

November 19, 2002

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Re: Regulatory Toxicology and Pharmacology

Dear Ms. Chrisman and Mr. Weislogel:

We write to you to express our concerns about apparent conflicts of interest, lack of transparency, and the absence of editorial independence of the journal *Regulatory Toxicology and Pharmacology* (RTP), which you publish. As you know, that journal is the official publication of the International Society of Regulatory Toxicology and Pharmacology (ISRTP).

Our concerns about *Regulatory Toxicology and Pharmacology* include:

- The journal's apparent bias in favor of industries that are subject to governmental health and environmental regulations and that provide financial support to RTP's sponsor, ISRTP. ISRTP is supported by, among others, the American Chemistry Council, Bristol-Myers Squibb Company, Dow AgroSciences, Eastman Kodak, Gillette Company, Indspec Chemical Corporation, Merck and Co., Inc., Procter and Gamble, R.J. Reynolds Tobacco Company, The Sapphire Group, Inc., Schering-Plough Research Institute, and SmithKline

Beecham Pharmaceuticals – all companies or trade associations that have a direct incentive to minimize the regulatory burden on industry.

- A significant percentage of members of the RTP editorial board has financial ties to companies whose products or by-products are the subject of studies published in RTP. The large number of industry-affiliated scientists and lawyers on the editorial board of RTP is indicative of the pro-industry bias of RTP. Those individualsⁱ include:
 - Gio Gori, the editor of RTP (a past vice-president and now council member of ISRTP), has been a paid consultant to Brown and Williamson Tobacco Company and the Tobacco Institute and an outspoken critic of the hazards of environmental tobacco smoke. Documents from tobacco litigation in Minnesota reveal that in 1991 Gori was paid \$30,077 by the Tobacco Institute to write the paper “Mainstream and environmental tobacco smoke,” which was subsequently published in RTP (1991;14:88-105).
 - Louis Lasagna, was a paid consultant to the pharmaceutical companies that made and distributed the diet drug Redux. The consulting arrangement involved testimony at the FDA on behalf of the drug before it was withdrawn from the market because of adverse effects.
 - Richard Adamson (National Soft Drink Association)
 - Joel Bender (Chief Medical Officer, Owens Corning)
 - Johanna Dwyer (consultant for Procter and Gamble, Marlow Foods)
 - Gary Flamm (consultant to Philip Morris and Monsanto)
 - Jerome Heckman (lawyer for the food and pharmaceutical industries)
 - Peter Hutt (lawyer for the food and pharmaceutical industries)
 - John Keller (lawyer for the food and pharmaceutical industries)
 - Georg Kimmerle (toxicologist, formerly of Bayer AG)
 - Steve Lewis (scientist, ExxonMobil Biomedical Sciences, Inc.)
 - Roger McClellan (industry consultant and former director of the Chemical Industry Institute of Toxicology)
 - Dennis Paustenbach (scientific consultant to industry)
 - Robert Scheuplein (scientific consultant to industry)
 - Robert Squire (consultant to Procter and Gamble, Calorie Control Council, American Paper Institute)
 - Gary Yingling (lawyer for the food, drug, medical devices, and cosmetics industries)
- RTP editorials commonly support industry’s anti-regulatory goals. (See e.g., G. Gori, “The costly illusion of regulating unknowable risks,” 2001;34:205-212; G. Gori, “The EPA and the courts: inching toward a showdown,” 1999;30:167-168; Editors, “Editorial on the interpretive review of potential adverse effects of chlorinated organic chemicals on human health and the environment,” 1994;20:xiii.)

- RTP serves as a convenient venue for the publication of industry research and gives the credibility of a peer-reviewed journal to articles that may not have been subjected to full and meaningful independent review. In three recent issues of RTP (2002;35(1, February), (2, April), and (3, June)), more than 60% of the articles were generated by scientists from industry laboratories. That, and the additional articles authored by industry-funded academics or consultants, are of particular concern given independent studies showing that industry-funded research is lower in quality and more likely to favor the sponsor's product or interests.ⁱⁱ
- RTP routinely fails to disclose relevant conflicts of interest. In contrast, because of the mounting evidence that financial ties to industry skew research and authors' conclusions in favor of the sponsor's interests, prominent science and biomedical journals have instituted disclosure policies that require publication of relevant conflicts of interest alongside published papers. It is increasingly acknowledgedⁱⁱⁱ that journalistic ethics requires that:
 - readers be given all relevant information about authors' competing and conflicting interests.
 - editors who make final decisions about manuscripts should have no financial interest in the issues they might judge.
 - editors should not submit their original research to the journal that they edit and, if they do, must recuse themselves from the editorial oversight process.

It appears that policies and practices of RTP reflect none of those principles. Last February a group of scientists wrote a letter (enclosed) to RTP urging the editors to adopt such a policy. RTP never responded.

Given the considerable industry support received by IS RTP, RTP's industry-oriented editorial board, the too-frequent anti-regulatory tenor of RTP's editorials, and the preponderance of publications by industry-funded scientists, we urge Academic Press/Elsevier to increase the credibility of the journal by insisting that RTP (1) sever its ties to the industry-sponsored IS RTP; (2) reconstitute its advisory board to dramatically reduce the influence of industry scientists, industry lawyers, and academic consultants to industry; and (3) adopt an editorial policy of transparency about conflicts of interest. At minimum, the latter would entail disclosing on the masthead (and web site) the relevant industry affiliations of the editorial board members and disclosing relevant financial affiliations of authors whose papers appear in the journal. The affiliations disclosed should include funding sources, consultancies, stock ownership, expert testimony, employment, and others. Consistent with the best interests of an informed public, if the journal fails to take those steps, we urge Academic Press/Elsevier to stop publishing the journal.

Aside from the credibility of RTP and ISRTP, your own reputation as a publisher of credible, peer-reviewed scientific journals is jeopardized by journals that fail to live up to basic journalistic standards as recommended by the Council of Science Editors^{iv} and the International Committee of Medical Journal Editors.^v

Thank you for considering our views. We look forward to hearing from you.

Sincerely,

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cc. Sallie W. Carr, Gio Gori

Notes

ⁱ Documentation of some of these ties can be found at www.IntegrityInScience.org.

ⁱⁱ See generally, Rochon P. Evaluating the quality of articles published in journal supplements compared with the quality of those published in the parent journal. *JAMA*.1994;272:108-113; Bero LA, Rennie D. Influences on the quality of published drug studies. *Int J Technol Assess Health Care*. 1996;12:209-237; Bero LA, Galbraith A, Rennie D. The publication of sponsored symposiums in medical journals. *N Engl J Med*. 1992;327:1135-1140; Rochon P, Gurwitz JH, Simms RW, et al. A study of manufacturer-supported trials of nonsteroidal anti-inflammatory drugs in the treatment of arthritis. *Arch Intern Med*.1994;154:157-163; Cho MK, Bero LA. The quality of drug studies published in symposium proceedings. *Ann Intern Med*. 1996;124:485-489; Stelfox HT, Chua G, O'Rourke K, Detsky AS. Conflict of interest in the debate over calcium-channel antagonists. *N Engl J Med*. 1998;338:101-106; DeAngelis C. Conflict of interest and the public trust. *JAMA* 2000;284:2237-2238.

ⁱⁱⁱ International Committee of Medical Journal Editors. Sponsorship, authorship, and accountability. *JAMA*. 2001;286:1232-1234 and <http://www.icmje.org/sponsor.htm>.

^{iv} Editorial policy statements approved by the CSE board of directors.
http://www.councilscienceeditors.org/services_DraftApproved.shtml.

^v See note iii above.