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AUTHORSHIP, GHOST-SCIENCE, ACCESS TO DATA AND CONTROL OF THE PHARMACEUTICAL SCIENTIFIC LITERATURE: WHO STANDS BEHIND THE WORD?

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"the integrity of a body of literature is itself our society's ultimate temporal forum for negotiating life and death, suffering and wellness... the medical well-being of the society it serves is dependent on the question of who stands behind the word." Fr. Mark Gruber, 1999 (cited in ref 1)

The past two years has seen widespread commentary about the integrity of pharmaceutical medicine (2-13). The suggested remedy is that pharmaceutical companies must be divorced from direct involvement in researching clinical aspects of their own drugs (3, 7). We are heading, like the Titanic, towards an iceberg of enormous size.

Pharmaceutical companies sell products under the banner of science and medicine. However, their raison d'être is to make money. If industry gets involved in science, it has to balance genuine hypothesis testing and transparency against commercial interests, bureaucracy of drug regulation, and the financial consequences of dishonesty. This is not in itself a criticism – it is a simple fact.

Universities exist for a different reason – to add to human knowledge and to disseminate that knowledge through publication and teaching. Subtle compromises (2) have allowed the pharmaceutical industry to develop an extraordinary stranglehold over the scientific process, academic discourse, regulatory safeguards and common sense (8-11,14). It is hard to see how safeguards for dispassionate scientific discourse can be sustained when medicine flagrantly disregards them.

Ghosts in the machine

The pharmaceutical industry is accused of overturning the usual safeguards of science. The most fundamental of these safeguards is the accountability of authors (1). Readers of legitimate science expect that stated authors are truly the authors, that they vouch for the work, and that they would be able to defend their findings if challenged. They expect that authors have seen and scrutinized raw data, and would be able to provide that data if asked. That it is necessary to write this indicates how much we have lost.

Industry has been inclined to use universities to give tainted science a veneer of respectability, while denying the very basis of that respectability. "Ghost-writing" has been repeatedly criticized. However, professional "medical writers" may sometimes have a legitimate role if clearly acknowledged. By emphasizing the "writing" aspect, we divert attention from the far more important problem – that of "ghost-science," of which "ghost-writing" is only a part.

International standards were adopted by many scientific journal editors following embarrassing disclosures. These standards (15) reassert the obvious – that authors should state in writing that they have full control of all primary data, controlled the decision to publish, and will supply raw data upon request.

The usual definitions of scientific misconduct do not apply to pharmaceutical research. In February 2006, Gerald Schatten was accused of research misconduct (16). His crime was to have co-authored a stem-cell publication with the discredited Dr. Hwang Woo Suk, while shirking the "responsibilities of verifying the data." Schatten might have been irked to discover that at the same time, Procter and Gamble Pharmaceuticals (P&G) declared to the media that it was "standard industry practice" (17) to deny authors access to raw data in drug studies.

Lessons from Sheffield

In 2002, I signed a research agreement with P&G in collaboration with another academic, Professor Richard Eastell. The consequences of my disagreement with the company and with my collaborator have been widely discussed in the media. (17,18) and some original documents have been disclosed on a blog (19).

In spring 2006, *The Journal of Bone and Mineral Research* (JBMR, 20) placed an undated "Statement of Concern" on its website. The statement relates to one of three intended P&G publications (21) about change in bone turnover and fractures in patients taking the osteoporosis drug Actonel. The other two publications (one based on an extended set of

(**Blumsohn** continued from page 1)

the same data and another based on new data) have only been published in abstract form because I declined, as first author, to sign journal declarations while being refused access by the company to randomization and event codes (17,18,19).

The research involved an important secondary endpoint in the key randomized trials used to gain regulatory approval for Actonel (annual sales ~$1 billion). P&G repeatedly refused to provide data codes to academic "collaborators." This breached the terms of its contract with the University. Data were required by the academics to verify scientific reports, statistical analyses, meeting abstracts, and draft publications "ghost written" in their names. Over time, increasing information emerged to suggest that the data analysis and data presentation had been incorrect and misleading, but underlying data were still not disclosed.

The first of the three intended publications was submitted by my collaborator to the *Lancet* in 2002, and upon rejection was published in *JBMR* (21). The *Lancet* prescribes that an author must "state that he or she had full access to all the data in the study," and "at any time up to 5 years after publication authors may be asked to provide the raw data." *JBMR* has similar guidelines. Academics at Sheffield would not have been able to provide data if asked (and were indeed not able to), because they never had them.

Various statements made by P&G officials in their defense are illuminating (17,18,19). They claimed that "*we don't need to ask an independent person to analyse the data just to make a few people happy*" (the independent person being the intended first author). They claimed that by supplying authors with data "*industry loses the opportunity to demonstrate its ability to be a true partner in scientific endeavours*" (17). They suggested (19) that refusal to supply data to authors was in accordance with "PhRMA guidelines" (PhRMA is the main US lobby group that represents pharmaceutical manufacturers). They defended their actions in the press (17) by saying that it is "*standard industry practice*" to limit authors access to data, and that "*occasionally the researcher is given temporary and limited access to data to perform the analyses directly."* In "legal" correspondence, P&G attempted to redefine the meaning of "access to data," suggesting that showing an author company outputs or statistical interpretations somehow constitutes access to data.

The Bill of Rights and disclosure of data

In response to media scrutiny, P&G produced a new "Bill of Rights" governing its relationships with academics in February 2006 (17). The bill stated that "*research authors will define and control the content and direction of any publication resulting from their work*" and will have "*final authority*" over all publication content. It stated that, although P&G would retain ownership of data, researchers will "*own the analysis and conclusions*" and will be "*in no way restricted*" from publishing their findings.It says that researchers will have "*full access to all relevant data to confirm the accuracy of statements and conclusions.*" This statement simply stipulates the rights and obligations academics have always had, as well as the conditions for publication in any respectable journal. Nevertheless, it is a step forward.

In April 2006, after a three-year delay, P&G supplied me and Eastell with the data codes underlying the three intended publications. These data, as well as many documents and dozens of tape recordings, confirm that the conclusions of the three publications were not in accordance with the data. Discrepancies were obvious. For example, in all three manuscripts, the x-axis of a critical graph was scaled so that about 40% of the data would not have appeared within the scale of the graph. A key conclusion of all three papers was that there was plateau at a commercially convenient point in the response relationship for the drug — a matter of practical clinical relevance (18 explains how this would have benefited P&G). The data provided no credible evidence to support this conclusion in any of the three publications (17, 22).

The problem of the regulators

The Sheffield dispute was discussed in the UK Parliament in December 2005, and was transmitted by the Health Minister to the UK drugs regulator (the Medicine and Healthcare Products Regulatory Agency, MHRA) for "investigation." The MHRA is itself accused of failing to examine or to secure raw data in drug licensing applications, simply accepting the word of industry with blind faith (6, 14). Since this was precisely the problem in Sheffield, its disinclination to investigate was hardly surprising.

No investigation (or at least anything fitting that definition) took place. The MHRA failed to produce any report, declined to accept any documentary evidence (17, MHRA response to FOI request #06/115), stated that the matter was of "low priority" (17), and that the agency does not have any procedure for investigating research misconduct (17, MHRA response to FOI #06/188). Further, it claimed that the drug regulator has no remit, nor any necessary obligation to be interested in the integrity of the scientific literature about drugs (17, MHRA FOI #06/188) unless related to licensing (and collected using documentation appropri -

(**Blumsohn** continued on page 3)

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(**Blumsohn** continued from page 2)

ate for licensing). It even argued that it is "illegal" for a scientist to have data pertaining to information written in his name without the consent of the company "owning" that data (17, MHRA FOI #06/115). It refused to compare data it was sent from Sheffield with the original data it should have received and examined as part of the licensing process for Actonel. Initially, this refusal was on the basis that it would be "too much work" (17, MHRA FOI #06/059). Later, it admitted that it had not in fact seen or retained raw data prior to approving the drug (17, MHRA FOI #05/404). With governments setting the standard for scientific conduct, it is hardly surprising that independent science has encountered such difficulties.

The problem of academics who don't acquiesce

There have been many cases where academics have refused to acquiesce. A dispute arose between James Kahn of UC San Francisco and Immune Response Corp. over effectiveness of an AIDS vaccine in a multi-center trial. The company objected to publication of the analysis of data (which was incomplete since the company refused to supply the rest to the researchers). When UCSF researchers refused to interpret the data more favourably, the company threatened legal action. The study was published with incomplete data (23). The company maintained that because it paid for the trial, it somehow owned the data and therefore the mode of presentation.

Many other cases happen beneath the radar. A recent example involves the drug Famciclovir, used to treat herpes. A 1997 study comparing Famciclovir with its main competitor was funded by the manufacturer (then Smithkline Beecham). Study findings were not beneficial to the sponsor. They were published only a few months ago after a nine-year delay, with a disclaimer that the authors were denied raw data and were forced to accept the company's own partial summary of findings (24). Scientists may disagree about the presentation of data. There can, however, be no legitimate debate when that data are not available for scrutiny even to the authors. Should we prescribe a drug knowing about such "missing" data? What of the patients who volunteered to take part in these studies?

Other disputes have related not so much to access to data, but to the right of authors to publish or speak about what they believe to be true. These include the celebrated cases of Nancy Olivieri (9,11), Betty Dong (25), David Healy (9), David Kern (9,26), among others. These instances should be discussed and analyzed so they are not repeated.

Where to from here?

The ethical challenge in pharmaceutical medicine is to use available data in the best possible way. Data are derived from human participants who subject themselves to risk in the public interest. They have the right to know that the data derived from their assumption of risk are used properly. When data are closed to scrutiny, even by the supposed authors of research, this cannot constitute an appropriate or ethical use of that data. Patients have to be involved in solving the problem.

We need to address the way in which drug regulators are currently operating. Recent reports about these agencies should provide a wake-up call (6, 13, 14). The stated intention of the FDA to support a preemption rule (27) is of grave concern. This would disallow lawsuits against drug makers if a drug is FDA approved, even apparently in the case of scientific fraud or the withholding of information by a company.

The problems of medicine could not happen without the complicity of medical journals (12), most of which receive substantial advertising and "reprint" income from industry. Anyone interested in the functioning of journals might wish to peruse my collated correspondence with the editor of *The Journal of Bone and Mineral Research* that I have placed online (29). Initially polite correspondence became confused as I encountered the endless distortion of reality that is part and parcel of pharmaceutical science. Other journals, such as *PLoS Medicine*, have made appropriate comments about their role (28), and we should, therefore, make sure such publications receive the respect they deserve.

Some continue to press for public right of access to anonymized raw clinical supporting the licensing of medicines (30). Reasonable as this might seem, such proposals are unthinkable when currently neither academic authors fronting publications nor the regulators have seen that data. Issues of "ownership" of data are irrelevant to the right of access or to the ethical requirements of journals. If the industry wishes to sell its products under the banner of science, it has to accept the rules of science.

Most importantly, as academics we need to reassert the importance of data and the meaning of authorship. We also need to assert "old fashioned" ideas of academic freedom, our right to speak the truth as we see it, and to allow that truth to be subjected to open debate.

In the words of George Orwell (1984), "Freedom is the freedom to say that two plus two make four. If that is granted, all else follows."

References

1. Sheikh, A. (2000). Publication ethics and the research assessment exercise: reflections on the troubled question of authorship. *Journal of Medical Ethics*, 2000: (26):422-6 <http://jme.bmjjournals.com/cgi/content/full/26/6/422>
2. Dieppe, P. Complicity theory: an explanation for the 'coxib problem'? *Journal of the Royal Society of Medicine*, 2006:(99):273-4.
3. Godley, F. Can We Tame the Monster? *British Medical Journal*, 2006: 333 <http://bmj.bmjjournals.com/cgi/content/full/333/7558/0-f>
4. Mintzberg, H. Patent nonsense: Evidence tells of an industry out of social control. *Canadian Medical Association Journal*, 2006:174(4) <http://www.cmaj.ca/cgi/content/full/175/4/374>
5. Chalmers, I. From optimism to disillusion about commitment to transparency in the medico-industrial complex. *Journal of the Royal Society of Medicine*, 2006:(99):337–41 <http://www.rsmpress.co.uk/0607JRSM.pdf>
6.Healy, D. Did regulators fail over selective serotonin reuptake inhibitors? *British Medical Journal*, 2006:(333):92-5.

(**Blumsohn** continued on page 4)

(**Blumsohn** continued from page 4)

7. Steinman, M.A., *et al.* Narrative Review: The Promotion of Gabapentin: An Analysis of Internal Industry Documents. *Annals of Internal Medicine*, 2006:(145):284-93 <http://www.annals.org/cgi/content/full/145/4/284>
8. Angell, M. *The Truth About The Drug Companies: How They Deceive Us and What To Do About It* (London: Random House, 2005).
9. Washburn, J. *University, Inc: The Corporate Corruption of Higher Education*. (New York, NY: Basic Books, 2005).
10. Krimsky, S. *Science in the Private Interest: Has the Lure of Profits Corrupted Biomedical Research?* (Lanham, MD: Rowman and Littlefield, 2004)
11. Kassirer, J. *On the Take: How Medicine's Complicity with Big Business Can Endanger* Your Health (New York, NY: Oxford University Press, 2004).
12. Smith, R. Medical Journals Are an Extension of the Marketing Arm of Pharmaceutical Companies. *PLoS Medicine*, 2005:2(5): e138 <http://dx.doi.org/10.1371%2Fjournal.pmed.0020138>
13. Graham, D. COX-2 Inhibitors, Other NSAIDs, and Cardiovascular Risk. The Seduction of Common Sense. *Journal of the American Medical Association*, 2006: 296 <http://jama.ama-assn.org/cgi/content/full/296.13.jed60058v1>
14. House of Commons Health Committee. *The Influence of the Pharmaceutical Industry*. Fourth Report of Session, 2005 <http://www.publications.parliament.uk/pa/cm200405/cmselect/cmhealth/42/42.pdf>
15. International Committee of Medical Journal Editors (ICMJE) <http://www.icmje.org/index.html>; World Association of Medical Editors (WAME) <http://www.wame.org/wamestmt.htm#fundres>
16. Wade, N. University Panel Faults Cloning Co-Author. *New York Times*, February 11, 2006.
17. Collated media reports on Blumsohn case <http://www.thejabberwock.org/presshw.htm> and <http://www.doctorsintegrity.org/blumsohn.htm>
18. Washburn. J. Rent-a-Researcher: Did a British university sell out to Procter & Gamble? *Slate Washington Post*, Newsweek Interactive, December 22, 2005 <http://www.slate.com/id/2133061/>
19. <http://www.scientific-misconduct.blogspot.com>
20. *The Journal of Bone and Mineral Research* <http://www.jbmronline.org/>
21. Eastell, R., *et al.* Relationship of early changes in bone resorption to the reduction in fracture risk with risedronate. *The Journal of Bone and Mineral Research*, 2003:18:1051-6
22. Bland, M., Report for the BBC, 2006.
23. Kahn, J.O., *et al.* Evaluation of HIV-1 immunogen, an immunologic modifier, administered to patients infected with HIV having 300 to 549 x 10(6)/L CD4 cell counts: A randomized controlled trial. *Journal of the American Medical Medicine*, 2000:284:2193-202.
24. Wald, A, Selke, S, Warren, T., *et al*. Comparative efficacy of famciclovir and valacyclovir for suppression of recurrent genital herpes and viral shedding. *Sexually Transmitted Diseases*, 2006:33: 529-33.
25. Rennie, D. Thyroid storm. *Journal of the American Medical Association*, 1997:277: 1238-43.
26. Kern, D.G. The Unexpected Result of an Investigation of an Outbreak of Occupational Lung Disease. *International Journal of Occupational and Environmental Health* 1998:4(1):19-32.
27. Avorn, J., Shrank, W. Highlights and a Hidden Hazard: The FDA's New Labeling Regulations. *New England Journal of Medicine*, 2006: 354(23):2409-2411.
28. The PLoS Medicine Editors: PLoS Medicine and the Pharmaceutical Industry. *PLoS Med*icine, 2006:3:e329 <http://dx.doi.org/10.1371/journal.pmed.0030329>
29. Correspondence with *The Journal of Bone and Mineral Research* <www.thejabberwock.org/jbmrs.htm>
30. Abraham, J. , *et al*., Rethinking transparency and accountability in medicines regulation in the United Kingdom. *British Medical Journal*, 1999:318:46-7.

IN THE NEWS

GOVERNMENT SCIENCE PANELS: FAIR AND BALANCED?

On July 24, The Center for Science in the Public Interest (CSPI) held a forum exploring the prevalence and impact of conflicts of interests within government advisory science panels.

Of the six panelists, three were quite wary of the dangers of potential conflicts of interest. Dr. Michael Jacobson[1] said conflicted scientists should not be on review or advisory scientific panels, including those commonly known as data synthesis panels. Yet, if the expertise of a particular scientist with a conflict of interest is needed, perhaps the EPA or other agency could allow the scientists into panel discussions but prohibit them from voting or lobbying. Dr. Steven Nissen[2] was sharply critical of the FDA, citing politici-zation and ineffectiveness of the FDA as key factors in the lack of public trust in the agency. He called for a three-prong solution: increased funding of the FDA to eliminate the need for industry "user fees"; more authority to allow the FDA to enforce regulatory standards; and, a review of the appointed FDA personnel to expose conflicts of interests that he alleges are present at the top management levels. Dr. Merrill Goozner[3] highlighted the release of the CSPI review of the National Academy of Sciences. This report found one in five scientists on NAS panels to have "direct financial ties to companies or industry groups with a direct stake in the outcome of the study."[4] However, Frederick Anderson[5] criticized the report, calling it wrong and misleading in parts. He argued for a conflict of interest criterion that shows a current, substantial financial incentive related to the subject under debate within a panel.

Dr. Scott Gottlieb[6] defended FDA policies, arguing that waivers for scientists with perceived conflicts of interests are often necessary to retain quality panelists. He stated the FDA is in the process of revising guidelines for giving these waivers and the ways in which it discloses waiver information to the public. Dr. James Conrad[7] advocated for disclosure of conflicts of interest, without prohibiting conflicted scientists from serving on advisory panels. While citing expertise as still the ideal criterion for inclusion on a panel, he noted the Federal Advisory Committee Act that requires advisory panels show balance in scientific perspectives.

1. Executive Director, Center for Science in the Public Interest
2. Former Chair, FDA Cardiovascular and Renal Drugs Advisory Committee, The Cleveland Clinic Foundation
3. Director, Integrity in Science Project at CSPI
4. The full CSPI report can be found at: http://cspinet.org/new/pdf/nasreport.pdf
5. Partner, McKenna, Long, & Aldridge, LLP
6.Deputy Commissioner for Medical and Scientific Affairs at the FDA
7.Asst. Chief Counsel for the American Chemistry Council

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(**News** continued on page 5)

(**News** continued from page 4)

ISSCR SETS OUT ETHICAL GUIDELINES FOR HUMAN EMBRYONIC STEM CELL RESEARCH

The International Society for Stem Cell Research (ISSCR) has released draft guidelines for the ethical conduct of human embryonic stem cell research. The guidelines reflect themes of openness and scientific collaboration. With regard to openness, the ISSCR urges researchers to be "transparent and truthful" when examining the potential of stem cell science. Researchers are cautioned against creating "unrealistic expectations of success" among the public community following such research. The unhindered distribution of research materials among non-commercial researchers is also emphasized. This must take place within the context of legal requirements of each country involved, but an overall environment of academic cooperation is the ideal. The guidelines specifically advocate wide distribution of stem cell lines in the research community, through centralized repositories. These repositories should establish a clearly defined protocol for the storage and distribution of lines.

Cognizant of the need for review of research, the ISSCR recommends establishing a process of Stem Cell Research Oversight (SCRO). This process, designed to exist in addition to the IRB review process, would monitor three components of the proposed research: 1) the scientific rationale and merit of the proposal; 2) the relevant experience of investigators; and 3) the ethical permissibility and justification. The panel overseeing the SCRO review would reflect a wide range of interested parties including scientists, ethicists, legal scholars, and community members without ties to the research institution.

Of particular concern is the procurement of materials for conducting human stem cell research. For the procurement of gametes, pre-implantation embryos and somatic cells, the ISSCR establishes a firm principle of voluntary informed consent or refusal. This inform-ed consent must be separated from the clinical treatment process to avoid pos-sible coercion. The guidelines prohibit any payment for donating embryos or gametes acquired in the course of clinical treatment. However, this does not pre-clude reimbursement for "direct expenses" incurred during the consent process. ISSCR charges senior investigators, funding agencies and academic journal editors to seek compliance with the guidelines when supervising or reviewing research.

ISSCR invites public feedback on the guidelines until September 1, 2006. The final version incorporating comments will be published on the ISSCR website in October 2006. Download the guidelines and submit comments here: http://www.isscr.org/scientists/guidelines.cfm

For further information:
http://www.isscr.org/
http://www.nap.edu/books/0309096537/html

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ETHICS CONSULTING IN THE BIOTECHNOLOGY INDUSTRY

The biotechnology industry has been on the frontline of controversy. From pricing policies to safety concerns, the industry is under greater public scrutiny than ever before. Many firms have sought advice from ethics consultants to help them understand and address questions and concerns raised by their work.

In 2004, AAAS launched a project to examine consulting practices and compile resources on the subject. Two surveys were conducted – one gathered information from biotech companies, and another queried ethicists about their experiences. Although the data do not permit one to draw definitive conclusions, the information collected provides insight into the use of ethics consultants.

Companies of all sizes were represented in the surveys. Most ethics consultation seems to be in the fields of biology, pharmaceuticals, and genomics. Advice was sought most frequently on issues involving data collection, confidentiality, storage, and/or disclosure and potentially controversial research or product development.

For those responding, having someone (e.g., legal counsel) – or a committee – on staff was more common than hiring a consultant, usually from academia, on an as-needed basis. Both internal and external consultants were asked to provide similar types of advice, including identifying potential problems and addressing existing/emerging ones.

Consultants were more likely to have training in medicine or philosophy/ethics than in other disciplines. When asked to identify reasons they had agreed to consult, "intellectual challenge" was the most often cited response. Respondents also welcomed the opportunity to acquire first-hand knowledge of impending scientific developments.

Both the company respondents and consultants rated, on a scale of 0 to 10, how helpful/useful they thought the advice had been. Average scores were 9 and 8, respectively.

The external ethics consultants were usually required to sign confidentiality agreements, but not non-competition provisions. Compensation usually consisted of either fee per consultation or payment by the hour. Daily fees ranged from $200-$1000, and hourly rates, $125-$200.

Few problems were reported. One respondent mentioned refusing to testify in a lawsuit, another reported a company's request to retract published findings, and a third mentioned a dispute over whether a particular experiment should be performed. Information-sharing between the companies and consultants was not cited as a problem.

Consultants described a few pitfalls in their work, including being used as an "ethical cover" for public relations, peer criticism, client-imposed restrictions on publication, and a drain on time for other activities such as teaching and research. A detailed report of the project, which was funded by The Greenwall Foundation, is posted on the Web at http://www.aaas.org/spp/sfrl/projects/bioconsult/index.shtml.

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(**News** continued on page 6)

(**News** continued from page 5)

HOW THE PUBLIC VIEWS SCIENTISTS AND ENGINEERS

Since 1977, The Harris Poll has measured the public's perception of various occupations, including scientists and engineers. The exact question asked is: "I am going to read off a number of different occupations. For each, would you tell me if you feel it is an occupation of very great prestige, considerable prestige, some prestige or hardly any prestige at all?"

Year after year, "scientist" has been near or at the top of the list of most prestigious occupations. In the most recent poll[1], conducted in July 2006, 54% of those surveyed thought that scientists have very great prestige, a statistic that has consistently been in the mid-50s since 1992. However, scientist ranked only fourth among the 23 occupations in the survey, unlike the three previous years. In 2003, for the first time, it held the number one spot. In 2004 and 2005, it tied for first place with doctor and firefighter, respectively. Firefighter now tops the list, with 63% of those surveyed giving that occupation the very great prestige designation, followed by doctor at 58%, and nurse at 55%. Engineer falls somewhere in the middle. In 2006, it ranked 10th, with 34% of the public saying it had very great prestige — the same level as 2005, but up from 29% in 2004.

Some notable changes have taken place during the 29 years Harris has been conducting the survey. Among the 11 occupations included in the survey since it began, only teachers saw an improvement in their rating, from 29% in 1977 to 52% in 2006. In contrast, scientists fell 12 points from 66% to 54%.

1. Complete poll results can be found at http://www.harrisinteractive.com/harris_poll/index.asp?PID=685

***MP**

IN THE SOCIETIES

WAR ON TORTURE: PSYCHOLOGISTS SPEAK OUT

In response to recent controversy on the permissibility of torture in times of war, the American Psychological Association (APA) has issued an updated resolution for August 2006, calling for psychologists to abstain from prisoner abuse and torture and to disclose knowledge of any such acts. The 2006 Resolution Against Torture and Other Cruel, Inhuman, or Degrading Treatment of punishment, an updated and more comprehensive version of the Association's 1986 Human Rights Resolution on Torture, clarifies its stance against such acts in the face of criticism over a commissioned report published by the group in June 2005.

The new resolution forbids psychologists to "knowingly engage in, tolerate, direct, support, advise or offer training" for the abuse and torture of prisoners, citing "an ethical responsibility to report these acts to the appropriate authorities." The guidelines encourage psychologists to comply with international law in establishing accepted norms of prisoner treatment, while leaving out specific areas of prisoner treatment to avoid except "deprivation and disorientation."

Unlike other medical science organizations, such as the American Psychiatric Association and the American Medical Association, the APA has yet to prohibit psychologists from participating in or consulting with regard to prisoner interrogations. To the contrary, the military still actively employs psychologists' knowledge of behavioral sciences in advisinginterrogation techniques.

There has also been wide criticism over the 2005 APA-published report by the Presidential Task Force on Psychological Ethics and National Security. The report, in which 6 of its 10 members were later disclosed by *Salon* to have ties to the military, described psychologists as playing "a valuable and ethical role to assist in protecting our nation, other nations, and innocent civilians from harm." Furthermore, 4 of the 10 Task Force members were found to have worked with interrogators at Guantánamo Bay in Cuba, Abu Ghraib in Iraq, or in Afghanistan, all of which have received international attention for prisoner abuse and torture.

Despite the new resolution and its guidelines, many APA members still consider the language too vague and are demanding more immediate results by banning all involvement with the interrogation process. With such acts as sexual humiliation, sleep deprivation, and psychological abuse and harassment having been deployed under the supervision of the Behavioral Science Consultation teams at places like Guantánamo Bay, opponents of the current policy have gathered almost 1,500 signatures on a petition protesting interrogations using psychologists. Talk has also circulated of another resolution effectively banning psychologists from participating in interrogations.

Resolution found at: http://www.apa.org/convention06/notortureres.html
Petition found at: http://www.thepetitionsite.com/takeaction/483607021?ltl=1156196075

***DJ**

THE ROYAL SOCIETY CONFRONTS EXXONMOBIL

The UN Intergovernmental Panel on Climate Change (IPCC) report due to be published in February 2007 includes data indicating climate change could result in higher global temperatures than formerly predicted. This new data, in combination with the director of the British Atlantic Survey Chris Rapley's findings that showed polar ice caps melting at much faster rates than anticipated, has prompted the UK Royal Society to urge ExxonMobil to stop funding organizations that discredit science, more specifically those disputing climate change.

Discrediting scientific data was initiated by Philip Morris, the tobacco company, when the Environmental Protection Agency (EPA) issued a report on Respiratory Health Effects of Passive Smoking in 1992. In order to discredit the report, Philip Morris hired APCO, a public relations company, which recommended founding The Advancement of Sound Science Coalition (TASSC), an organization that seemed like a grassroots movement, to question not only scientific reports on smoking, but also global

(**Societies** continued on page 7)

(**Societies** continued from page 6)

warming, nuclear waste, and biotechnology.

ExxonMobil has followed the precedent set by Philip Morris by funding the TASSC and 39 organizations publishing misleading data on their websites with $2.9 million in 2005. In addition, the 2005 ExxonMobil Corporate Citizens Report contained a section on Environmental Performance, which stated there was no reproducible statistical data to determine whether man-made emissions have contributed to recent climate changes. In the letter challenging ExxonMobil, the Royal Society stresses that statistical analysis of climate change by human actions has been reproduced, and there are 167 references to support this claim. The Royal Society wrote to express "disappointment at the inaccurate and misleading view of the science of climate change" contained in the 2005 ExxonMobil Corporate Citizenship Report. The Royal Society conveyed difficulty in "reconciling the misrepresentations of climate change science in these documents with ExxonMobil's claim to be an industry leader."

As of this year, ExxonMobil continues to fund organizations that dispute climate change. According to George Monbiot, the author of a new book, *Heat*, the doubt organizations disputing climate change have sown among the public has "delayed" effective global action on climate change by years." Until the public perceives a scientific consensus on the severity of global warming, it will be difficult to combat.

The Royal Society Letter found at: http://image.guardian.co.uk/sys-files/Guardian/documents/2006/09/19/LettertoNick.pdf The excerpt from George Monbiot's book *Heat* found at: http://environment.guardian.co.uk/climatechange/story/0,,1875762,00.html

***SC**

RESOURCES

THE SHAPE OF THOSE TO COME

A Review of *Surgically Shaping Children: Technology, Ethics, and the Pursuit of Normality*, edited by Erik Parens (336 pages), Johns Hopkins University Press, Baltimore, 2006 http://www.press.jhu.edu/books/title_pages/8953.html

This volume is the culmination of a Hasting Center project on the psychosocial and ethical impact of surgical procedures aimed at improving quality of life for children. Editor Erik Parens focuses on surgical interventions for cleft palate, achron-droplasia (dwarfism), and intersexed conditions. Parens weaves together wrenching patient narratives, candid reflections from doctors and social workers, and harrowing accounts from parents faced with these unimaginable decisions to show that, while all were united in the effort to provide care for children, ideas about what constitutes care are often divergent.

There is a consensus among the authors that the children themselves should be involved, and if possible, make the final decision concerning surgery. One option heavily promoted in the book is waiting until the child is older. Waiting makes operating safer, allows parents time to recover from the shock initial diagnosis may cause, provides time for parties to become more informed about the consequences of a particular procedure, and acknowledges the child's wishes. This class of surgeries is reported to be painful (limb-lengthening), lengthy, and often leave dissatisfying results (increased height yet physically weaker limbs; lost sensation in genitalia; and create massive scarring). Because of what is at stake, many argue that only the individuals themselves can determine if these procedures are worth the cost.

Another strain of argument focuses on how interests become conflated when an individual is deciding on surgery for himself versus deciding on behalf of another. Ellen Feder's chapter "In Their Best Interests" refers to research by Suzanne Kesseler on college students and preferences about intersexed surgery. Kesseler's work shows that when students were asked if they would correct hypothetically abnormal genitalia (an abnormally large clitoris for a female, or an abnormally small penis for a male), once informed of the possible loss of stimulation, most opted not to have the surgeries. Yet, when another group of students was asked to make such decisions on behalf of their hypothetical children, students were more likely to proceed with corrective surgeries. Feder believes these responses suggest that parents may unintentionally be looking out for their own best interests, opting for surgery to assuage their own fears and confusion, not to protect the child.

Maybe it's not the children that should change, it's the society, argue some members of the SSC group. Sherri Morris, former patient of intersexed surgery, writes, "physicians are sometimes overly impressed with new technologies, losing sight of the fact that there is meaning and purpose to being born "different," and that surgery and secrecy have the potential to invalidate the patient's experience… Having AIS (an intersexed condition) is not for me the tragedy my parent and doctors thought it would be." (pg. 11) Just as there are surgical options for dealing with many of these conditions, non-surgical alternatives such as social and family support are also available.

Along with narratives and specific case studies, the book included broader philosophical arguments about the role of cosmetic surgeries in society. One theme was the concept of body commodification. James Edwards and Arthur Frank argue that modern society presents thebody as raw clay to be shaped for consumer-oriented, self-fulfillment purposes like fashion (Edwards, pg. 57 & Frank, pg. 73). While referencing a 2003 article in *Vogue* fashion magazine on the benefits of undergoing cosmetic foot surgery in order to wear designer shoes, Arthur Frank explained,

"These shoes 'require designer feet'. As *Vogue* told the story, surgical practice is being pushed by patient-consumers, who are in turn being pushed by shoe designs … [This frames] the practice of surgery as standing reserve for fashion. What comes first is the shoe, which dictates the shape of feet. If the shoe does not fit, then perform surgery on the foot." (pg.73)

Frank used this case to emphasize the importance of understanding the deeper

(**Resources** continued on page 8)

(**Resources** continued from page 7)

social impetus for not only cosmetic "foot" enhancing surgeries, but for any medically unnecessary procedure.

Another philosophical argument presented was that no matter how individualized such decisions appear, they have a larger social impact. "The possibility of fixing renders inescapable the question of whether or not to fix." (Frank, pg. 68) Not only have these surgeries changed the lives of the individuals themselves, their experiences enter into a larger ongoing dialogue on how these conditions and surgeries affect patients.

While this book does an admirable job of bringing together a cross-section of perspectives, there were noticeable gaps in the dialogue that left this reader concerned. First, patient and parent narratives seemed to all be accounts of women, with a noted absence of male voices. Second, these procedures where not discussed in the context of different ethnic or religious groups. Finally, while medical costs were acknowledged, there was little discussion of the influence of cost in decision-making.

The absence of male parent and patient narratives prevent the reader from forming a more complete picture of the dynamics involved in making these surgical decisions. Fathers and male relatives seemed to be very much in the periphery on these decisions. How did their reactions play into the final decisions? Do male patients have different experiences in the cases of cleft palate and limb-lengthening surgeries where different social norms of attractiveness and height are play? This gap in information warrants further research.

Authors lumped ethnic and cultural norms into the broader category of social pressures. While occasional references to one's religious back ground and cultural identity were alluded to in a few accounts, little time was devoted to situating decisions in the context of religious and cultural identities. Filtering this dialogue does send a powerful message that across economic classes, ethnic groups, and cultural lines, parents and patients must equally grapple with decisions about surgery. At the same time, it ignores an important part of identity, while discussing potentially identity-altering surgeries.

Health care costs constituted the elephant in the room in the essays. Without acknowledgement of the obstacles of cost, decisions about whether or not to have this class of surgeries are painted as a question of choice and risk, not a question of means. With significant portions of society without health coverage, and health care providers adhering to specific coverage standards, how do financial factors affect the surgical decisions?

Despite these criticisms, *Surgically Shaping Children* managed to bring anumber of different perspectives to bear on the complexities surrounding surgically "fixing" what society may have arbitrarily deemed "broken."

More information about SSC project is available at:
Surgically Shaping Children Project
http://www.thehastingscenter.org/research/biot07.asp

ORI INTRODUCTION TO THE RESPONSIBLE CONDUCT OF RESEARCH

The Office of Research Integrity has created a web version of its *Introduction to Responsible Conduct of Research* posted at http://ori.hhs.gov/publications/ori_intro_text.shtml.

Support From the Following Societies is Gratefully Acknowledged:

American Anthropological Association
American Political Science Association
American Psychological Association
Association for Psychological Science
American Society for Engineering Education
American Sociological Association

ANNOUNCEMENTS

The 7th International Computer Ethics Conference will meet July 12-14, 2007 at the University of San Diego, California. The deadline to submit papers is November 10, 2006. Further conference informa-tion can be found at http://cepe2007.sandiego.edu/

The 2006 Annual Human Research Protection Programs conference entitled "A Commitment to Ethical Research: Advancing the Mission on Human Research Protection Program" will be held November 15-18, 2006 in Washington, DC. Topics covered will include embryonic stem cells, institutional biosafety committees, conflict of interests, and the concept of vulnerability. An introduction to component analysis and HHS regulations will be available. To learn more, visit http://www.primr.org/education/2006_HRPP/reg_HRPP06.html.

The Society for Ethics Across the Curriculum will host its 8th international conference this November 16-19, 2006 in Hanover, NH. This year's theme is: "Brave New World: Genetics, Computers, and Nanotechnology." More information is available at www.rit.edu/~692awww/seac/conferences.html.

The Office of Research Integrity, HHS, and the University of South Florida College of Medicine together with the American Association for the Advancement of Science and the Association of American Medical Colleges are convening the 2006 Research Conference on Research Integrity on December 1-3, 2006 on Safety Harbor, FL. The conference will address integrity issues in a broad range of science and social science disciplines. For registration and information, visit http://www.cmehsc.usf.edu/research_integrity. Limited travel stipends are available to graduate students studying in related fields of research. Contact: Dr. Mary Scheetz at mary@researchintegrity.us.