SELLING SICKNESS 2013

People Before Profits

February 20-22, 2013

Washington, D.C.

Confidential Company Documents Obtained in Litigation: Revelations in the interest of public health

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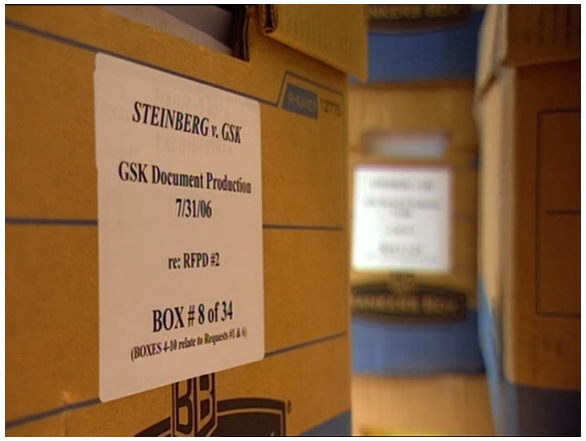
Uncovering Misconduct

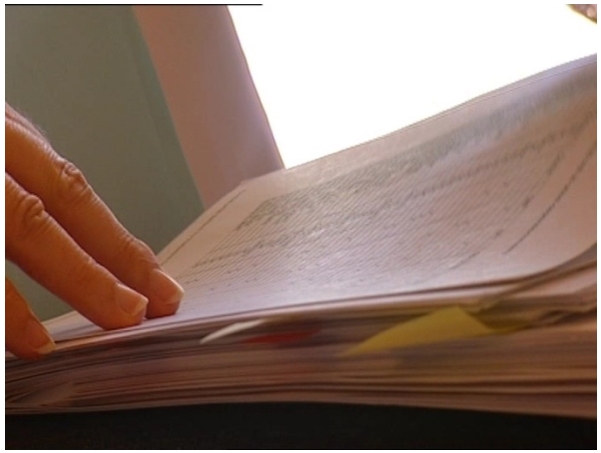
CONFIDENTIAL



Confidential documents obtained in litigation have revealed:

- pharmaceutical industry misconduct;
- exposure of hidden risks and overblown efficacy;
- conflicts of interest;
- manipulation of science through ghostwriting.

Law firms can play a vital role in gaining public release of important health-related documents designated by companies as confidential.



Documents publicly released as a result of litigation have played a key role in:

- government investigations (Grassley);
- oversight and regulation of industry;
- media coverage of pharmaceutical industry misconduct;
- academic access and commentary on these subjects (ghostwriting).

JAMA®

The Journal of the American Medical Association

"The Role of Litigation in Defining Drug Risks"
Aaron S. Kesselheim, M.D., J.D. and Jerry Avorn, M.D.

"Litigation brought by government agencies and individual patients can help uncover previously unavailable data on adverse effects, questionable practices by manufacturers, and flaws in drug regulatory systems."

There is a strong common-law presumption in favor of public access to judicial records.

Presumption of Public Access is "Strong and Sturdy"

The presumption of public access is "no mere paper tiger. If not 'overpowering' … the presumption is nonetheless strong and sturdy … the citizens' right to know is not lightly to be deflected." *F.T.C. v. Standard Financial Management Corp.*, 830 F. 2d 404, 410 (1st Cir. 1987).

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The political branches of government claim legitimacy by election, judges by reason. Any step that withdraws an element of the judicial process from public view makes the ensuing decision look like fiat and requires rigorous justification."

Hicklin Engineering, LC. v. Bartell, 439
F. 3d 346, 348 (7th Cir. 2006).

Circumstances under which Courts may keep documents out of the public view -- when a company makes a strong showing that the document(s) contain trade secrets the disclosure of which would result in a “clearly defined and very serious injury.”

However, intense public interest in the facts surrounding a particular case, particularly when there are public health implications, warrants public access. Documents that demonstrate wrongdoing, if unsealing is sought by a party, media or public interest group, are unlikely to remain under court seal.

“The societal interest in knowing what went wrong and why is great.”

Judge Jack B. Weinstein, Secrecy In Civil Trials: Some Tentative Views”
9 J.L. & Pol’y 53, 58 (2000).

Examples of unsealed court documents

Takeda "secretly surveyed" doctors in 2003 to see if they would use a diabetes drug if the label carried a warning about a potentially fatal ailment. According to company documents, the survey found "a bladder cancer warning would destroy the sales of Takeda's most important drug."

Bloomberg, February 15, 2013

writing about

Cooper v. Takeda, Case No. CGC-518535, Actos JCCP 4696

Los Angeles Superior Court

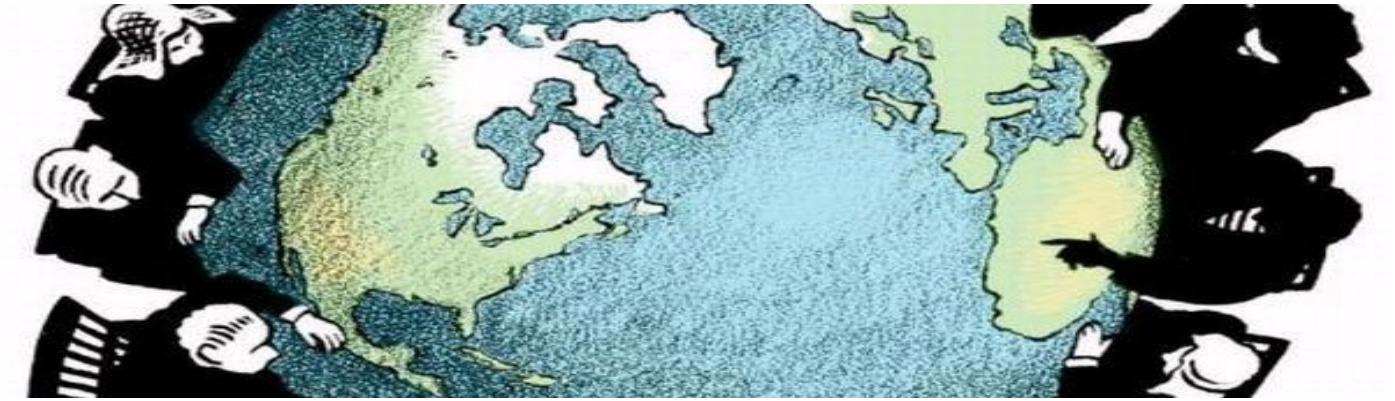
Bloomberg

If Doctors Don't Ask, Don't Tell

Takeda Told Sales Force

"During the ensuing nine years, Takeda fended off the FDA's suggestions that it add a clear bladder-cancer warning to Actos' label …"

In 2010, Takeda told its sales force "**if no questions/concerns, do not discuss bladder cancer and sell, sell, sell!**"



A March 29, 2001 email from a GSK consultant to the company discusses an Avandia study that "**was done for the US business, way under the radar and we lost both in terms of LDL and Tgs. Per Sr. Mgmt request, these data Should not see the light of day to anyone outside of GSK**."

"GSK documents suggest that Defendant acted with a wanton and willful disregard for the safety of its consumers. In the most telling of these documents, dated October of 1998, Defendant, discussing the problematic results of its Study 329, stated as follows:

TARGET: To effectively manage the dissemination of these data in order to minimise [sic] any potential negative commercial impact.

PROPOSALS• Based on the current data from Studies 377 and 329, and following consultation with SB country regulatory and marketing groups, no regulatory submissions will be made to obtain either efficacy or safety statements relating to adolescent depression at this time…. The rationale for not attempting to obtain a safety statement at this time is as follows; i) regulatory agencies would not approve a statement indicating that there are no safety issues in adolescents, as this could be seen as promoting off-label use. ii**) it would be commercially unacceptable to include a statement that efficacy had not been demonstrated, as this would undermine the profile of paroxetine**.• Positive data from Study 329 will be published in abstract form at the ECNP (Paris, November 1998) and a full manuscript of the 329 data will be progressed."

Knipe v. SmithKline Beecham, 583 F. Supp. 2d 602, 640-41 (E.D. Pa. 2008)

The $30 Billion Placebo

The Emperor Has No Clothes

The Case of Zoloft

Unsealed court documents show Pfizer knew it had an efficacy problem with Zoloft from the get-go …

In discussing a report that needed to be submitted to the FDA, a Pfizer employee commented that the **data "are not in favor of [Zoloft] as the placebo group has the most beneficial response in all of these instances … placebo still seems to be the most effective group in this subset of patients …"**

Meanwhile, Dr. Paul Leber, Director of the FDA's Division of Neuropharmacological Drug Products, wrote in a memo that **"[i]n recommending [the approval of Zoloft], I have considered the fact that the evidence marshaled to support [Zoloft's] efficacy as an antidepressant is not as consistent or robust as one might prefer it to be."**

Dr. Leber acknowledged that other foreign regulatory agencies were not willing to allow Zoloft marketing in their countries due to Pfizer's inability to prove efficacy.

However, Dr. Leber did "**not believe we [US FDA] can successfully introduce similar, more demanding requirements domestically, at least until there is significant 'sea change' in our society's collective attitude towards Federal regulation of new drug approvals**."

Pfizer itself found it odd that the FDA did not question Pfizer about efficacy despite the fact that several European regulators were troubled by the drug's lack of efficacy. According to a February 25, 1991 internal Pfizer email between two of its employees:

"**There were no questions on efficacy … I find it odd that FDA not at all questioning efficacy and there are significant questions raised by several European companies."**

Ultimately, Dr. Leber warned that the FDA's approval of Zoloft was likely to be challenged because …

FDA is not "as demanding as it ought to be in regard to its standards for establishing the efficacy of antidepressant drug products."


PHARMACOLOGICAL
DRUG TRIAL RESULTS
OUR TRIALS SHOW THAT
THE NEW DRUG PERFORMS
NO BETTER THAN PLACEBO
MAYBE WE SHOULD
INVEST IN PLACEBOS
CHRIS
MADDEN

Reader's Digest®

Kim Witczak

"Going After Goliath"

Mary A. Fischer

December 2009

After her husband's suicide while under the influence of Zoloft, Kim Witczak "took on the powerful, global drug company she blames for her husband's death." Kim Witczak took her case to court and "numerous corporate documents [were released in the court case] showing that both drug companies and federal regulators were aware of a possible connection between SSRIs and suicide from the earliest days of Prozac. Kim took those documents to Washington" in 2005.