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Driven to Settle: Eliot Spitzer v. GlaxoSmithKline and Undisclosed Clinical Trials Data Regarding Paxil

I. INTRODUCTION

Before the introduction of Selective Serotonin Reuptake Inhibitors (SSRIs), doctors and psychiatrists with depressed patients faced the difficult decision of whether or not to prescribe strong medications with serious and often debilitating side effects to best treat their patients. SSRIs appeared as a panacea: medication that alleviated mild to serious cases of depression without the severe side effects of the earlier generation drugs. Beginning with Eli Lilly's Prozac, SSRIs seemed to be a magic bullet for both patients and doctors, and a cash-cow for the pharmaceutical industry. Following on the heels of Eli Lilly's successful drug, newer-generation antidepressants joined the market in spates; Pfizer introduced Zoloft, Forest Laboratories, Inc introduced Celexa, Wyeth came out with Effexor, and GlaxoSmithKline ("GSK" or "Glaxo") launched both Wellbutrin and Paxil. While the antidepressants all differ slightly from one another in chemical makeup, each company needed to cultivate brand recognition in order to distinguish themselves and gain market share while the drugs remained patented. To successfully compete with one another the pharmaceutical companies launched aggressive ad-campaigns on television, in newspapers and magazines, and in medical journals, aiming to seduce both potential patients and physicians making prescribing decisions.

Despite the approval of these drugs by the Food and Drug Administration ("FDA"), the federal agency responsible for allowing pharmaceuticals on the market, SSRIs proved to have less than miraculous side effects for some patients.[1] Some patients complained of severe withdrawal symptoms and other varied negative effects. Even more damaging to the manufacturers, researchers began conjecturing about a possible link between SSRI use and violent and suicidal behaviors. Furthermore, except for Prozac, SSRIs were not FDA approved for use on patients under 18 years of age. Still, physicians have the freedom to prescribe medications to treat illnesses and populations for which they have not been approved (called "off-label" use), so a growing number of young patients were taking these drugs despite the lack of formal approval. Speculation began to mount that the link between these antidepressants and suicide was especially substantial in these younger users.

[1] www.fda.gov

Because of concerns about suicidal behavior and increasing research suggesting such a link, drug regulators in the United Kingdom announced in June, 2003 that Paxil "should not be used in children and adolescents under the age of 18 years" to treat depression. US regulators followed suit but used less commanding language than regulators in the UK, only "recommending" that doctors not prescribe Paxil to treat depression in young patients.[2] In making its recommendation, the FDA indicated that it would begin its own investigation of such claims, and emphasized that the research linking the drug to suicidal behaviors remained unclear, and further research was necessary before taking serious action. [3] In fact, the FDA announced as its official public stance that there existed insufficient evidence to support a link between suicide and SSRI use.[4] Further, that same month, Glaxo put out a news release in the US stating, "there is no evidence that Paxil is associated with an increased risk of suicidal thinking or acts in adults" and "not a single person" who participated in the trials committed suicide.[5] Physicians in the US making prescribing decisions thereby faced confused and inconsistent warnings.

In the face of ambiguous cautions put forth by the FDA, individuals began bringing private suits against antidepressant makers, attracting greater media attention to the potential side effects of SSRIs.[6] The trickling of disparate lawsuits culminated in June, 2004 when the State Attorney General of New York, Eliot Spitzer, launched a massive attack against manufacturers by suing GlaxoSmithKline, the maker of Paxil, for concealing clinical trial data indicating that Paxil was ineffective for use in pediatric patients, and could possibly be linked to inducing suicidal behavior.[7] Spitzer pointed to four clinical trials that GSK allegedly suppressed, each indicating Paxil's ineffectiveness and potential risks. According to the suit, although GSK had negative

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[2] Barbara Martinez, *Spitzer Charges Glaxo Concealed Paxil Data*, WALL ST. J., June 3, 2004, at B1.
[3] Press Release, FDA Public Health Advisory, (Oct 27, 2003) (*available at* http://www.fda.gov/cder/drug/advisory/mdd.htm); Press Release, FDA, FDA Issues Public Health Advisory on Cautions for Use of Antidepressants in Adults and Children (March 22, 2004) (*available at* http://www.antidepressantsfacts.com/2004-03-22-FDA-Talk-Paper-use-SSRIs.htm)
[4]Elizabeth Shogren, *FDA Sat On Report Linking Suicide, Drugs*, LA TIMES, April 6, 2004 (*available at* http://www.antidepressantsfacts.com/2004-04-06-FDA-suicide-children-SSRI.htm).
[5]Martinez, *supra* note 2.
[6] For example, in 2001 a Wisconsin man brought suit against SmithKline Beecham (a company now part of GSK) alleging that Paxil caused him to fatally shoot three family members and himself. Similarly, in criminal cases, perpetrators of violent crimes began arguing that their behavior was brought on by these drugs. *Id*.
[7] In clinical trials patients and healthy volunteers take experimental drugs or drugs that are already FDA approved, and the goal is usually to determine the proper dose, identify possible side effects, test drug interactions, or consider how well the body processes the chemicals in a drug. *Supra*, note 1.

information about safety and efficacy it continued to give its sales representatives a positive image of Paxil.[18]

Although pharmaceutical companies are often maligned in the public consciousness, Spitzer's lawsuit does not represent the simple paradigm of an evil pharmaceutical company suppressing data solely to reap greater profits. Rather, the suit reveals the complexity involved in assessing the reliability of clinical trials and the interaction between manufacturers and the FDA. In reality, the clinical trials at issue do not clearly indicate a correlation between Paxil and suicidal behavior, as Spitzer's lawsuit suggests; two of the trials in question state that suicidal thoughts were "unrelated or probably unrelated" to Paxil, and the other two studies do not specify whether Paxil was to blame for the side effects.[9] Furthermore, it is possible that GSK thought it was protected by the FDA which assured the company it was best not to release the data or include warnings, for fear of confusing physicians and patients.[10] Still, in the wake of the GSK settlement and the slew of private suits against pharmaceutical makers, the FDA now requires black box warnings, the most severe type of caution, on all SSRIs, and called on all doctors to carefully monitor patients taking SSRIs for indications of increased depression or suicidal thinking.[11] Such a reversal indicates that the clinical trials GSK failed to make public likely contained important warnings, lending credence to Spitzer's allegations.

Still, Spitzer's announcement of his suit against GSK, regardless of its merits, left GSK with little choice but to settle. By accusing GSK of defrauding the public and calling attention to the tragedies of teen suicides, GSK knew it would be unable to garner sympathy from the community, much less a jury. Regardless of whether the accusations were legally sound, the investing community has learned that the proper financial response to a suit by Spitzer is to distance oneself as much as possible from the offending company. Indeed, GSK saw its stock go down tremendously. Any investor knew that should GSK proceed to litigation it could lose hundreds of millions of dollars against Spitzer alone, and if other states joined in the move to disgorge profits, GSK could end up bankrupt. Further, once the private suits began, juries would clearly have little sympathy for the pharmaceutical behemoth up against sobbing plaintiffs. While GSK denied any wrongdoing, that fact was almost superfluous – fighting Spitzer in court was

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[8] Press Release, Office of the New York State Attorney General Eliot Spitzer, Major Pharmaceutical Firm Concealed Drug Information (June 2, 2004) (*available at* www.oag.state.ny.us/press/2004/jun/jun2b_04.html).
[9] Jeanne Whalen, *Glaxo Releases Studies on Drug for Depression*, WALL ST. J., June 16, 2004, at D3.
[10] *House Committee, Journals Call for More Clinical Trial Data*, OMB WATCHER Vol. 5 No 19, September 20, 2004 (*available at* http://www.ombwatch.org/article/articleprint/2420/-1/281/)
[11] Anna Wilde Mathews, *FDA Revisits Issue of Antidepressants for Youths*, WALL ST. J., August 5, 2004, at A1.

tantamount to financial suicide. As such, GSK had little choice but to settle as soon as possible, regardless of its legal rights and actual wrongdoing.

While researchers continue to investigate the actuality of a correlation between Paxil and suicidal behavior in adolescents, the propriety of Spitzer bringing suit against GSK seems to have slipped from public debate. Putting aside the vital question of whether or not Paxil is safe for use on adolescents, questions of whether Spitzer was the proper official to take GSK to task, and whether a state attorney general ("AG") filing suit was the proper method for regulating an industry that operates under a carefully legislated federal regime still remain unanswered.

This paper first outlines the suit Spitzer brought against GSK and the resulting settlement. Next the paper considers potential defenses a pharmaceutical company in GSK's position would attempt to raise, should it choose to proceed toward litigation rather than settle, focusing on federal preemption and commercial free speech. Finally, the paper addresses the policy implications behind Spitzer's suit against GSK. Is it proper for a state AG to use his power to oversee information flows that relate to the heavily regulated drug industry? If the FDA is, indeed, an ailing agency that no longer serves the public interest, should the state AG be the individual to step in and fill the gaps? Finally, where merely bringing suit against a company results in huge financial losses, such that the company has no choice but to settle, even if potentially innocent, should we worry about people and organizations losing certain rights in the face of state AG regulatory power?

II. THE PAXIL LAWSUIT

1. Eliot Spitzer Sues GlaxoSmithKline

On June 2, 2004, Eliot Spitzer, AG of New York, filed a lawsuit against the British pharmaceutical giant, GlaxoSmithKline ("GSK"), in the New York State Supreme Court.[12] Spitzer's suit alleged that the makers of the popular antidepressant, Paxil, engaged in "repeated and persistent fraud" by concealing information about the safety and efficacy of using Paxil to treat depression in children and adolescents. Spitzer accused GSK of intentionally keeping the results of clinical studies on Paxil from the public and physicians. He alleged that GSK only publicly released one clinical trial, which revealed mixed results in effectiveness and safety for use in young patient populations, but four other trials were also conducted. "The studies that GSK suppressed, Spitzer said, revealed negative results, failed to demonstrate that Paxil was effective,

[12] GSK is a publicly traded company that trades on the New York and London Stock exchanges. The company had sales of $35.2 billion in 2003 and made a before tax profit of $11 billion. *Glaxo Hid Studies 'Linking' Paxil to Child Suicide Risk, Suit Says*, 20 No. 5 ANDREWS PHARMACEUTICAL LIT. REP. 11, June 29, 2004.

and suggested a possible increase of suicidal thinking and related acts in certain users."[13] Spitzer claimed that GSK took "affirmative steps" to conceal negative information.[14] The lawsuit cited an internal GSK memo from 1998 stating that GSK aimed to "manage the dissemination of [the] data in order to minimize any potential negative commercial impact."[15] Further, GSK failed to disclose the negative findings from the other four clinical trials in "Medical Information Letters" it sent to physicians making prescribing decisions.[16]

Spitzer's suit claimed that GSK also misrepresented Paxil's efficacy and safety in treating adolescent depression to the sales and marketing representatives charged with influencing doctors to write prescriptions for juveniles.[17] According to the suit, a member of Paxil's product management team sent a memo to the representatives saying "Paxil demonstrates remarkable efficacy and safety in the treatment of adolescent depression." Spitzer alleges that although that memo stated it was only intended for the sales representatives, the company expected the information to reach prescribing physicians via its spokespeople.[18]

Spitzer also contends that a drug company informing the FDA about the negative trials is not sufficient to escape liability, and GSK is not shielded simply by virtue of having disclosed the trials to the FDA; a company must disseminate such information to doctors in order to avoid charges of fraud.[19] Spitzer claimed jurisdiction to bring suit under New York Executive Law 63, which allows the AG to gather restitution and damages from companies that engage in "any deception, misrepresentation, concealment or suppression" of data.[20] Spitzer argues that if a company's marketing message is contrary to the results from its own unreleased clinical trials, then the company is defrauding consumers.[21] According to the theory of the suit, for a doctor to appropriately prescribe medication for off-label uses he needs access to all the scientific data surrounding a drug's safety, efficacy and risk.[22] Although GSK did not explicitly market Paxil as

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[13] *Glaxo Posts Paxil Data on Web, Settles N.Y. Suit for $2.5* Million, 20 No. 8 ANDREWS PHARMACEUTICAL LITIGATION REPORTER 2 (September 30, 2004)
[14] 20 No. 5 Andrews Pharmaceutical Lit. Rep. 11, *supra* note 12.
[15] *Id.*
[16] *Glaxo Misled Doctors about safety of Paxil, NY Charges*, CONSUMER AFFAIRS.COM, (June 2, 2004) (*available at* www.consumeraffairs.com/news04/paxil_ny.html).
[17] The company allegedly portrayed the drug as having "remarkable efficacy and safety in the treatment of adolescent depression..." *Id.*
[18] *New York Attorney General Sues GlaxoSmithKline Over Alleged Concealment of Paxil Trials, Citing Consumer Protection*, KAISER NEWTOWRK.ORG, June 3, 2004 (*available at* www. Kaisernetwork.org/daily_reports/rep+index.cfm?DR_ID=24035).
[19] Stephan Evans, *A Spitzer in the Eye for Glaxo*, BBC NEWS, UK EDITION, June 4, 2004 (*available at* http://news.bbc.co.uk/1/hi/business/3778377.stm).
[20] KAISER NEWTOWRK.ORG, *supra* note 18.
[21] *Id.* (*citing* Harris, N.Y. TIMES, 6/3).
[22] CONSUMER AFFAIRS.COM, *supra* note 16.

safe for use in younger populations, by failing to release data of possible risks, GSK knew physicians would freely prescribe the drug to those populations using their own discretion. The suit claims that patients whose doctors made prescribing decisions with imperfect information were defrauded by GSK.[23]

GSK responded to the allegations with a public denial of any wrongdoing. A spokesperson stated, "GlaxoSmithKline has acted responsibly in conducting clinical studies in pediatric patients and disseminating data from those studies… All pediatric studies have been made available to the FDA and regulatory agencies worldwide."[24] Further a spokeswoman for GSK stated that, though they remained unpublished, the company publicly communicated the results of all the studies in various forms, such as medical conventions and letters to physicians, "[t]here are many many studies each year… It's impractical to believe that every company in the industry will be able to publish every study."[25] While GSK emphasized that all data on Paxil were made available to the FDA and other regulatory agencies, that information was never made public.[26]

Importantly, in suing GSK, Spitzer clearly stated that he was not making a statement about whether or not Paxil does indeed cause suicidal tendencies in young users. Rather, the lawsuit focused on the suppression of negative information in a manner that was fraudulent. [27] Such a distinction purports to place Spitzer's suit in the realm of consumer protection, rather than addressing an issue of scientific judgment which traditionally belongs within the province of the FDA.

Spitzer's lawsuit asked the New York Supreme Court to order disgorgement of GSK's profits earned from Paxil sales in NY. The suit did not specify the amount of disgorgement, but noted that in 2002 alone GSK sold $55 million worth of Paxil in the US. [28]

2. <u>The Settlement</u>

The progression from Spitzer's filing to GSK's decision to settle occurred with striking rapidity. Spitzer filed suit on June 2, 2004, and although the settlement agreement was not formally filed until the end of August, Glaxo began to indicate to the investing community that it planned to cooperate with Spitzer as early as June 16, a mere two weeks after Spitzer filed suit.

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[23] In 2002 there were more than two million prescriptions for Paxil written for children and adolescents to treat mood disorders. 20 NO. 5 ANDREWS PHARMACEUTICAL LIT. REP. 11, *supra* note 12.
[24] *Id.*
[25] Martinez, *supra* note 2.
[26] *Id.*
[27] *Id.*
[28] *Id.*

On June 18, Glaxo announced that it would publicly reveal the nature of its clinical trials. Although the terms of that disclosure were still under negotiation, Glaxo's announcement indicated that it would not challenge Spitzer's accusations.[29]

The official settlement agreement between Glaxo and Spitzer was filed on August 26, 2004, and by October of the same year most major pharmaceutical companies, as well as the Pharmaceutical Research and Manufacturers of America ("PhRMA"), the industry's Washington-based lobbying group, had developed online clinical trial registries, consistent with the terms of GSK's settlement with Spitzer. Further, on October 15, 2004, the FDA announced that all antidepressants must carry a "black box warning" to warn users that the drugs are linked to suicidal thoughts and behavior.[30] Thus, within the short span of four months following the filing of Spitzer's suit, the nature of the entire industry's handling of clinical trial disclosure, as well as the FDA's official stance toward antidepressant safety had drastically altered.

GSK agreed to settle with Spitzer by paying $2.5 Million, and posting on its website, www.gsk.com, the results of company-sponsored clinical studies on how Paxil affects children and adolescents.[31] As per the settlement agreement, GSK must also establish a clinical trial register that will provide the public summaries of all company-sponsored research conducted since Dec. 27, 2000, and maintain the site for at least 10 years, posting clinical reports within 10 months of completion.[32] GSK stated that while it believed Spitzer's allegations were "unfounded," it agreed to enter the accord "to avoid the high costs and time required to defend itself in protracted litigation."[33]

While the $2.5 Million settlement could be considered a "relatively small sum" the agreement to publish details of clinical trials was seen as momentous.[34] The clinical trials register envisioned by the accord was required to include summaries "set out in standard form and [that] include data regarding effectiveness, type and severity of side-effects and whether the goals of other components of the study were changed mid-stream."[35] Also, GSK was required to advertise the clinical trials register in medical journals, and agreed to ensure that all Medical Information Letters and other communications provided to doctors concerning off-label use of Paxil and other

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[29] *Glaxo Settles Over Paxil Studies*, REUTERS, August 26, 2004 (*available at* http://www.bruha.com/pfpc/html/glaxo_settles.html).
[30] Virginia Citrano, *Garnier: Glaxo's Paxil Must Have 'Black Box' Warning*, FORBES.COM (October 15, 2004) *at http://www.forbes.com/facesinthenews/2004/10/15/1015autofacescan04.html*
[31] *People v. GlaxoSmithKline Plc*, WL 1932763 (S.D.N.Y. 2004).
[32] *Glaxo Posts Data on Web, Settles NY Suit for $2.5 Million*, 20 NO. 8 ANDREWS PHARMACEUTICAL LITIGATION REPORTER 2 (September 30, 2004).
[33] *Id*.
[34] David Teather, *Spitzer Forces Glaxo to Publish Drug Trials*, THE GUARDIAN, August 27, 2004, at 28.
[35] *Id*.

drugs would fairly and accurately reflect the safety and efficacy data from clinical studies concerning off-label use. [36] Although $2.5 Million was a small sum for such an enormous drug manufacturer, the burdens of the settlement terms create entirely new duties and standards for GSK, and presumably the industry at large.

3. The Effect of the Lawsuit and Settlement

Following the settlement agreement, Eliot Spitzer stated publicly, "this settlement is transformational in that it will provide doctors and patients access to the clinical testing data necessary to make informed judgments."[37] Spitzer indicated that his actions were not limited to GSK, "[i]f the drug makers do not take action, Mr. Spitzer threatened more lawsuits. 'We have ongoing inquiries,' he said."[38] Spitzer's prediction that other drug companies would swiftly follow suit and create their own registries in the wake of the GSK lawsuit proved prescient. By October 22, 2004, Pfizer, Eli Lilly, Merck and other large pharmaceutical companies publicly stated plans to create their own clinical trials registries. PhRMA began posting clinical trial results generated by its 36 member companies, "from Abbott Laboratories to Wyeth."[39]

Spitzer's suit brought attention to the "black-hole" in medical research, where up to half the studies conducted on medications, and mostly those with negative results, are never published.[40] Many blame drug-industry funding of clinical trials for the failure to publish many negative studies; researchers rely on drug industry endowments which may create perverse incentives against publishing negative outcomes which could hurt the company providing the researcher's paycheck.[41]

While there is clearly an information gap between prescribing physicians and the data from clinical studies run by researchers, it is unclear whether the use of clinical trials registers is the solution. The value of having such registers came under close scrutiny after the GSK settlement terms became public; some critics emphasized that more information is not always a good thing, as test results may confuse patients and caretakers, rather than enhance their knowledge. Furthermore, the registries could generate anxiety in already concerned patients. Observing GSK's recently introduced summaries for clinical trials, such critics lamented, "[t]he

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[36] Press Release, Office of New York State Attorney General Eliot Spitzer, Settlement Sets New Standard For Release of Drug Information, (August 26, 2004).
[37] Gardiner Harris, *Maker of Paxil to Release All Trial Results*, N.Y. TIMES, August 27, 2004, at C4.
[38] *Id*.
[39] Sabine Vollmer, *Details of Drug Trials Accessible But Will it Help?*, RALEIGH NEWS AND OBSERVER, Oct. 22, 2004 (*available at* www. Knoxstudio.com/shns/story.cfm?pk=DRUGTRIALS-10-22-04&cat=LC).
[40] Scott Hensley and Leila Abboud, *Medical Research Has 'Black Hole': Negative Results Often Fail to Get Published in Journals; Some Blame Drug Industry*, WALL. ST. J., June 4, 2004, at B3.
[41] Barry Meier, *Contracts Keep Drug Research Out of Reach*, N.Y. TIMES, Nov. 29, 2004 at A1.

results are peppered with terms, numbers and abbreviations likely to puzzle all but physicians and statisticians."[42] However, the settlement agreement with Spitzer explicitly requires that GSK's registry not interpret or highlight the data results, as the purpose of such trials is to provide raw, unbiased data.[43] While criticism about the use of puzzling statistics focuses on the patient-as-consumer, really it seems that the clinical trial registries are geared towards providing information to prescribing physicians. In reality, Spitzer's suit against GSK was focused on concealing information from doctors, and not the actual users, indicating that much criticism of the registries is misguided, as raw data and statistics may be accessible and useful to trained physicians.

The GSK settlement purports to set a new standard for the entire pharmaceutical industry, a standard marked by encouraging the release of both positive and negative studies regarding a company's drugs. "'The immediate impact is sending a signal to other pharmaceutical manufacturers that this is the new standard with regard to disclosure of clinical studies.' Said Joe Baker, Spitzer's health care bureau chief."[44] In June, 2004 PhRMA introduced a proposal suggesting that pharmaceutical companies publish results on marketed or soon-to-be introduced drugs. "The standards represent the most specific response by the drug industry to charges that it has played down unfavorable results from human tests of drugs."[45] PhRMA's description of its new standards appears to represent an industry-wide response to Spitzer's suit against GSK and an attempt to help the industry avoid similar lawsuits in the future.

Finally, the combination of Spitzer's high profile suit against GSK and the subsequent release of information indicating a link between antidepressants and suicide helped to bring about the historic decision by the FDA to require a "black box" warning label on all antidepressants, except Prozac.[46] The black box warning label must describe the increased risk in suicidal thinking among children and adolescents using antidepressants, and must indicate that the medication has not been approved for such use. Black box warning labels are the most serious type of warning labels required by the FDA and are much feared by drug manufacturers. The FDA prohibits the use of "reminder ads" on medications with black box labels; "reminder ads" are advertisements designed to remind doctors to prescribe a certain medication and an important advertising vehicle for pharmaceutical companies. The agency also required pharmacists to distribute "MedGuides,"

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[42] Vollmer, *supra* note 39.
[43] *Id*.
[44] Richard Casey, "GlaxoSmithKline Settles Lawsuit with Spitzer," *www.ecommercetimes.com*, (August 26, 2004).
[45] *Id.*

or information intended for the patient describing risk factors, with these medications.[47] Most likely, the FDA was driven to act so dramatically, in part, because of the attention brought by Spitzer's suit against GSK, which framed the FDA as an absentee agency amid serious safety risks.[48]

III. POSSIBLE DEFENSES

Because GSK settled with Spitzer rather than proceed to litigation, the possible defenses GSK may have raised remain subject to speculation. Should an AG bring a similar suit in the future, and should a pharmaceutical company wish to litigate rather than settle, considering potential defenses and their relative merit will prove helpful for all parties involved. A pharmaceutical company may argue that federal preemption demands that the FDA, and not a state regulator, handle such a case and therefore the AG's suit cannot stand. Also, a manufacturer may argue that free speech doctrine ensures that the government cannot regulate commercial speech, such that a state AG's suit is constitutionally unsound. While the viability of such arguments remains questionable, the potential for such defenses suggests that Spitzer's suit against GSK was more complicated than an AG going after a company for simple consumer fraud, and may implicate the very foundation of our federal system and constitutional principles.

1. Federal Preemption

A. The FDA

The Federal Food, Drug and Cosmetic Act ("FDCA") is an enabling statute passed by Congress, which grants the FDA the authority and responsibility to ensure that drugs marketed in the United States are both safe and effective.[49] To accomplish its goal the FDA monitors the development of new pharmaceuticals through pre-market approval clinical trial testing, and

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[47] Press Release, FDA, FDA Launches a Multi-Pronged Strategy to Strengthen Safeguards for Children Treated With Antidepressant Medications (October 15, 2004) (*available at http://www.antidepressantsfacts.com/2004-10-15-FDA-Black-Box-SSRIs-suicide.htm*).

[48] On the Federal side, Congress is currently considering legislation that would require all makers of drugs and medical devices to list clinical trials and their results in a public database. Democratic House Rep. Henry Waxman of California is working with others on a bill that would create a government registry that would contain clinical-trials results. Sen. Edward M. Kennedy, a democrat from Massachusetts is developing similar legislation on the Senate side. Some may argue that Spitzer's suit against GSK has helped propel such legislation by bringing attention to the consequences of allowing pharmaceutical companies to selectively disclose the results of clinical trials. *Meier, supra* note 41; *Martinez, supra* note 2.

[49] 21 USCA § 301.

oversees the marketing and advertising of approved drugs.[50] Thus, the FDA carefully regulates clinical as well as commercial aspects of the pharmaceutical industry.

A manufacturer may only introduce a drug into the market after official FDA approval. The process begins with the manufacturer submitting a New Drug Application, comprised of the manufacturer's proposed labeling which includes the risks associated with the drug, and the manufacturer's evidence that its drug is safe and effective for the uses specified on the label.[51] After the FDA receives the application, the agency engages in a complicated and extensive survey of all the clinical data the manufacturer provides, in order to determine whether the drug is safe enough for public use, and which risks to include on the label.

Under the FDCA's grant of authority regarding drug labeling, the FDA oversees "all labels and other written, printed or graphic matter (1) upon any article or its containers of wrappers, or (2) accompanying such article."[52] Accompanying material refers to printed matter used by sales representatives and the information reproduced in the Physicians Desk Reference Manual, the guide doctors use to learn about risks and side effects of medication.[53] The label is designed to give a physician all the information she requires in making safe prescription decisions. [54] Thus, the process of approval is geared toward ensuring safety for the consumer, while the label itself is designed for the physician.

The importance of clinical trials data is apparent: for the FDA to understand the risks a label must indicate such that physicians can make proper prescription decisions, the agency must be apprised of all the negative data the manufacturer has encountered. Of course the manufacturer would like to minimize such negative data, both to ensure that its drug gets approved, and also to induce physicians to view the drug as safe for a large consumer base. Similarly, even when the pharmaceutical company does submit negative data to the FDA, it is the FDA, and not the manufacturer, that ultimately decides which risks should be included on the label.

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[50] "Specifically, once approved for public use, prescription drugs must be labeled and advertised within stringent parameters under the Food Drug and Cosmetic Act to ensure that they are not misbranded or advertised in a misleading manner." Todd A. Rodriguez, *Physicians and the Pharmaceutical Industry: Knowing When to Look a Gift Horse in the Mouth*, HEALTH LAW HANDBOOK §8:8 (2002).

[51] The "label" is the package insert or prescribing information that is usually included with the drug, but not necessarily affixed to the bottle.

[52] W. John Thomas, *Direct-To-Consumer Pharmaceutical Advertising: Catalyst for a Change in the Therapeutic Model in Psychotherapy?* 32 CONN. L. REV. 209, 213 (1999) (*citing* 21 U.S.C. § 321(m) (1994).

[53] *Id.*

[53] *Id*.

[53] *Id.*

[54] Denise K. Top, *How the Rise of Federal Bureaucratic Powers Challenges the Role of Courts in Adjudicating Claims of Injury Inflicted by Prescription Drugs*, 34 GOLDEN GATE U. L. REV. 393, 400 (2004).

B. Federal Preemption, Generally

Federalism requires a balance of power between state and federal governments to maintain and order a predictable and effective schema for regulation. The Supremacy Clause of the United State Constitution demands that federal law preempt state law in certain situations.[55] "If it is possible to comply with both the federal and non-federal requirements, the federal requirements win."[56] However, it is well established that "[c]onsideration of issues arising under the Supremacy Clause start[s] with the assumption that the historic police powers of the States [are] not to be superceded by … [a] Federal Act unless that [is] the clear and manifest purpose of Congress."[57]

Four situations where courts recognize preemption are: 1) Where congress, using its power from the Supremacy or Commerce Clause, expressly states within a statute that federal law preempts state law ("express preemption"); 2) Where the federal government clearly occupies the entire field, leaving no space for the states to contribute to the regulatory schema, or where an act of Congress touches a field where federal interest is so dominant that it is assumed to preclude state laws on the same subject ("field preemption"); 3) Where federal law conflicts with state law ("conflict preemption"); and 4) Where overlap between state and federal law makes the federal laws difficult to uphold ("obstacle preemption"). [58] Still, "[t]he purpose of Congress is the ultimate touchstone" of preemption analysis.[59]

C. The FDA and Federal Preemption

A pharmaceutical company raising a defense to a state AG bringing suit for failure to disclose would argue that the any action by the state that purports to regulate the pharmaceutical industry is preempted by the FDCA. While the FDCA does contain some provisions that expressly preempt state law, none of those provisions are at issue under the present circumstances. Thus, a pharmaceutical company up against a state AG bringing suit for fraudulent concealment would have to rely on one of the implied forms of preemption: field,

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[55] U.S. Const. art. VI, cl. 2; Gibbons v. Ogden, 22 US 1, 3 (1824).
[56] James T. O'Reilly, FOOD AND DRUG ADMINISTRATION, *Preemption of Tort Cases by FDA Activities*, FDA 2d §26:7 (2004) (*citing Fidelity Federal Savings & Loan Ass'n v. De La Cuesta*, 458 US 141, 153 (1982)).
[57] Dowhal v. SmithKline Beecham Consume Healthcare, 88 P.3d 1, 7 (2004) (*citing* Cipollone v. Liggett Group, Inc., 505 U.S. 504, 516 (1992)).

[58] James T. O'Reilly, *A State of Extinction: Does Food and Drug Administration Approval of Drug Label Extinguish State Claims for Inadequate Warnings?* 58 FOODDLJ 287, 289 (2003).
[59] Dowhal, *supra* note 57, at 7 (citing Cipollone at 516).

conflict or obstacle preemption, in arguing that the FDA, and not the state AG is the proper regulator.

As discussed, the FDA closely regulates drugs and the labeling used on drug products, including the warnings those products must provide. A new drug cannot enter the marketplace until its claims are extensively pre-approved by medical review officers who examine the safety data of the drug.[60] The FDCA was amended in 1984 by the addition of the Hatch-Waxman amendments; the dual goals of the amendments were to expedite the introduction of lower cost generics by easing the burden of applying for FDA approval, while simultaneously inducing pharmaceutical companies to invest in research and development of new drugs. The FDCA, with the Hatch-Waxman amendments do not allow for a private right of action, but have been held to not completely preempt state law claims.[61]

Where congress does not expressly preempt state law regulation, as is the case with the FDCA under these circumstances, federal courts routinely apply a four factor test to determine whether or not there is implied preemption. The test considers: "1) the aim and intent of Congress as revealed by the statute itself and its legislative history; 2) the pervasiveness of the federal regulatory scheme as authorized and directed by the legislation and as carried into effect by the responsible federal administrative agency; 3) the nature of the subject matter regulated and whether it is one which demands exclusive regulation in order to achieve a uniformity vital to national interest; and 4) whether, under the circumstances of the particular case, state law stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress."[62]

a. Court Decisions

Courts have divided in applying the four factor test to FDA Preemption cases. Some courts applying the four factor preemption test in the context of the FDA have found that, under the circumstances presented, there was no federal preemption, and state laws could apply to pharmaceutical companies, indicating that a pharmaceutical company raising federal preemption as a defense will have to make a strong argument for preemption. In one case a federal court found no federal preemption for state-law claims brought against manufacturers for damages

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[60] *W. J. Thomas, Supra*, note 53 (*citing* 21 USCA §355).
[61] Anne K. Wooster, Annotation, *Construction and Application of Hatch-Waxman Act*, 180 ALR Fed. 478 (2004); In re Cardizem CD Antitrust Litigation, 105 F. Supp. 2d 618 (E.D. Mich. 2000).
[62] Beverly L. Jacklin, Annotation, *Federal Pre-Emption of State Common-Law Products Liability Claims Pertaining to Drugs, Medical Devices, And Other Health-Related* Items, 98 ALR FED. 124 (2004) (*citing*, for example, Abbot v. American Cynamid Co., (1988 CA4 VA), *cert den.*102 S. Ct. 260; Hurley v. Lederle Laboratories Div. of American Cynamid Co., 851 F.2d. 1536 (CA5 Tex 1988)).

suffered because of a failure to warn of dangers associated with oral contraceptives.[63] Another court found no federal preemption in a claim for damages arising out of a failure to warn tetracycline users of dangers associated with using the drug.[64] These cases suggest that if a court considering a pharmaceutical company's defense of federal preemption views a suit for fraudulent non-disclosure as akin to a failure to warn, that court is unlikely to rule that federal law preempts state regulation, and would allow the state AG to go forth.

However, the issue is far from settled, as another court has ruled that the FDCA does, indeed, preempt claims against pharmaceutical companies for a failure to adequately warn about adverse effects brought under state law. A New Jersey Appellate court stated that deciding upon the legality of a warning label involves balancing competing interests and "The FDA's active involvement at every step of the test's development, approval, and use in the field reflected the risk –utility analysis undertaken by the FDA to address significant public policy considerations."[65] As such, a court may carefully weigh the FDA's role in the purported non-disclosure, and whether the manufacturer's decision not to disclose is part of a larger regulatory design. Interestingly, after Spitzer filed suit against GSK, in a House Energy and Commerce Committee hearing held by the Subcommittee on Oversight and Investigations, on September 9, 2004, committee members indicated that the FDA encouraged drug companies to withhold negative clinical trials from the public, stating that releasing such information could scare parents and physicians, and keep them from prescribing potentially helpful medication. [66] Considering GSK's argument that it submitted all available information to the FDA which, in turn, encouraged non-disclosure to avoid "needlessly" confusing and frightening the public, the argument that the FDA engages in a careful balance, with which states should not interfere, may indicate to some courts that the FDA does carefully control the field, and the pharmaceutical companies should not be subject to state AG jurisdiction.

Notably, however, in Foyle v. Lederle Laboratories, a North Carolina state court found that a manufacturer *can* be held liable under state law despite compliance with federal law if it engaged in fraud or purposefully withheld information. [67] That decision indicates that a court may be sympathetic to the FDA's complicated regulatory scheme, but simultaneously find a pharmaceutical company independently responsible to ensure that its compliance with the FDA does not result in fraud. Another court stated that a defendant may present evidence of

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[63] Stephens v. G.D. Searle & Co., 602 F. Supp. 379 (E.D. Mich. 1985).
[64] In re Tetracycline Cases, 1989 US DIST LEXIS 4130 (WD MO. 1989).
[65] R.F. v. Abbott Laboratories, 745 A.3d 1174, 1180 (2000).
[66] OMB WATCHER, *Supra*, note 10.
[67] Foyle v. Lederle Laboratories, 674 F.Supp. 530 (ED. NC. 1987).

compliance with federal regulations to the jury as a mitigating factor, allowing the jury to use that evidence as relevant in making its decision as to liability.[68]

Also worth noting, in the court's decision in MacDonald v. Ortho Pharmaceutical Corp, a Massachusetts judge responded to a pharmaceutical company's concerns that FDCA requirements regarding disclosure may seem inadequate to juries by pointing out that the FDA commissioner himself noted at 43 Fed Reg 4214 (1978) that the boundaries of civil tort liability for failure to warn are controlled by applicable state law. [69]Although the common-law duty the court usually recognizes is coextensive with the duties imposed by the FDA, where a jury or judge could reasonably conclude that a manufacturer's compliance with the FDA labeling requirements or guidelines was not adequate, arguably the manufacturer should not be shielded from liability by only complying with FDA guidelines.[70] As such, pharmaceutical companies are put on notice that compliance with FDA guidelines may not be enough to avoid liability in tort.

Finally, consumers have tried to bring state law claims based upon common-law "Fraud-on-the FDA" theories of liability.[71] Such a theory posits that a drug company which has defrauded the FDA by failing to properly disclose harmful effects of drugs during the approval process may also be liable to individuals under state law. In Flynn v. American Home Products Corp., a Minnesota intermediate appellate court found that such theories *will* be preempted by federal law. The decision was mostly based on policy, as the court was concerned that allowing such suits could result in claims from all fifty states which would make the burden of applying for FDA approval inappropriately high, perhaps having a chilling effect on submitting approval applications.[72] The concern articulated in Flynn indicates that courts will indeed consider policy in evaluating whether federal law should preempt state claims regarding the FDA. Courts may be especially wary of state suits that would make the liability to pharmaceutical companies so great that the price of introducing new products to the market would result in fewer applications for potentially useful drugs. A defendant in GSK's position could argue that allowing each of the fifty state AG's to potentially bring suit against a manufacturer creates an inappropriate burden and defeats one of the objectives of the FDCA, which was to create a uniform regulatory schema in order to induce manufacturers to engage in expensive research and development.[73]

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[68] Malek v. Lederle Laboratories, Div. of American Cynamid, 125 Ill. App. 3d. 870 (1st Dist. 1984).
[69] MacDonald v. Ortho Pharmaceutical Corp,[69] 394 Mass. 131 (1985).
[70] Beverly L. Jacklin, *supra* note 62.
[71] *Id*.
[72] *Id.* (citing Flynn v. American Home Products Corp., 627 N.W.2d. 342 (Minn. Ct. App. 2001)).
[73] One should note that states can choose, by statute, to shield pharmaceutical companies from facing state liability in addition to FDA regulation. Michigan passed a statute shielding drug companies from liability after approval by the FDA. The state supreme court upheld the statute as constitutional in Taylor v.

However, the usual federal preemption arguments include policy considerations placing a premium on uniformity. Within the context of the FDA a pharmaceutical company will probably make the argument that allowing state claims to stand will result in the balkanization of administering safe and efficacious drug products, and frustrate the FDA's mission. On the other hand, those arguing against preemption often point to the central role of the jury in the American judicial system, and the dangers of allowing federal agencies to cede that role from juries. Also, an argument against preemption could point to the traditional role of the states in protecting consumer rights, and the necessity of having multiple regulators where public safety is concerned.

While canvassing the scope of cases upon which federal courts have addressed federal preemption is beyond the scope of this paper, the current case-law indicates that while federal courts seem to allow state law claims to stand in certain circumstances, the issue is far from certain. Given the unsettled state of the law, a pharmaceutical company will raise a preemption argument. Should a state AG find herself up against a defense from a drug manufacturer that federal preemption disallows the state AG's jurisdiction to bring suit, the state AG should consider the ample case law in support of state law claims surviving the FDCA, and specifically, argue that the FDA sets minimum standards for the drug companies, but the states are entitled to demand greater protection for consumers.

D. Preemption and Pharmaceutical Advertising

In 1962 the FDA became the sole arbiter of prescription drug advertising.[74] Thus, there exists a complicated scheme of regulations promulgated by the FDA regulating the advertising in which drug manufacturers may engage.[75] A pharmaceutical company in GSK's predicament would frame the state AG's suit as an attempt to regulate an issue that is specifically about advertising, and thereby preempted by the FDA. Given the rapidity with which generic drugs are introduced, and the importance of brand recognition in pharmaceuticals, effective advertising has

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SmithKline Beecham Corp., 658 NW2d 127 (Mich. 2003) and under a federal analysis in Garcia v. Wyeth-Ayerst Laboratories, 265 F. Supp. 2d 825 (ED Mich. 2003), Affirmed by Garcia v. Wyeth-Ayerst Laboratories, 385 F.2d 961 (6th cir. 2004). 2 FDA 2d. 25:7 (2004).

[74] 31 USCA §352(n).

[75] Some examples of principles underlying the FDA's advertisement regulation scheme includes: 1. Claims made for drugs with approved applications should not "vary from or exaggerate upon the labeling claims which were reviewed and approved during the drug clearance process at the FDA;" 2. Non-new drugs must have support in data for claims that meet substantial evidence tests or reflects clinical experience; 3. Negative information about the drugs contraindications and warnings must be clearly communicated to the professional audience in "brief summaries," and must be complete enough to withstanding review by the FDA; 4. Exaggerating a drug's effectiveness while playing down its safety-negative aspects may bring regulatory action against the advertiser" *Id.* (citing Bass, *A Basic Checklist for Pharmaceutical Advertising Copy Reviews*, 8 NY ST. BAR FOOD DRUG COSM &MED DEVICE L DIG 8, Jan. 1991, at 10).

become an essential part of the success of the pharmaceutical industry.[76] Originally, under the FDCA and its companion legislation the FDA would regulate the labeling accompanying the pharmaceutical product, while the advertising separate from the drug itself was under the control of the FTC.[77] FDA's guidelines for drug advertising were revised in January of 2004 to be more precise in the extent to which drug companies must disclose negative effects of drugs in consumer advertising.[78] The common FDA remedy for what it perceives to be misleading advertising is to enjoin the continued use of those advertisements, and potentially require remedial advertisements correcting the misleading information conveyed.[79] However, the FDA lacks statutory authority to impose civil damages on drug companies for its unfair marketing practices.[80]

A pharmaceutical company could argue that Spitzer's suit was really about the information included in the labels accompanying the drugs, and regulating those labels is entirely within the FDA's advertising authority. An AG could counter such an argument by arguing that a suit alleging fraudulent withholding of clinical trials goes beyond advertising and addresses disclosure responsibilities, and the content of the labels are merely incidental.

2. First Amendment and Commercial Speech

The lawsuit Spitzer filed against GSK, by alleging fraud in GSK's failure to disclose information, potentially implicates first amendment free speech issues. A pharmaceutical company taken to task for failing to disclose results of clinical trials would raise a constitutional objection to an AG's attempt to regulate speech.

A. Commercial Free Speech, Generally

The Supreme Court has recognized that commercial free speech is not entirely unprotected, and "has afforded commercial speech a measure of first amendment protections 'commensurate' with its position in relation to other constitutionally guaranteed expression.[81] Under the Supreme Court case Central Hudson Gas & Elec. Corp. v. Public Serv. Comm'n of NY, in an opinion written by Justice Powell, a divided court recognized the "distinction between

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[76] James T. O'Reilly, *Drug Economic and Advertising Issue.* 1 FOOD AND DRUG ADMIN. §15:10 (2004).
[77] *Id.*
[78] *Id.* (citing www.fda.gov/cber/gdlns/consumad.pdf (Jan. 2004)).
[79] *Id.*
[80] *Id.* (citing United States Ex. Rel. Franklin v. Parke-Davis, 147 F. Supp. 2d 39 (D. Mass. 2001)).
[81] Lorillard Tobacco Co. v. Reilly, 533 U.S. 525, 553 (2001) (*citing* Virginia Bd. Of Pharmacy v. Virginia Citizens Consumer Council Inc., 425 U.S. 748, 762 (1976); Florida Bar v. Went For It, Inc., 515 U.S. 618, 623 (1995)).

speech proposing a commercial transaction, which occurs in an area traditionally subject to government regulation, and other varieties of speech," and introduced a test for evaluating government regulation of commercial speech.[82]

Under the Central Hudson framework, a court should determine whether regulation of commercial speech is acceptable by asking as a threshold matter whether the speech concerns unlawful activity or is misleading. If the answer is no, then the speech is not protected by the first amendment. If, however, the speech is lawful and not misleading then the court will ask whether the asserted governmental interest is substantial, whether the regulation directly advances the governmental interest asserted, and whether the regulation is more extensive than necessary to advance that interest. [83] For the regulation to be constitutional the court must answer all three questions in the affirmative.

In Thompson v. Western States Medical Center, the Supreme Court indicated that it would also consider "the amount of beneficial speech prohibited" by a government regulation. [84] In that case the court struck down a provision under the Federal Drug Administration Modernization Act ("FDMA") prohibiting pharmacists from advertising compounded drugs. The court found that the speech-related provisions of the FDMA were unconstitutional because they could have been less restrictive and achieve the same ends. Thus, while commercial speech may be evaluated less searchingly than non-commercial speech, the court is clearly willing to find government restrictions on commercial speech unacceptable, even where the government's goal is laudable and aims to protect consumers.

Importantly, however, the Court's analysis in Thompson focused on a regulation that purported to restrict advertising in a manner such that a consumer would receive *less* and not *more* information. In a regulation the court labeled "paternalistic," the majority stated, "We have previously rejected the notion that the Government has an interest in preventing dissemination of truthful commercial information in order to prevent members of the public from making bad decisions with that information."[85] Applying this reasoning to the present scenario suggests that government action purporting to submit *more* and not *less* information to allow the public to make educated choices would not be viewed as curtailing constitutional rights, but rather, would be a substantial governmental interest.

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[82] Central Hudson Gas & Elec. Corp. v. Public Serv. Comm'n of NY, 447 U.S. 557, 562 (1980). Blackmun, Stevens and Brennan all concurred in the decisions, while Rehnquist dissented.
[83] *Id.*
[84] *Id.;* Thompson v. Western States Medical Center, 535 U.S. 357 (2002)
[85] Dowhal v. SmithKline Beecham Consumer Healthcare, 88 P.3d 1, 14 (2004) (*citing* Thompson at 374).

Freedom of commercial speech simultaneously recognizes the freedom not to speak. Still, "[a]lthough '[t]here is necessarily, and within suitably defined areas, a concomitant freedom not to speak publicly, one which serves the same ultimate end as freedom of speech in the affirmative aspect' the Supreme Court has indicated that '[p]urely commercial speech is more susceptible to compelled disclosure requirements' than is non commercial speech due to its 'greater objectivity and hardiness.'[86] Therefore, a manufacturer asserting a free speech right not to disclose negative clinical data comes up against potentially unfriendly Supreme Court dicta.

B. State AGs, Pharmaceutical Companies and Freedom of Commercial Speech

While the freedom of commercial speech inquiries taken to court are usually in response to affirmative legislation or regulation, whether promulgated by the federal or state governments, a company brought to court by a state AG for failure to disclose could equate such a lawsuit with an attempt at regulating speech. Although Spitzer did not promulgate affirmative regulations requiring disclosure, GSK could have argued that by bringing suit, Spitzer effectively acted as though such regulations existed within the fabric of state fraud doctrine. As such, GSK may have argued that Spitzer's ability to bring such a suit unconstitutionally curtails its right not to speak. As mentioned in the media, had GSK not settled, "Mr. Spitzer may have a constitutional hurdle to overcome… freedom of speech [includes] the right to stay silent. Having informed regulators about the studies it performed, Glaxo had no duty to inform doctors or patients about trials the FDA itself takes responsibility for evaluating and passing along. Moreover, it's hardly a crime for a company to talk up its products; that's how many consumers learn about remedies in the first place."[87] The reality that GSK did submit the data to the FDA indicates that its speech rights may protect it from the duty to speak, given its disclosures.

There are two kinds of speech potentially at issue. One type of speech is the commercial advertising a drug company uses to raise awareness and interest in its product. The second kind of speech at issue is the drug companies' labels which are directed more towards physicians than consumers. It is the second kind of speech that was under consideration in Spitzer's suit against GSK.

An AG countering a free speech defense should note the threshold inquiry in the Supreme Court's analysis of commercial free speech. Where speech is misleading the constitution does not protect the speaker. Just as a speaker has a right *not* to speak, where silence is misleading it may

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[86]Greg W. Evans, *The Food and Drug Administration's Regulation of Prescription Drug Manufacturer Speech: A First Amendment Analysis,* 58 FOOD & DRUG L.J. 365, 379 (2003) (*citing* Harper & Row Pub., Inc. v. National Enters., 471 U.S. 539, 559 (1985)).

[87] Editorial, *Paxil Man,* WALL. ST. J., June 21, 2004, at A16.

not be protected. Where a pharmaceutical company does not disclose negative results from clinical trials, even if it does not affirmatively indicate that a drug is effective for a certain use, given the prevalence of off-label prescriptions, silence can be seen as misleading speech that it subject to regulation without raising constitutional issues.

However, an AG may have a difficult time making the prima facie assertion that a pharmaceutical company's non-disclosure is per se misleading. In evaluating freedom of speech claims the burden of showing that commercial speech is misleading lies with the government entity purporting to regulate that speech. The regulator must present sufficient evidence to support its claim of deception. Further, "[e]ven when advertising communicates only an incomplete version of the relevant facts, the First Amendment presumes that some accurate information is better than no information at all."[88]

Because it may be difficult to end the free speech inquiry at the threshold question of whether concealing clinical trials is inherently misleading, an AG bringing suit should argue substantial government interest, direct advancement of that interest, and narrow tailoring in the attempt to bring suit for fraudulent behavior.

An AG may define it substantial and direct interest as protecting public health and a consumer's ability to make educated decisions regarding use of medication as well as a physician's ability to make informed prescription choices. The AG must show that the potential for real harm without regulation by the state.[89] Next, the AG should argue that a suit for fraudulent concealment of material information is brought precisely to remedy the harms caused by that non-disclosure. The AG should be able to "establish a direct and material link between alleviation of the harm it seeks to prevent and its speech restraint."[90] If the harm is withholding information that is valuable in prescription and usage decisions, then allowing a state AG to bring suit where disclosures are inadequate could be viewed as linked to preventing that harm. Finally, the AG should show that allowing suits of this kind are narrowly tailored to serve its legitimate goals. The Supreme Court explained that this requires the regulator to "carefully calculate the costs and benefits associated with the burden on speech imposed."[91] The State AG could argue that allowing lawsuits for fraudulent concealment is much less burdensome than affirmative regulations, and given the cost to the AG for bringing such suits, the likelihood of frivolous

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[88] Evans, *Supra* note 88 (*citing* Central Hudson, 447 U.S. at 662).
[89] *Id.* At 386.
[90] *Id.*
[91] *Id.* (*citing* Cincinnati v. Discovery Network, Inc., 507 U.S. 410, 417 (1993)).

claims would be low. Further, an AG like Spitzer in the GSK suit is not purporting to create comprehensive regulations that will preempt the federal control of pharmaceutical advertising. [92]

Furthermore, an AG litigating off-label use may have an especially robust argument. Spitzer claims that the off-label prescription of drugs is a grey area that is not completely regulated by the FDA. Because the FDA does not regulate the actual practice of medicine, doctors' off-label uses for drugs are beyond FDA jurisdiction.[93] Also, according to Spitzer, the FDA has been hampered by first amendment rulings that keep it from fully controlling the information companies must provide to doctors. Spitzer maintained that his lawsuit was not meant to limit off-label usage of drugs, but rather to insure that doctors receive complete information in a regulatory realm where the FDA's hands are tied by first amendment rulings. [94] Such an argument may persuade the court that even where the FDA seems to control the entire field, the case of off-label drug usage is uniquely unregulated by the FDA, and therefore relies on the states to ensure proper disclosure for the safe and effective usage of drugs. However, a pharmaceutical company can attempt to counter any arguments regarding speech rights by pointing to the Freedom of Information Act ("FOIA"), arguing that it properly disclosed the information, and that information was available to outside associations and state governments though a FOIA request, precluding the need for litigation as a means of disseminating information.

IV. POLICY

1. The Role of State Attorney General

The state AG occupies a unique position in state government. The AG derives his power from the common and statutory law of a given state.[95] While the negative unpublished studies on antidepressants came to light gradually in medical journals, Spitzer's suit was the first to label the suppression of data "illegal." An attorney in Spitzer's office referred to the suit as a "garden-

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[92] In Lorillard Tobacco Co. v. Reilly, 533 U.S. 525 (2001), the Supreme Court held that certain regulations promulgated by the AG to control tobacco advertisements were preempted by the Federal Cigarette labeling and advertising act. In considering the commercial speech argument as it applied to smokeless tobacco, not covered by the Federal Law and therefore not preempted, the court applied the Central Hudson test and found that the regulations were not reasonable to fit the ends of the regulatory scheme and was therefore an unconstitutional restraint on commercial speech.

[93] *Id.* (citing Klein v. Biscup, 109 Ohio App. 3d 855 (1996)).

[94] *New York Attorney General Sues GlaxoSmithKline Over Alleged Concealment of Paxil Trials, Citing Consumer Protection*, Kaiser Newtowrk.Org, June 3, 2004 (*available at* www. Kaisernetwork.org/daily_reports/rep+index.cfm?DR_ID=24035).

[95] 7 AM. JUR. 2D *Attorney General* §§7-49 (2004)

variety" consumer fraud case that AGs often bring.[96] However, when applied in the context of pharmaceuticals, the lawsuit appears less garden-variety, and more like an inventive use of AG prosecutorial power.

Many describe Spitzer as over-stepping his circumscribed role as state AG, calling him at worst, an extortionist, and euphemistically an "activist" AG. "Businesspeople, defense attorneys, and… insurance men" allege that Spitzer has "turned prosecutions into power showdowns and personal drubbings. 'Authoritarian, liberal egomaniac,' says one businessman."[97] While many lauded his taking the pharmaceutical industry to task by suing GSK, others see it as not only exceeding his prescribed role, but contrary to the public interest. An editorial in the Wall Street Journal accused the suit of threatening to "damage good science and public health," and refers to Spitzer as "America's new self-anointed drug czar."[98] Referring to Spitzer stepping on the toes of the FDA, the editorial accuses Spitzer of "gate-crashing" one of the most regulated industries in the US. "Though it may come as a surprise to the New York Attorney General, Congress has for better or worse given no little thought to drug regulation. It has amended the insanely detailed Food, Drug and Cosmetic Act 100 times. Though it all one principles has remained in tact: The only entity authorized to enforce federal drug law is the FDA."[99] The editorial argues in no uncertain terms that it is dangerous for a prosecutor to making health-policy decisions for which he is not accountable.

Still, Spitzer's suit reveals precisely how necessary state AG's are when federal agencies are clearly not adequately doing their jobs. "'Just like with the S.E.C.' Mr. Spitzer said, 'we're asking where has the F.D.A. been all these years when clinical data has been hidden from public scrutiny? They have simply failed to confront the problem."[100] The role of the state AG should not be considered in a vacuum; rather, in deciding whether or not an AG is "gate-crashing" it is best to consider the political and regulatory climate the AG purports to crash. In the case of the FDA, perhaps a gate-crasher is necessary to break up the comfortable tea-party between the industry and its federal regulator.

2. Agency Capture

State AGs are especially vital in vindicating consumer rights where the federal agency assigned to regulate an area seems to be acting in the interest of the industry, rather than the broad

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[96] Martinez, *supra* note 2.
[97] Steve Fishman, *Inside Eliot's Army*, NEW YORK MAGAZINE, Jan. 10, 2005 at 18.
[98] WALL ST. J., *supra* note 89.
[99] *Id.*
[100] Gardiner Harris, *Maker of Paxil to Release All Trial Results*, N.Y. TIMES, August 26, 2004.

public interest. Given the economic and political strength of the big pharmaceutical companies in the US, concern that the FDA has been "captured" by the industry is more than mere Kafkaesque cynicism, but a real concern for those worried about whether or not the FDA can do its job.

One indication that the FDA is no longer serving the public, as per its congressionally mandated mission, are the copious examples of the FDA intervening in private pharmaceutical litigation on the side of manufacturers. In March 2002, the FDA appeared as amicus curiae on behalf of the defendant manufacturer in Dowhal v. SmithKline Beecham Consumer Healthcare, "a citizen suit backed by the California Attorney General" where the defendant failed to abide by a California regulation requiring certain warnings on over the counter nicotine replacement products.[101] In its brief, the FDA stated that the plaintiff's claims conflicted with the FDA's determinations regarding misbranding, and therefore the FDA's determinations were preemptive. Similarly, in August 2002 the FDA intervened in a class action against GSK for failure to warn about the side effects associated with Paxil withdrawal. In In re Paxil Litigation the FDA made federal preemption arguments ultimately rejected by the California District Court. The court stated, "FDA's… position vitiates, rather than advances the FDCA's purpose of protecting the public. That is, FDA and GSK invite the Court to find that in enacting the FDCA for the purposes of protecting public health, Congress not only declined to provide for a private cause of action, but also eliminated the availability of common law state claims. This position contravenes common sense."[102] While the court did not accuse the FDA of agency capture as such, it was clearly dismayed by the FDA's intervention on the side of the pharmaceutical company, and also indicated a willingness to allow state claims.

Some argue that the FDA's stance in favor of big manufacturers began with President Bush's appointment of Daniel Troy as chief counsel of the FDA in August 2001. [103] "Rep. Maurice Hinchey (D-N.Y.) -- a member of the House Appropriations Subcommittee on Agriculture, Rural Development, FDA and Related Agencies -- in July said that Troy had violated an FDA tradition to avoid intervention in lawsuits against pharmaceutical companies unless asked by the courts."[104] Troy resigned in November 2004, leaving an ailing FDA reeling from recent announcements that Vioxx causes heart disease and the flu vaccine shortage. The appointment of Daniel Troy as chief counsel of the FDA, and the serious criticism surrounding his decisions to side with big PhRMA in various scenarios, contrary to FDA tradition, indicates the importance of

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[101] Barth, *The Fox in The Chicken Coop: FDA's Recent Intervention in Pharmaceutical Litigation*, I-1
[102] *Id.* At I-2
[103] Daniel Troy allegedly represented Pfizer while working as a partner at the Washington law firm Wiley, Rein & Fielding.
[104] MEDICAL NEWS TODAY , November 18, 2004, available at www.medicalnewstoday.com/medicalnews.php?newsid=16540.

having a check on the unbridled power of the FDA, where it can, and has, been captured by the industry it purports to regulate. [105]

FDA drug safety reviewers themselves have been vocal about the failure of the FDA to protect consumers. "In testimony before the senate finance committee, Dr. David Graham, the reviewer in the Food and Drug Administration's Office of Drug Safety, used fiery language to denounce his agency as feckless and far too likely to surrender to demands of drug makers… 'We are faced with that may be the single greatest drug catastrophe in the history of this country or the history of the world,' Mr. Graham concluded."[106] An FDA that panders to the pharmaceutical industry is inadequate to protect public health and safety, suggesting that a state official who steps in to vindicate the rights of his constituents is using his prosecutorial power for the essential purpose of protecting the public interest.

3. FDA Failures

Additionally, the FDA itself recognizes that its resources are not great enough to manage its workload, indicating the value of an alternative source of regulation. "The FDA's website notes that 'trends in a wide variety of external factors are generating workloads and public expectation that are poorly matched with FDA's capacity to respond in a timely, adequate manner,'… indeed the FDA reportedly has only 14 employees to review 32,000 pieces of promotional material from drug makers."[107]

Specifically, in the case of antidepressants and teenage suicide, the FDA proved itself incapable of properly managing seemingly inconclusive data. In June 2003 when concerns first arose regarding links between antidepressant use and suicidal behavior, the FDA decided to engage in its own investigation, rather than rely on the external studies it received. The FDA assigned its leading expert, Andrew Mosholder, to begin examining the alleged links between Paxil and suicide; however, reports indicate that when the expert submitted his findings, indicating that children taking Paxil were twice as likely to engage in suicide-related behavior, rather than release that data to the public the FDA ordered more studies.[108] In March 2004, after Mosholder's data had been presented to the agency, the FDA issued a warning to doctors that the

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[105] "Troy's office, which dispatches warning letters to drug companies about potentially false advertising, has cut the rate by which the FDA issues those warnings by two-thirds in the past year. Previously, such letters were sent out by a branch within the FDA. But Troy, after arriving at the FDA in August 2001, arranged for all warnings to go through his office." Barth, *The Fox in the Chicken Coop: FDA's Recent Intervention in Pharmaceutical Litigation*, I-8 (citing Michael Kranish, *FDA's Counsel's Rise Embodies US Shift*, BOSTON GLOBE , Dec. 22, 2002).
[106] Gardiner Harris, *supra* note 35.
[107] Barth, *supra* note 105, at I-8.
[108] Elizabeth Shogren, *supra* note 4.

use of antidepressants could lead to potential problems in young users, but stated that no conclusive scientific evidence existed, and its warnings were based on "anecdotal complaints."[109] In its defense, the FDA claims that its officials had questioned the reliability of data upon which Mosholder had based his conclusions, and that even the pharmaceutical companies conducting clinical trials may have been too quick to label certain behaviors "suicidal."[110] Further, Mosholder was forbidden from making his conclusions public at an advisory committee meeting in February, as the agency considered his research premature and ambiguous. The FDA then commissioned an outside examination on pediatric-trial data by a team of reviewers led by researchers at Columbia University. [111] While the FDA attempted to find conclusive data before making it public, it worked too slowly, and, some might say, with too much caution.

Furthermore, there is debatably an inherent conflict of interest in the FDA's dual role of approving medication by announcing its safety, and its simultaneous responsibility to prove itself wrong by continuously reviewing and releasing risk factors on those very same medications. Some critics argue that the US needs an independent agency to consider drugs that are already on the market. The current system for monitoring the side effects of approved drugs, called Medwatch, is arguably "rife with inadequacies" as the drug makers provide the information about side effects on their own products and report that information to the FDA. "The companies 'may be tempted to conceal' unfavorable data… and the drug agency may be too slow to order studies to follow up hits of trouble."[112] Even without the problem of agency capture, the FDA seems inadequate to fully police the pharmaceutical industry on its own.

4. Overly Activist Attorneys General?

Even those who concede that the FDA is an ailing agency in dire need of reform still may argue that state AGs are not the proper officials to step in and regulate. In response to Spitzer's suit J-P Garnier, GSK chief executive, accused Spitzer of "bullying" and "extortion."[113] The proper inquiry, however, seems not to be whether the state AG is abusing his power, but rather, whether the stock market effects of bringing suit can be so dramatic that regardless of the legal merits a company will have no real opportunity to defend itself. Thus, one fear in allowing AGs

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[109] *Id.*
[110] *Id.* (An example of a behavior the agency would not have labeled as suicidal were instances where children taking SSRIs deliberately cut themselves but were not planning on killing themselves).
[111] Anna Wilde Mathews, *FDA Revisits Issue of Antidepressants for Youths: New Analysis May Pressure Agency to Set Limit on Use Because of Suicide Risk*, WALL ST. J. August 5, 2004.
[112] Denise Grady, *A Medical Journal Calls for a New Watchdog on Drugs*, N.Y. TIMES, Nov. 23, 2004 at A18.
[113] Ingrid Mansell, *Spitzer Climbs Down on Claims Against GSK*, TIMES ONLINE , August 27, 2004.

to bring high profile lawsuits in heavily regulated areas is the potentially inordinate burden such suits can place on companies merely as a cost of doing business in the US. As Garnier stated after Spitzer filed suit, "[t]his is becoming an outrageous cost of doing business… The legal system is getting out of control… Lately the pharmaceuticals industry has been attacked on many fronts, and it's a distraction factor for all companies."[114]

In the present case, GSK's stock prices fell 1.38 points, or 3.2%, to 41.39 following Spitzer's accusations of consumer fraud for concealing data regarding safety and efficacy of using Paxil to treat children.[115] Shares in GSK then rose swiftly after the announcement of the $2.5 Million settlement "on relief that Mr. Spitzer had not gained a huge financial settlement, as he has from Wall Street Investment banks over the dot-com bubble and from fund managers over market timing abuses."[116]

While any company targeted by a state AG, especially Spitzer, is likely to consider the suit an unfair cost of doing business, it may be a very real problem when the financial strains of AG litigation make it such that an entity can no longer exercise its legal right to be heard. It is worrisome when a state regulator can so influence the market that he can shape industry behavior merely by filing a lawsuit. At the same time, however, Spitzer's history proves that AGs can be especially adept at uncovering widespread fraud and protecting consumers where federal agencies fail. Further, it is not so clear that Spitzer has truly stepped beyond his proscribed duties: "'It is not unusual for state attorneys general to be involved in pharmaceutical cases, and it is not unusual for them to bring cases against unfair and deceptive practices," said James E. Tierney, who heads Columbia Law School's National State Attorneys General Program. "This is a natural outgrowth.' "[117] While Spitzer's "activism" may worry members of the business community, perhaps he is acting in alignment with the natural evolution of the state AG's role in a constantly shifting regulatory scheme.

5. <u>The Settlement between GSK and Spitzer: Case Study in AG's Success at Addressing Broad Problems</u>

Spitzer's suit against GSK was brought, purportedly, not to remake the federal scheme of regulating drugs, but rather, to fill a gaping hole in the FDA's regulatory regime. The lawsuit indicates that Spitzer viewed the withholding of information from physicians as not only illegal,

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[114] Jeanne Whalen, *Glaxo CEO says Paxil Suit Shows Unfair Burden*, Wall. St. J., June 4, 2004, at.B3.
[115] *Abreast of the Market*, WALL ST. J., June 3, 2004, at C3.
[116] Mansell, *supra* note 113.
[117] Brooke A. Masters, *N.Y. Sues Paxil Maker Over Studies on Children*, WASHINGTON POST, June 3, 2004 at E1.

but contrary to the public interest. As reflected by the settlement with GSK, Spitzer views a public register of clinical trials managed by pharmaceutical companies to be an adequate response to that problem. Those who argue that Spitzer over-stepped by entering a heavily regulated realm may argue that the settlement Spitzer reached with GSK evinces the inability of a state regulator to properly confront issues facing the pharmaceutical industry. Such arguments allege that if Spitzer's suit against GSK continues to influence pharmaceutical companies to release all of its clinical data physicians may experience information-overload and end up less informed than under the current, selective-disclosure regime.

On the other hand, Spitzer's message that pharmaceutical companies that conceal data will be held accountable may be viewed as an important piece of a greater attempt to allow comprehensive information to reach prescribers. In recent years, health care organizations have been independently analyzing research findings about drugs and creating "evidence-based reviews" that consider the quantity and quality of clinical trials and studies on a drug and look at the drug's effectiveness and risks as compared to competing products. These reviews are guided both by quality and cost, as "many newer drugs prove to be only marginally better, if that, than older ones," and older drugs, with generics available tend to be less expensive.[118] The reviews act, in part, to unearth scientific information in order to balance the aggressive advertising of drug companies that can drive doctors to write prescriptions for newer, potentially less effective medications. To complete these reviews researchers attempt to pull together all published and unpublished clinical trials by reviewing all available literature and asking pharmaceutical companies for data.[119] Such reviews are meant to close the "medicine's data gap." Still, such an effort remains reliant on drug companies releasing negative clinical data. While such attempts at allowing greater information to doctors making prescribing decisions are well-founded, the current FDA schema provides no incentives to drug companies to disclose the information requested. As such, Spitzer's signal that drug companies will be held accountable for withholding information that thereby misleads prescribing physicians seems to have more force than any regulatory obligation now in place. Given the broad attempt across different levels of the health care industry to truly determine the efficacy and safety of drugs, and the continued reliance on clinical studies produced by the drug companies, Spitzer's indication that drug companies must disclose all data seems to advance multiple aspects of attempts to improve the safety of drug use in America. [120]

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[118] Barry Meier, *Doctors, Too, Ask: Is This Drug Right?*, N.Y. TIMES, December 30, 2004 at B1.
[119] *Id.*
[120] Some say that focusing on the pharmaceutical companies may not be enough, as the researchers themselves may be blameworthy. In fact, most of the pediatric antidepressant studies were run, in part, at

Although Spitzer's suit indicates that pharmaceutical companies may face additional liability from state attorneys general for withholding clinical trial results, the actual impact of the suit on industry behavior remains questionable. Following Spitzer's suit against GSK, PhRMA as well as most large pharmaceutical manufacturers in the US announced plans to voluntarily disclose clinical trial data, but have largely failed to follow through on these promises. "A Globe review of the websites indicates that the voluntary approach has produced limited disclosures thus far. Last year's commitment by members of [PhRMA]… has resulted in a total of 26 drugs listed on the clinical trials results website… That is out of a total of more than 10,800 prescription medications and dosages sold in the United States."[121]Furthermore, most of the data posted on the websites was already publicly available. Critics argue that the industry's periodic announcements about their commitment to transparency are "thinly disguised public relations efforts."[122] In its defense, PhRMA argues that upon announcing its plans to publicize clinical trials data in September of 2004, the organization stated that it would take a full year to post all the results.[123] Thus, although Spitzer's suit against GSK added "momentum" to the push for clinical trials disclosures, it remains uncertain whether a regime encouraging voluntary disclosure will sufficiently induce drug companies to publicize negative clinical trial data, or whether Spitzer's suit has merely led the industry to make promises it does not plan on keeping.

Clearly, the settlement between GSK and Spitzer should not be viewed as the quintessential solution to the problem of non-disclosure of clinical data to prescribers. From the manner in which studies are conducted to the complicated regulatory scheme, Spitzer's attempt to foster greater transparency is but one piece of the puzzle. Still, the outcome of the GSK litigation has brought about changes in standards applied to disclosure in the drug industry and has brought the issue to the forefront of public debate, indicating that Spitzer's foray into pharmaceuticals was at least marginally successful.

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medical schools and led by academics. Contracts between the drug companies and academic scientists may include confidentiality clauses, confusing scientists about whether they are allowed to disclose data. Furthermore, there is potentially a conflict of interest, where drug companies are paying the researchers to conduct the studies. "academic researchers are frequently guilty of spinning test findings, either to please a test sponsor or a journal editor or to advance their own agenda… Studies of the issue suggest more bias in industry-sponsored studies." The researchers may also earn speaking and consulting fees from the drug company. Many research facilities have conflict-rules and conflict review to make sure researchers are not unduly influenced by the companies for whom they are conducting research. Scott Hensley and Leila Abboud, *supra*, note 4o.

[121] Christopher Rowland, *Drug Firms Lagging on Openness Despite Vow Few Studies Publicized,* BOSTON GLOBE, Jan. 9, 2005 (*available at* http://www.boston.com/business/articles/2005/01/09/drug_firms_lagging_on_openness/).
[122] *Id.*
[123] *Id.*

V. Conclusion

Eliot Spitzer's lawsuit, filed during the summer of 2004 against GlaxoSmithKline, reveals the tremendous power and, some may argue, importance of state AGs in protecting the public interest. Spitzer ingeniously chose a lawsuit with a particularly human element, suing GSK over an issue that centered on the prevalence of suicide among young Paxil users as a means of attempting to induce greater disclosure of clinical trial information across the pharmaceutical industry as a whole. While the abstract issue was non-disclosure, the media predictably geared coverage toward maudlin tales of depressed teenagers driven to violence and suicide by virtue of pharmaceutical company fraud. While GSK could have attempted to cling to esoteric legal arguments of federal preemption and free speech, it was clear these theories of non-liability would have little effect on a jury facing the human fall-out of the Paxil allegations, or upon investors concerned about floundering stock prices. While GSK seemingly had little legal recourse given the context of the suit and the stock market repercussions, the suit provides a forum for considering the role of the state AG and the powerful effect lawsuits can have on entire industries.

Considering the possible defenses a pharmaceutical industry can raise in the context of such litigation reveals the stark chasm between the human element at stake and the legal defenses available. Spitzer's case was, legally, about fraud and disclosure, but elementally about protecting public health and safety. Where there is a wide information gap, a powerful industry, an ineffective federal agency, and children committing suicide, defenses focusing on preemption and free speech would raise little public support. Eliot Spitzer took a stance in attempting to correct a market failure where competition drove an industry to withhold important data and the regulatory agency designed to prevent that failure had been utterly captured. Pharmaceutical manufacturers will do everything in its power to maintain the current regime, where the powerful industry's practices are shrouded in secrecy, protected by the FDA and geared toward maximizing profits. Yet, while manufacturing pharmaceuticals is indeed a competitive business, it is a business that intrinsically implicates the safety of the population. However his critics may choose to classify him, Spitzer's suit against GSK was geared toward protecting public health and successfully revealed the gaping hole in regulation of the industry, thereby rooting itself firmly within the province of the state AG. Spitzer v. GSK illuminates the ways in which the state AG can serve the important function of protecting the public when the federal government fails.