Withholding Information

Withholding Data

Withholding data from publication, from public health officials, from clinical investigators, or from clinicians can be detrimental to public health and safety. Corporations pay for much of the clinical drug research and for a significant part of the toxicological studies on industrial chemicals.

For science to advance it must have *all* the evidence, not just positive results that might financially benefit a company. The examples given in this presentation illustrate just how widespread withholding of data has been.

Vioxx and Merck

- "In 2000, amid rising concerns that its painkiller Vioxx posed heart risks, Merck overruled one of its own scientists after he suggested that a patient in a clinical trial had probably died of a heart attack"
- In later reports to the Food and Drug Administration and in a published paper in 2003, Merck listed the cause of death as "unknown" for the patient, a 73-year old woman." *

* Alex Berenson. Evidence in Vioxx suits shows intervention by Merck officials. *New York Times*, April 24, 2005

Merck's VIGOR Study

"After Merck's VIGOR (VIOXX Gastrointestinal Outcomes Research) study reported increased heart attack risks, Merck directed its sales force to show physicians a "cardiovascular card" that made it appear Vioxx could be 8-11 times safer than other anti-inflammatory drugs. This card omitted any reference to VIGOR findings and was based on data FDA considered to be inappropriate for a safety analysis." *

* Henry A. Waxman. Memo: The marketing of Vioxx to physicians, May 5, 2005.

Immune Response Corporation threatens scientists to withhold publication

James Kahn, Professor of Medicine at UCSF was the lead investigator in a clinical trial involving 2,527 patients at 77 medical centers of an experimental AIDS drug called Remune. The trial was funded by Immune Response Corp. (IRC). By the end of the trial Kahn reached the conclusion that Remune was no more effective than a placebo. IRC contested Kahn's findings and launched a suit against Kahn and UCSF requesting $7-10 million in damages if he published the findings. IRC excluded Kahn from the final database and demanded to execute the analysis at IRC out of Kahn's hands.

* Jennifer Washburn. *University Inc*. New York: Basic Books, 2005, pp. 103-110.

Survey of biomedical scientists shows that scientific results are often withheld

- A survey of nearly 2,200 biomedical scientists revealed that more than 410 delayed publication more than 6 months within the previous 3 years.
- Of the 410 scientists who reported that they held back results, 28 percent indicated that it was to delay publication of undesired results.
- 9 percent of respondents refused to share research results or scientific materials with other university scientists in the previous 3 years. *

* Richard A. Knox. Biomedical results often are withheld. *Boston Globe*, April 16, 1997.

Data Withholding in Academic Genetics

"Data withholding occurs in academic genetics and it affects essential scientific activities such as the ability to confirm published results."

"Forty-seven percent of geneticists who asked other faculty for additional information, data, or materials regarding published research reported that at least 1 of their requests had been denied in the preceding 3 years."

* E.G. Campbell, B. R. Clarridge, M. Gokhale et al. Data withholding in academic genetics. *Journal of the American Medical Association* 287:473-480 (Jan. 23/30, 2002).

Unpublished data indicate risks outweigh benefits

Comparing published and unpublished trials of certain serotonin reuptake inhibitors reveals that the unpublished trials show an unfavorable risk/benefit ratio compared to the published trials. "Non-publication of trials, for whatever reason, or the omission of important data from published trials, can lead to erroneous recommendations for treatment. *

* C.G. Whittington, T. Kendall, P. Fonagly, et al. Selective serotonin reuptake inhibitors in childhood depression: systematic review of published versus unpublished data. *The Lancet* 363:1341-1345 (April 24, 2004).

Drug companies keep valuable data from the public

"The pharmaceutical industry—and in particular large transnational companies—generates and collates vast amounts of information. Much of this material remains secret or is shared exclusively with regulatory authorities…lack of openness..threatens patients' interests."

* Joe Collier. The pharmaceutical industry as an informant. The *Lancet* 360:1405-1409 (November 2, 2002).

Registering All Clinical Trials

Dickersin and Rennie write in *JAMA* that "all stakeholders—investigators, research organizations and institutions, journal editors, lawmakers, consumers and others—must act now, together and in their own domains, to ensure comprehensive registration of clinical trials." *

* K. Dickersin and D. Rennie. Registering clinical trials. *Journal of the American Medical Association* 290:516-523 (July 23/30, 2003).

Secrecy is increasing in academia

In 1966 50% of 1,042 respondents reported feeling safe in talking with all others about their current research; by 1998, when 202 scientists from the same three fields were surveyed only 26% expressed feeling safe talking about their research.

"Experimental biologists have become particularly secretive with only 14% willing to talk openly about their current research in 1998."

* J.P. Walsh and W. Hong. Correspondence: Secrecy increasing in step with competition. *Nature* 422:801-2 (April 24, 2003).