New York’s Attorney General Eliot Spitzer has accused the British-based drug giant Glaxo-SmithKline of consumer fraud because of the manner in which GSK promoted Paxil, an anti-depressant, for children and adolescents. He has accused GSK of misleading consumers by suppressing studies which did not support the drug's efficacy, especially for teenagers with depression.

Going after GSK dovetails nicely with public anti-big pharma sentiment, which has been building over the past few years and stoked by opportunistic pols. This mistrust has been promoted by media attacks highlighting "exorbitant" profits of the industry, escalating drug costs, and the controversy over re-importing cheaper drugs from Canada and elsewhere.

Doctors, not consumers, normally make treatment decisions, and their choices are limited by the FDA’s extremely arduous drug-approval process. So how can drug promotion be labeled consumer fraud? Drug promotion is the bailiwick of the FDA. But Spitzer has had success in other areas usually reserved for the federal regulators, most notably in the securities industry. But our federal drug regulators are widely regarded as the most demanding pharmaceutical regulatory body in the world -- it takes about one billion dollars and over ten years for a drug to win approval. Paxil went through this process and was approved for adult depression in 1992. It was never approved for treatment of youngsters, but physicians can use any FDA approved drug for "off label" use for non-approved indications. One of Spitzer's charges is that GSK promoted Paxil for use in young people, which is a violation of FDA mandates.

Here is where the story gets really dicey: GSK denies promoting Paxil for use in kids and teens. They admit that they did not press for publication of the four studies they did on such use that did not show efficacy, while they did support presentations and publication of the one study that showed efficacy for kids. But they also submitted all of their study data to the FDA, as required, and did not object when one of the authors of a negative study proposed to, and did, present these findings at a major meeting of child and adolescent psychiatrists in 1999. Is that "suppression"?

Spitzer also accuses GSK of fudging data indicating a possible increased risk of suicide, or at least "emotionally labile behavior" which might have been a sign of self-destructive attitude, among young users of Paxil. The FDA analyzed studies involving thousands of subjects over several months, and in March decided to issue stronger warnings to doctors about this possibility, but did not proscribe such use -- although the drug regulators in the UK did so. Again, this does not indicate any plan to hide risk on the part of GSK -- all the study data was available to the FDA committees from the get-go.

It is also relevant that studies of teenage depression therapy are notoriously sensitive to the placebo effect, wherein over one-third of young people respond to inactive "treatment," rendering
statistically significant response rates very difficult to come by.

So it should come as no surprise - and certainly not be actionable - when a study actually does demonstrate efficacy of statistical significance. And of course, such a study is bound to be widely publicized. Prior to approval of a new drug, it must go through up to seventy different clinical trials. A good number of these are bound to fail to support efficacy, even for a safe and effective drug. How should these be dealt with?

If you want to hear about suppression of relevant data, consider this: at the recent national meeting of cancer specialists, more reports of the efficacy of raloxifine (Lilly's Evista) in the prevention of breast cancer in post-menopausal women were published. But the FDA will not allow Lilly to so much as mention this to doctors nor to the public, as the drug has not been approved for cancer prevention, despite numerous "preliminary" studies supporting this use over the past six years or more. A Novartis drug has, once again, demonstrated life-saving properties for women with breast cancer. Effective drugs languish for years while the bureaucrats at the federal drug agency contemplate smidgens of differences in responses. Such excess of caution is the hallmark of the FDA. Some call that suppression of free speech. This is hardly an agency to approve dangerous drugs cavalierly, as Spitzer implies with his prosecution.

The essence of the pending litigation is whether the lack of ardor GSK showed for the negative studies rises to suppression of salient facts for consumers, or at least for their doctors; and if so, does this deserve the label of "fraud"? And if the NYS AG is making this assessment, where does that leave the FDA?

Of course, waiting in the wings are the plaintiffs' attorneys, some of whom have gotten a head start suing drug companies for sociopathic behavior allegedly brought on by anti-depressants. If Spitzer's suit progresses, a cascade of such suits awaits, surely as night follows day.

I suspect the AG knows full well that his attempt to conflate less-than-zealous promotion of ambiguous studies with fraud is bound to fail on its merits -- but his threat will convey his intended message to pharmaceutical companies. Spitzer is beginning a new crusade against drug makers, although he coyly declines to say so outright (nor does he deny it). They have become the PC punching bag du jour, despite being responsible for a large part of America's (and the world's) current level of good health and extended longevity. As the CEO of GSK noted, this new onslaught will have a chilling effect on drug innovation, as drug makers pull away from our litigious climate and consider friendlier shores.