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# Science with Health Consequences

**D**r. Hwang Woo Suk, a South Korean scientist conducting stem-cell research, resigned from his university on December 23, 2005, after a faculty committee found he had "intentionally falsified data in a landmark paper on cloning that appeared in the journal *Science* this summer."<sup>1</sup> Not only was Dr. Suk guilty of falsifying data, but he likely brought dishonor on himself, his family, his university, and his country.

In 1985 three officers of Film Recovery Systems were found guilty of the murder of Stefen Golub in an Illinois trial court under a law in which murder is the killing of an individual without justification and the agent "knows that such acts create a strong probability of death or great bodily harm to that individual." Mr. Golub died of convulsions caused by exposure in the workplace to sodium cyanide used in a silver chloride recovery process. *Film Recovery Systems* was overturned on appeal by the Illinois Supreme Court for technical reasons, but the justices concluded that the evidence "was not so insufficient as to bar retrial."<sup>2</sup>

Both these cases are extremes—a scientist intentionally fabricated data and a company had such a contaminated workplace that an employee collapsed and died from acute toxic exposures. While extreme and both deserving of great criticism, the two cases are on different continua that pose substantial questions about scientists who conduct human health and safety research and the companies that authorize it. Health and safety research needs to be taken more seriously for its consequences for those at risk.

Dubious scientific research conducted for the pharmaceutical industry is often well known because its effects can adversely affect millions of consumers and receive considerable publicity. Thus, for example, many are probably aware that the editors of the *New England Journal of Medicine* expressed great concern about Merck scientists' withholding disease data from an article published in the Journal.<sup>3</sup> The Merck scientists' actions tended to underestimate the life-threatening effects of Vioxx.

Suspect research that affects occupational and environmental health is much less visible and ordinarily receives little or no publicity. However, reliance on such research can ultimately affect thousands to hundreds of thousands of people exposed to potentially toxic substances in the workplace and hundreds of thousands to millions of ordinary citizens who are exposed to toxic substances through the environment.

For example, the *Wall Street Journal* just reported that a consulting firm hired by Pacific Gas & Electric Co. (PG&E) to fight the "Erin Brockovich" lawsuit modified data from a Chinese study, reversing the study's original conclusion that linked chromium to cancer.<sup>4, 5</sup> The consulting firm, ChemRisk, run by toxicologist Dennis Paustenbach, has been used by a number of firms that, according to documents in a legal proceeding, paid over \$7 million for its chromium work.<sup>6</sup> The modified chromium-(6) article misled the medical journal about the true authorship of the study (the consulting firm, not the original Chinese author in whose name

it was submitted, conceived and wrote the altered paper).<sup>4</sup> And, the research was sufficiently tainted that the state of California, now considering regulations for chromium-(6), has "concluded [that the study] is dubious."<sup>4</sup> Rankin Bohme, Zorabedian, and Egilman, in a recent issue of this journal, have documented other shortcomings of Paustenbach's research, much of it conducted for corporate clients who are faced with liability lawsuits.<sup>5</sup>

It would be a mistake, however, merely to focus on a few individuals who have risen to the level of notoriety. The stage is set for misleading scientific studies by the U.S. post-market legal environment, combined with large amounts of money at stake. Together these create conditions that can lead to the corruption of science and put scientists' integrity at risk in collaboration with these goals.

Our legal system is far from dedicated to protecting public and workplace health. Most laws permit products into commerce with little or no legally required testing for health effects (drug and pesticide laws are exceptions). Moreover, what laws there are tend to be underutilized and poorly enforced.

Little is known about the 70,000 to 100,000 chemical substances and their derivatives registered for use in U.S. commerce.<sup>7</sup> Another 1,000 to 2,000 substances are developed each year without legally required toxicity testing.<sup>8</sup> In 1984 the U.S. National Academy of Sciences estimated there were nearly 13,000 general chemicals produced in volumes exceeding one million pounds per year for which there was no toxicity information avail-

able. Data were missing for 3,000 substances produced in the highest volume.<sup>9</sup> In the early 1990s there was insufficient change in the data to justify updating the Academy's report.<sup>10</sup>

The law also provides the context that influences scientific integrity, corporate behavior, and risks from toxicants. Post-market laws create structural incentives for those subject to regulation to resist, delay, and frustrate actions aimed at protecting the public and the workforce. Where there is too little evidence to support protective regulations, adverse health effects become disease externalities for which the company does not pay, resulting in higher profits than would otherwise occur. Similar structures create barriers for citizens harmed by toxic exposures who seek redress in the tort or personal injury law. Nothing happens if there is no or poor evidence of the relationship of harm to corporate negligence or malfeasance. Moreover, this context invites both gross and subtle violations of social and scientific ethics.

Individual scientists or firms that intentionally withhold data implicating health harms mislead authorities, peers, and the public, and in permitting harm to occur unabated approach being accessories to resulting injuries. Firms or scientists that intentionally destroy and withhold studies showing adverse health consequences are guilty of serious moral shortcomings. Nearly as disturbing are scientists who delete positive results from studies to minimize reported risks and harms, the concern expressed by the *New England Journal of Medicine*.<sup>3</sup> Such acts are presumptively acts of scientific and social dishonesty, with injurious consequences for citizens, who go unprotected as a result of misleading research.

Somewhat more subtly, companies and scientists may design, conduct, and interpret studies in ways that will prevent or minimize the

discovery of harm. The scientific techniques are less crude than destruction or withholding of studies. Nonetheless, if studies show no harm there are no adverse legal effects, but there can be unfortunate health effects for those exposed. Human studies can be too small, too short, too specific for sub-species of disease, or they may be conducted too long after exposure has ceased to identify real adverse effects. Controls can be contaminated, and statistics can be manipulated contrary to good scientific practice.<sup>11</sup> Sander Greenland in legal testimony has criticized scientists who *assume* there are no toxic effects until these are established by overwhelming human evidence.<sup>12</sup>

How should we assess the behavior of firms and their scientists who design studies that aim to minimize adverse findings? An American Petroleum Institute document (recently unveiled in litigation and similar to a proposal Dr. Paustebach made 15 years ago<sup>5</sup>) strongly suggests that API knows what studies will find before they are ever conducted.<sup>13,14</sup> Are independent studies by the National Cancer Institute and university scientists on the relation between benzene exposure and blood diseases so threatening that they must be challenged at any cost to the integrity of those involved and to the health consequences of workers and the public?

Have some scientists deliberately adopted extremely high standards of proof to ensure that findings of harm have not been "proven?" It can be tempting and financially rewarding to ratchet up standards of proof when interpreting data, but veil one's actions by claiming that one is only demanding "sound" or rigorous science.<sup>15, 16</sup> "Doubt is our product" strategies<sup>17</sup> have been mounted on behalf of tobacco,<sup>18</sup> asbestos,<sup>19</sup> vinyl chloride,<sup>20</sup> lead,<sup>20</sup> the general chemical industry (fighting the Delaney Clause),<sup>21</sup> benzidine dyes,<sup>22</sup> and others recently noted in this journal.<sup>23</sup> There can be plausibility to a claim that "more

evidence is needed," since these relationships are difficult to diagnose and most scientific papers routinely employ this phrase. However, it can also be easily exploited for self-interest with far from benign results to those exposed when harmful exposures are present.

There are also subtle issues here, of course. There will be well-motivated researchers who disagree about the science. These points should be argued out in journals.<sup>24,25</sup> Moreover, scientists on the other side of the issues may testify too far beyond the science and exhibit shortcomings of their own.<sup>26</sup> However, in contested areas with large amounts of money at stake there are powerful incentives that invite culpability in designing, conducting, interpreting, and presenting studies. Nonetheless, we should be past the time when scientists can claim ignorance about misleading study designs, interpretations of data, extremely high standards of proof, demands for high relative risks, and denigration of animal studies when such stances are widely known to minimize or fail to detect existing adverse effects. Those at risk of harm deserve even-handed, honorable, and professional scientific approaches in a legitimate effort to identify harms that they might incur.

Dr. Suk's research so far as we know did not physically harm anyone. Film Recovery Systems did not cause death of Stefan Golab because of dubious research practices. However, what unites the two is that when researchers in occupational and environmental health knowingly falsify studies, delete data, or design or interpret them so that adverse effects will be minimized or not revealed, their decisions have real human consequences. Firms that engage in this behavior may not immediately cause disease and death as Film Recovery Systems did. However, over the longer term, when substantial chances of harm are known or strongly suspected, how close do

they and their scientists come to knowingly creating a "strong probability of death or great bodily harm" by failing to conduct scientific studies with integrity to protect their employees and the general public? At what point do violations of professional and social ethics approach more serious legal transgressions?

CARL F. CRANOR, MSL, PHD  
*Professor of Philosophy*  
*Department of Philosophy*  
*University of California*  
*Riverside, CA 92521*  
*E-mail: <carl.cranor@ucr.edu>*

### References

1. Sang-Hun C, Wade, N. Korean cloning scientist quits over the report he faked research. *The New York Times*, December 24, 2005. A1.
2. *People v. O'Neill, Film Recovery Systems, et al.*, 550 N.E. 2d 1090 (1990).
3. Curfman GD, Morrissey S, Drazen JM. Expression of concern: Bombardier et al. Comparison of upper gastrointestinal toxicity of Rofecoxib and Naproxen in patients with rheumatoid arthritis. *N Engl J Med*. 2005;343:2813-4. *N Engl J Med* 35326, <www.NEJM.org>. December 20, 2005. Merck and Company.
4. Waldman P. Study tied pollutant to cancer; the consultants got hold of it. *Wall Street Journal*. December 23, 2005. <[http://online.wsj.com/article\\_print/SB113530126572230084.html](http://online.wsj.com/article_print/SB113530126572230084.html)>.
5. Egilman D, Rankin Bohme S. Over a barrel: corporate corruption of science and its effects on workers and the environment. *Int J Occup Environ Health*. 2004;11:331-7. <[www.ijoe.com](http://www.ijoe.com)>.
6. Lane, A. Polluters gain as Jersey lifts limit for toxin. Work of scientist paid by the firms viewed skeptically by other experts. *The [Newark, NJ] Star-Ledger*, March 7 2004.
7. Huff J, Hoel D. Perspective and overview of the concepts and value of hazard identification as the initial phase of risk assessment for cancer and human health. *Scand J Work Environ Health*. 1992;18:83-9.
8. Dennison R. U.S. HPV challenge and beyond. Ward, Kershaw, and Center for Progressive Regulation Environmental Law Symposium: The Data Gaps Dilemma: Why Toxic Ignorance Threatens Public Health, May 6, 2005.
9. National Research Council. *Toxicity Testing: Strategies to Determine Needs and Priorities*. Washington, DC: National Academy Press, 1984: 84.
10. Bailar JC, Bingham E. Personal communication, Collegium Ramazzini, 2002.
11. Gennaro V, Tomatis T. How epidemiologic studies may underestimate or fail to detect increased risks of cancer and other diseases. *Int J Occup Environ Health*. 2005;11:356-9.
12. Written Direct Testimony of Sander Greenland, DrPH, in Opposition to Baxter Healthcare Corporation's Petition for Declaratory Judgment. (1999, April 30) (critiquing a scientist for Baxter Health Care).
13. American Petroleum Institute. Shanghai Study: Internal Documents. 54-7.
14. Capiello D. Oil industry funding study to contradict cancer claims. *Houston Chronicle*, April 29, 2005, AD: A1.
15. Eysenck HJ. Were we really wrong? *Am J Public Health*. 1991;133:429-32 [arguing that studies must be established "beyond a reasonable doubt" before finding that cigarette smoke causes cancer].
16. Greenland S. Invited commentary: science versus public health actions: those who were wrong are still wrong. *Am J Public Health*. 1991;133:435-6 [critiquing the Eysenck paper].
17. Michaels D. Doubt is their product. *Scientific American*. 2005;96:96-101.
18. Brown & Williamson—Smoking and Health Proposal, Doc. No. 332506. <<http://tobaccodocuments.org/bw/332506.html>>.
19. Brodeur P. *Outrageous Misconduct*. New York: Pantheon Books, 1985.
20. Markowitz G, Rosner D. *Deceit and Denial: The Deadly Politics of Industrial Pollution*. Berkeley, CA: University of California Press, 2002: 226-33, 300-1.
21. Michaels D, Monforton C. Manufacturing uncertainty: contested science and the protection of the public's health and environment. *Am J Public Health*. 2005;95:S39-S48, esp. S41, note 46 [citing internal Hill and Knowlton memos].
22. Michaels D. Waiting for the body count: corporate decision making and bladder cancer in the U.S. dye industry. *Medical Anthropology Quarterly*. 1988;2:215-27.
23. Rankin Bohme S, Zorabedian J, Egilman D. Maximizing profit and endangering health: corporate strategies to avoid litigation and regulation. *Int J Occup Environ Health*. 2005;11:338-48.
24. Breilh J, Branco JC, Castleman BI, et al. Texaco and its consultants. *Int J Occup Environ Health*. 2005;11:217-20.
25. Rothman KJ, Arellano E. Elevating the level of scientific discourse [letter]. *Int J Occup Environ Health*. 2005;11:327-8.
26. Gitlin JN, Cook LL, Linton OW, Garrett-Mayer E. Comparison of "B" readers' interpretations of chest radiographs for asbestos related changes. *Acad Radiol*. 2004;11:834-56 [found highly significant differences between plaintiffs' experts' readings of chest radiographs compared with independent readers'; plaintiffs' experts' positive readings suggesting lung impairment were much more frequent than independent readers'; the differences are too substantial to be attributed to inter-observer variability].

Carl F. Cranor is Professor of Philosophy at the University of California, Riverside, specializing in legal and moral philosophy. He has written widely on philosophic issues at the intersection of science and the law. He published *Regulating Toxic Substances: A Philosophy of Science and the Law*, as well as numerous articles in philosophy, science and law journals. He has just completed a book, to be published by Cambridge University Press, *Toxic Torts: Science, Law and the Possibility of Justice*.