S. Postal Service and the FBI.

This resolution is part of the government’s emphasis on combating health care fraud and another step for the Health Care Fraud Prevention and Enforcement Action Team (HEAT) initiative, which was announced in May 2009 by Attorney General Eric Holder and Kathleen Sebelius, Secretary of HHS.  The partnership between the two departments has focused efforts to reduce and prevent Medicare and Medicaid financial fraud through enhanced cooperation. Over the last three years, the department has recovered a total of more than $10.2 billion in settlements, judgments, fines, restitution, and forfeiture in health care fraud matters pursued under the False Claims Act and the Food, Drug and Cosmetic Act.

Court documents related to today’s settlement can be viewed online at [www.justice.gov/opa/gsk-docs.html](http://www.justice.gov/opa/gsk-docs.html).

**Acting Assistant Attorney General for the Civil Division Stuart F. Delery Speaks at the GSK Press Conference**

Washington, D.C. ~ Monday, July 2, 2012

Thank you, Bill, for that introduction.

As Deputy Attorney General Cole mentioned, today’s $3 billion resolution resolves several major investi gations of the company.  Specifically, t he global settlement resolves allegations relating to three major issues:

First, GSK will pay $1.8 billion to resolve criminal and civil liability related to off-label marketing.  This includes $757 million in criminal fines and forfeitures for misbranding the drugs Paxil and Wellbutrin, and $1.043 billion under the False Claims Act to resolve civil allegations regarding off-label promotion and the payment of kickbacks involving these and other drugs.

The second investigation resolved today relates to the diabetes drug Avandia.  GSK will pay a $243 million criminal fine for failing to report required safety data to FDA.  In the related civil settlement, GSK will pay $657 million to resolve allegations about representations it made concerning Avandia’s safety and efficacy.

The third investigation involves allegations of false best prices and the underpaying of rebates owed under the Medicaid Drug Rebate Program. GSK will pay $300 million to resolve civil liability under the False Claims Act related to these allegations.

In a moment, U.S. Attorney Carmen Ortiz will describe the conduct revealed by our investigations.  But today’s resolution is significant not just because GSK’s conduct was egregious or because it is the largest health care fraud settlement in the Department’s history.

Health care fraud is an epidemic that touches every aspect of our lives. And yet, for far too long, we have heard that the pharmaceutical industry views these settlements merely as the cost of doing business.  That is why this Administration is committed to using every available tool to defeat health care fraud.

As we did with Abbott Laboratories a few weeks ago, today’s resolution seeks not only to punish wrongdoing and recover taxpayer dollars, but to ensure GSK’s future compliance with the law.  The Corporate Integrity Agreement, which Department of Health and Human Services Inspector General Dan Levinson will describe in a moment, exemplifies best practices in compliance.  Both that agreement and the plea agreement require GSK to maintain certain compliance policies that the company has recently put into effect.

In addition, for the next five years, the plea agreement requires GSK to report to the Department of Justice any probable violations of the Federal Food, Drug, and Cosmetic Act concerning promotional activities and reporting obligations.  And GSK’s U.S. President and Board of Directors must personally certify the company’s compliance with the law every year.

And for every day that one of these reports or certifications is late, or one of these policies is not maintained, GSK agrees to pay the government $20,000 in stipulated damages.

The changes we are requiring of GSK and others may not end health care fraud, but they will go a long way to bringing about much-needed change in the way the pharmaceutical industry conducts business.  And because we know that many companies already play by the rules, these changes will help level the playing field, reduce the incentives to cut corners, and make clear that good compliance is also good business.

I want to echo the Deputy Attorney General’s comments about all of the many public servants in Boston, Colorado and across the country that contributed to this matter.  In particular, I want to recognize the dedicated attorneys, investigators and support staff of the Civil Division – here in Washington – who are the backbone of all of our health care fraud enforcement efforts.

Now, it’s my pleasure to introduce Carmen Ortiz, the U.S. Attorney for the District of Massachusetts.

**Deputy Attorney General James M. Cole Speaks at the GSK Press Conference**

Washington, D.C. ~ Monday, July 2, 2012

Good afternoon. We are here today to discuss the latest development in the Administration’s continuing fight against health care fraud.   It’s my privilege to be joined by Bill Corr, Deputy Secretary for the Department of Health and Human Services; Stuart Delery, Acting Assistant Attorney General for the Civil Division; Daniel Levinson, Inspector General for the Department of Health and Human Services; Carmen Ortiz, the United States Attorney for the District of Massachusetts; Deborah Autor, Deputy Commissioner for Global Regulatory Operations and Policy at the Food and Drug Administration; John Walsh, the United States Attorney for the District of Colorado; and Kevin Perkins, Acting Executive Assistant Director of the FBI.

Today, I am pleased to announce that the Justice Department and our law enforcement partners have reached an historic $3 billion resolution with the pharmaceutical manufacturer GlaxoSmithKline, LLC, to resolve multiple investigations into the company’s sales, marketing, and pricing practices. This action constitutes the largest health care fraud settlement in United States history. It underscores our robust commitment to protecting the American people from the scourge of health care fraud. And it proves the effectiveness of the strong relationships we’ve forged with our partners to help ensure the health and safety of the American people, and to safeguard the integrity of our health care system.

Under the agreements announced today, GSK will plead guilty to criminal charges and pay $1 billion in criminal fines and forfeitures for illegally marketing and promoting the drugs Paxil and Wellbutrin for uses not approved by the FDA – including the treatment of children for depression, and the treatment of other patients for ailments ranging from obesity, to anxiety, to addiction and ADHD – and for failing to report important clinical data about the drug Avandia to the Food and Drug Administration.  GSK will pay an additional $2 billion to resolve civil allegations that it caused false claims to be submitted to federal health care programs for these and other drugs as a result of the company’s illegal promotional practices and payments to physicians.  This settlement also resolves a civil investigation of the company’s alleged underpayment of rebates that were required under the Medicaid Drug Rebate Program.

Today’s multi-billion dollar settlement is unprecedented in both size and scope. It underscores this Administration’s firm commitment to protecting the American people and holding accountable those who commit health care fraud. At every level, we are determined to stop practices that jeopardize patients’ health; harm taxpayers; and violate the public trust – and this historic action is a clear warning to any company that chooses to break the law.

Since May 2009 – when Attorney General Eric Holder and HHS Secretary Kathleen Sebelius announced the creation of the Health Care Fraud Prevention and Enforcement Action Team – or HEAT – this fight has been a Cabinet-level priority. Over the last three years,  the Justice Department has recovered a total of more than $10.2 billion in settlements, judgments, fines, restitution and forfeiture in health care fraud matters. And our Medicare Strike Forces have brought criminal charges against more than 800 defendants seeking to defraud Medicare.

These results – and the groundbreaking resolution we announce today – are extraordinary. They’ve been made possible by close and seamless coordination between state and agency partners, both here in Washington and throughout the country. And they demonstrate the fierce determination – shared by every official, attorney, and investigator who has contributed to these efforts – to be relentless in pursuit of those who break the law; to stop those who would endanger the health and safety of the American people; and to hold accountable those who violate the public trust by committing waste, fraud, or abuse.

Let me be clear: we will not tolerate health care fraud. And, in every instance where we uncover it, we will use all available tools to hold those responsible to account.

Before I turn the podium over to our next speaker, I want to acknowledge our colleagues and partners at the Department of Health and Human Services; its Office of Inspector General; the Federal Bureau of Investigation; the Food Drug and Administration; the Massachusetts Medicaid Fraud Control Unit; and all of our other federal and state partners who have made invaluable contributions to this effort.

I’d also like to thank Carmen Ortiz, the United States Attorney for the District of Massachusetts – along with her outstanding staff – for all they’ve done to make this historic settlement possible, and for their longstanding commitment to eradicating health care fraud. Thank you also to John Walsh, the United States Attorney for the District of Colorado, and his office for their significant contributions to the investigation into GSK’s off-label promotion. And finally, I’d like to express my gratitude for the hard work of the Justice Department’s Civil Division – and the teams in both the Commercial Litigation Branch and the Consumer Protection Branch – whose efforts have proved instrumental in advancing both this investigation and other important ones like it.

At this time, it’s my pleasure to introduce Deputy Secretary Bill Corr.

**Documents and Resources from the July 2, 2012 GlaxoSmithKline (GSK) Press Conference**

**Speech:** [Deputy Attorney General James M. Cole Speaks at the GSK Press Conference](http://www.justice.gov/iso/opa/dag/speeches/2012/dag-speech-1207021.html)

**Press Release:** [GlaxoSmithKline to Plead Guilty and Pay $3 Billion to Resolve Fraud Allegations and Failure to Report Safety Data](http://www.justice.gov/opa/pr/2012/July/12-civ-842.html)

**Speech:** [Acting Assistant Attorney General for the Civil Division Stuart F. Delery Speaks at the GSK Press Conference](http://www.justice.gov/iso/opa/civil/speeches/2012/civ-speech-1207021.html)

**Court Documents**

[US Complaint](http://www.justice.gov/opa/documents/gsk/us-complaint.pdf)

[GSK Criminal Information](http://www.justice.gov/opa/documents/gsk/gsk-criminal-info.pdf)

[HHS-OIG Corporate Integrity Agreement](http://www.justice.gov/opa/documents/gsk/hhs-oig-corp-integrity-agreement.pdf)

[Civil Avandia Settlement Agreement](http://www.justice.gov/opa/documents/gsk/avandia-agreement.pdf)

[Civil Nominals Settlement Agreement](http://www.justice.gov/opa/documents/gsk/nominals-agreement.pdf)

[Civil Off Label Settlement Agreement](http://www.justice.gov/opa/documents/gsk/off-label-agreement.pdf)

**Government Complaint Exhibits**

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| [Complaint Exhibit # 1](http://www.justice.gov/opa/documents/gsk/complaint-ex1.pdf)[Complaint Exhibit # 2](http://www.justice.gov/opa/documents/gsk/complaint-ex2.pdf)[Complaint Exhibit # 3](http://www.justice.gov/opa/documents/gsk/complaint-ex3.pdf)[Complaint Exhibit # 4](http://www.justice.gov/opa/documents/gsk/complaint-ex4.pdf)[Complaint Exhibit # 5](http://www.justice.gov/opa/documents/gsk/complaint-ex5.pdf)[Complaint Exhibit # 6](http://www.justice.gov/opa/documents/gsk/complaint-ex6.pdf)[Complaint Exhibit # 7](http://www.justice.gov/opa/documents/gsk/complaint-ex7.pdf)[Complaint Exhibit # 8](http://www.justice.gov/opa/documents/gsk/complaint-ex8.pdf)[Complaint Exhibit # 9](http://www.justice.gov/opa/documents/gsk/complaint-ex9.pdf)[Complaint Exhibit # 10](http://www.justice.gov/opa/documents/gsk/complaint-ex10.pdf)[Complaint Exhibit # 11](http://www.justice.gov/opa/documents/gsk/complaint-ex11.pdf)[Complaint Exhibit # 12](http://www.justice.gov/opa/documents/gsk/complaint-ex12.pdf)[Complaint Exhibit # 13](http://www.justice.gov/opa/documents/gsk/complaint-ex13.pdf)[Complaint Exhibit # 14](http://www.justice.gov/opa/documents/gsk/complaint-ex14.pdf)[Complaint Exhibit # 15](http://www.justice.gov/opa/documents/gsk/complaint-ex15.pdf)[Complaint Exhibit # 16](http://www.justice.gov/opa/documents/gsk/complaint-ex16.pdf)[Complaint Exhibit # 17](http://www.justice.gov/opa/documents/gsk/complaint-ex17.pdf)[Complaint Exhibit # 18](http://www.justice.gov/opa/documents/gsk/complaint-ex18.pdf)[Complaint Exhibit # 19](http://www.justice.gov/opa/documents/gsk/complaint-ex19.pdf)[Complaint Exhibit # 20](http://www.justice.gov/opa/documents/gsk/complaint-ex20.pdf)[Complaint Exhibit # 21](http://www.justice.gov/opa/documents/gsk/complaint-ex21.pdf)                  | [Complaint Exhibit # 22](http://www.justice.gov/opa/documents/gsk/complaint-ex22.pdf)[Complaint Exhibit # 23](http://www.justice.gov/opa/documents/gsk/complaint-ex23.pdf)[Complaint Exhibit # 24](http://www.justice.gov/opa/documents/gsk/complaint-ex24.pdf)[Complaint Exhibit # 25](http://www.justice.gov/opa/documents/gsk/complaint-ex25.pdf)[Complaint Exhibit # 26](http://www.justice.gov/opa/documents/gsk/complaint-ex26.pdf)[Complaint Exhibit # 27](http://www.justice.gov/opa/documents/gsk/complaint-ex27.pdf)[Complaint Exhibit # 29](http://www.justice.gov/opa/documents/gsk/complaint-ex29.pdf)[Complaint Exhibit # 30](http://www.justice.gov/opa/documents/gsk/complaint-ex30.pdf)[Complaint Exhibit # 31](http://www.justice.gov/opa/documents/gsk/complaint-ex31.pdf)[Complaint Exhibit # 32](http://www.justice.gov/opa/documents/gsk/complaint-ex32.pdf)[Complaint Exhibit # 33](http://www.justice.gov/opa/documents/gsk/complaint-ex33.pdf)[Complaint Exhibit # 34](http://www.justice.gov/opa/documents/gsk/complaint-ex34.pdf)[Complaint Exhibit # 35](http://www.justice.gov/opa/documents/gsk/complaint-ex35.pdf)[Complaint Exhibit # 36](http://www.justice.gov/opa/documents/gsk/complaint-ex36.pdf)[Complaint Exhibit # 37](http://www.justice.gov/opa/documents/gsk/complaint-ex37.pdf)[Complaint Exhibit # 38](http://www.justice.gov/opa/documents/gsk/complaint-ex38.pdf)[Complaint Exhibit # 39](http://www.justice.gov/opa/documents/gsk/complaint-ex39.pdf)[Complaint Exhibit # 40](http://www.justice.gov/opa/documents/gsk/complaint-ex40.pdf)[Complaint Exhibit # 41](http://www.justice.gov/opa/documents/gsk/complaint-ex41.pdf)[Complaint Exhibit # 42](http://www.justice.gov/opa/documents/gsk/complaint-ex42.pdf)[Complaint Exhibit # 43](http://www.justice.gov/opa/documents/gsk/complaint-ex43.pdf) |

**GSK Plea Agreement Exhibits**

[Plea Agreement](http://www.justice.gov/opa/documents/gsk/plea-agreement.pdf)

[Plea Exhibit A](http://www.justice.gov/opa/documents/gsk/plea-ex-a.pdf)

[Plea Exhibit B](http://www.justice.gov/opa/documents/gsk/plea-ex-b.pdf)

[Plea Exhibit C](http://www.justice.gov/opa/documents/gsk/plea-ex-c.pdf)

[Plea Exhibit D](http://www.justice.gov/opa/documents/gsk/plea-ex-d.pdf)

[Plea Exhibit E](http://www.justice.gov/opa/documents/gsk/plea-ex-e.pdf)

[Plea Exhibit F](http://www.justice.gov/opa/documents/gsk/plea-ex-f.pdf)

[Plea Exhibit G](http://www.justice.gov/opa/documents/gsk/plea-ex-g.pdf)

[Plea Exhibit H](http://www.justice.gov/opa/documents/gsk/plea-ex-h.pdf)

[Plea Exhibit I](http://www.justice.gov/opa/documents/gsk/plea-ex-i.pdf)

[Plea Exhibit J](http://www.justice.gov/opa/documents/gsk/plea-ex-j.pdf)

[Plea Exhibit K](http://www.justice.gov/opa/documents/gsk/plea-ex-k.pdf)

**GSK Side Letter Exhibits**

[Side Letter](http://www.justice.gov/opa/documents/gsk/side-letter.pdf)

[Side Letter Exhibit # 1](http://www.justice.gov/opa/documents/gsk/side-letter-ex1.pdf)

[Side Letter Exhibit # 2](http://www.justice.gov/opa/documents/gsk/side-letter-ex2.pdf)

[Side Letter Exhibit # 3](http://www.justice.gov/opa/documents/gsk/side-letter-ex3.pdf)

[Side Letter Exhibit # 4](http://www.justice.gov/opa/documents/gsk/side-letter-ex4.pdf)

[Side Letter Exhibit # 5](http://www.justice.gov/opa/documents/gsk/side-letter-ex5.pdf)

[Side Letter Exhibit # 6](http://www.justice.gov/opa/documents/gsk/side-letter-ex6.pdf)

[Side Letter Exhibit # 7](http://www.justice.gov/opa/documents/gsk/side-letter-ex7.pdf)

[Side Letter Exhibit # 8](http://www.justice.gov/opa/documents/gsk/side-letter-ex8.pdf)

Due to public interest in this case, the Department of Justice is releasing documents that may not be in an accessible format. If you have a disability and the format of any material on the site interferes with your ability to access some information, please email the Department of Justice webmaster at webmaster@usdoj.gov or contact Alisa Finelli at 202.514.2007. To enable us to respond in a manner that will be of most help to you, please indicate the nature of the accessibility problem, your preferred format (electronic format (ASCII, etc.), standard print, large print, etc.), the web address of the requested material, and your full contact information so we can reach you if questions arise while fulfilling your request.

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| This article appeared in the Campaign's *Secrets* newspaper in August 1993.  |
| Many clinical trials are never published - which means that the published literature may give a very inadequate picture of what is known about a drug.According to a recent article: "This phenomenon is particularly alarming because unpublished trials may have systematically different results from those that are published. This publication bias obviously increases the chances that reviews based only on published reports will themselves be biased and will in turn promote inappropriate health care". (1) Unpublished studies may even conceal fraud. Researchers using the US Freedom of Information Act obtained nearly 2000 US Food & Drug Administration audits of clinical trials. They learnt that the FDA had discovered "serious deficiencies" in 11% of cases, ranging from poorly designed studies to flagrantly falsified results. (2)  No similar study could be done in Britain, because of the secrecy clause in the Medicines Act.The problem certainly exists here. The medical director of the Association of the British Pharmaceutical Industry, Dr Frank Wells, recently wrote: "For some time there has been an impression among British pharmaceutical physicians, clinical research associates, and quality assurance professionals that a small but significant amount of data supplied by British clinical investigators is fraudulent". (3) **Footnotes**1. I. Chalmers et al, British Medical Journal, 3.10.92. 786-8
2. J. of the American Medical Assn, 5.5.89, 2505
3. 'Fraud & Misconduct in Medical Research', BMJ Publishing Group, 1993.
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**Analysis: U.S. foreign bribery penalties for drugmakers may lack bite**

**Bill Berkrot**

**Reuters**

*7:11 a.m. CDT, October 29, 2012*

NEW YORK (Reuters) - Global drugmakers are paying tens of millions of dollars to settle U.S. allegations that they bribed their way across emerging markets, but harsher penalties may be needed to deter the practice in untapped regions where billions are at stake.

Federal authorities have cast a wide net to weed out suspected gift-giving and kickbacks to foreign doctors and government officials to gain a foothold in burgeoning new markets in Asia, Eastern Europe and Latin America.

At least eight of the world's top 10 drugmakers, including Bristol-Myers Squibb Co, Pfizer Inc and Johnson &, have disclosed U.S. probes under the 1977 Foreign Corrupt Practices Act (FCPA).

Pfizer agreed to pay $60 million this year to settle FCPA charges and J&J reached a $70 million settlement last year. Pfizer is on track to record $10 billion in sales from emerging markets this year, while J&J said Brazil, Russia, India and China accounted for just under 10 percent of the $65 billion in sales it reported last year.

With so much at stake outside of established markets in the United States and Europe, some experts say fines like these are hardly a deterrent.

"The $60 million fine for Pfizer to a lay person sounds like quite a bit of money, but in perspective it took less than two days of Lipitor sales during its peak. It's really just chump change for them," said Michael Leibfried, a senior analyst with market research consulting firm GlobalData. The cholesterol pill at its height was a $13 billion a year cash cow for Pfizer.

Kara Brockmeyer, chief of FCPA investigations within the Securities and Exchange Commission's enforcement division, said the SEC and Department of Justice make a considerable effort to ensure penalties are appropriate and a deterrent. And there has yet to be a repeat FCPA prosecution.

The SEC relies on legal provisions that call for disgorgement of profits based on ill-gotten gains plus penalties. Companies that report violations and cooperate with authorities are often rewarded with penalty reductions.

"I would hate to think the companies view enforcement actions as the cost of doing business," Brockmeyer told Reuters. "If we find that out, it will certainly increase the size of the penalty," she said.

The law firm Shearman & Sterling, which puts out a semi-annual report tracking FCPA enforcement, found that penalties across all industries have averaged less than $20 million.

In 2009 Danish insulin maker Novo Nordisk paid $9 million for FCPA violations, while medical device maker Smith & Nephew this year agreed to $22 million in fines and profit disgorgement. The largest FCPA penalty on record was $800 million paid in 2008 by Germany-based Siemens.

The industry's FCPA payments pale in comparison to billion-dollar settlements over allegations drugmakers promoted medications for unapproved uses in the United States. These penalties often involve how much federal Medicare and Medicaid programs spent on the so-called off-label prescriptions.

"I'm not terribly surprised that dollar settlements (for FCPA violations) are strikingly lower because the government isn't directly being harmed," said Boston University law professor Kevin Outterson.

PLAYING THE RIGHT WAY

Pfizer's settlement covered infractions dating back to 2004, including some attributed to drugmaker Wyeth, which it bought in 2009. The company lightened its penalty by voluntarily providing information about kickbacks and bribes in Bulgaria, Croatia, Kazakhstan, Russia, China, the Czech Republic, Italy, Serbia, Indonesia, Pakistan and Saudi Arabia.

"Pfizer subsidiaries in several countries had bribery so entwined in their sales culture that they offered points and bonus programs to improperly reward foreign officials who proved to be their best customers," Brockmeyer said in a statement at the time the settlement was announced.

Pfizer executives say their emerging market operations will not repeat those practices. It has introduced an anti-corruption audit program, closer monitoring of relationships with non-U.S. healthcare providers and government officials, a mandatory global training program for appropriate employees and enhanced due diligence to make sure buyout targets follow the rules.

J&J said it has enacted similar anti-corruption initiatives.

"We're not out there to play the game that's been played before," said Adele Gulfo, head of Latin America for Pfizer's emerging markets unit. "We're either going to win by playing the right way or we're going to find another place to go."

[2012](http://www.pharmalot.com/2012/) » [November](http://www.pharmalot.com/2012/11/) » [12](http://www.pharmalot.com/2012/11/12/)

[Glaxo Employee Blows Whistle On Drug Promotions](http://www.pharmalot.com/2012/11/glaxo-employee-blows-whistle-on-drug-promotions/)

By Ed Silverman

At a time when GlaxoSmithKline execs have been arguing that off-label promotional activity is no longer standard operating procedure, they must have been chagrined to learn that a Glaxo employee earlier this year complained to the UK trade group for the pharmaceutical industry that promotional and training efforts involving sales reps crossed the line.

In a ruling issued last week, a Association for the British Pharmaceutical Industry panel found that Glaxo violated the code of conduct three different ways in connection with a promotional push for the Revolade treatment for a rare bleeding disorder known as immune thrombocytopenic purpura, or ITP.

The unnamed Glaxo (GSK) employee complained that a sales rep had promoted Revolade for myeloid fibrosis to a National Health Service consultant through e-mails and meetings. And the panel ruled that the communications, which referred to both maladies involving a particular patient, could have been misconstrued and the rep should have known better.

Moreover, the panel also noted that the language in the e-mail sent by the rep was actually provided by the Revolade brand team, suggesting that the confusing language was part of a deliberate campaign to promote the drug for an unapproved use. Consequently, the drugmaker violated the code, although not the section that brings the industry into disrepute.

The panel, known as the Prescriptions Medicine Code of Practice Authority found that the rep “should have been mindful of the impression given by the subject matter of the email” and, as a result, the drugmaker failed to maintain high standards and the sales rep did not maintain ethical standards.

The only goods news for Glaxo was that the PMCPA simultaneously ruled that staff training efforts for two other drugs – the Requip XL medication for Parkinson’s disease and the Seretide asthma treatment – did not breach the code of conduct, as alleged by the same Glaxo employee).

The episode occurred just as Glaxo execs were negotiating with the US government over various violations, including off-label promotion. The drugmaker paid a $3 billion fine and ceo Andrew Witty declared the problems “originated in a different era for the company” and “in the US, we have taken action at all levels in the company. We have fundamentally changed our procedures for compliance, marketing and selling”.

Of course, infractions can and will occur, despite the best efforts of any company. Nonetheless, the PMCPA ruling should be seen as a notice to Glaxo execs that the efforts undertaken in the US need to be reinforced elsewhere as well.