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*This letter represents the position of the authors and does not reflect the official position of the National Institute of Mental Health.

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Questions About Disclosure

IN THEIR POLICY FORUM "DISCLOSURE IN regulatory science" (19 Dec., p. 2073), D. Michaels and W. Wagner overstate the potential problems with privately funded research being used by regulators. Their proposed remedy is more moderate, however, and worthy of broader debate.

Most ominously, they advert to "accounts of... sponsor suppression or termination of research showing adverse effects" in light of the "limited prohibitions" against such behavior. In fact, federal law clearly mandates reporting to the EPA of information that "reasonably supports the conclusion that [a chemical] presents a substantial risk of injury to health or the environment" (1). A similar disclosure requirement applies specifically to pesticides (2). A manufacturer could also face staggering civil liability for covering up results that indicated adverse effects from its products.

The authors likewise contend that the quality of privately funded research is subject to little or no oversight. All research conducted at the direction of the EPA must

be performed according to the Agency's Good Laboratory Practices (GLP) (3), and much privately initiated research for submittal to EPA also follows GLP. (By contrast, biomedical research funded by the EPA and NIH does not.) Any privately generated information that an agency relies on or otherwise adopts becomes subject to the Information Quality Act, which requires it to meet quality standards and mandates that it, and any supporting data, be made publicly available subject to confidentiality limits (4). And any federal agency has complete access to all information submitted to it, whether or not it is claimed to be confidential business information.

Finally, the authors imply that agencies and the public are unaware of potential conflicts of interest. EPA's Integrated Risk Information System (IRIS), which records most of the Agency's health effects assessments, clearly references the key studies it relies upon, and those entries typically disclose study sponsors. Studies published in the scientific literature virtually always cite funding sources. Much of EPA's data comes from mandated studies, and the source of such reports is clear to the agency.

Michaels and Wagner propose that, for research submitted to the federal govern-

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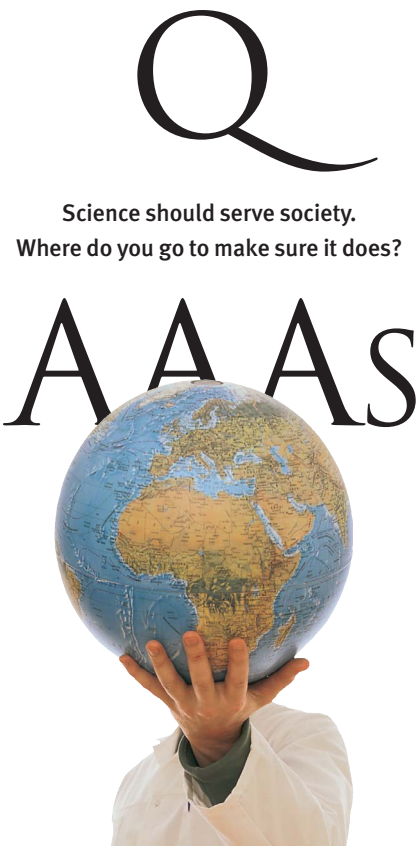
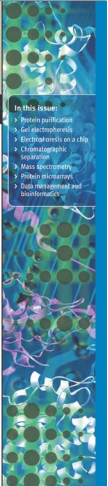
Proteomics, the study of all the proteins in biological systems, represents the cutting edge of a research field that started with the successful sequencing of the genome of various organisms. It has advanced through the application of genomics, but whereas genes usually behave in predictable ways, proteins are erratic, resistant, flexible, and generally difficult to handle.

"Having gene transcripts translated, cloned, and analyzed, individual proteins are much more than simple linear codes because of their more complex nature, variable charges, and secondary and tertiary structures," says Hank Kistner, senior vice president, marketing, at **Caliper Life Sciences**. "There's such a diversity of proteins from throughout the genome, from high to low abundance, from high to low abundance, and from a practical perspective, from stable to less stable, soluble and insoluble, and so on."

Proteomics is a much more complex task than genomics because of the sheer number of proteins and their complex nature, variable charges, and secondary and tertiary structures.

These difficulties have driven researchers to seek out more powerful tools and techniques for separating and characterizing proteins. "You have to have advanced tools if you want to do advanced technology," says Philippe Baudry, sales and marketing director at **GE Healthcare Analytical and Life Sciences**. "There's not the same technology in proteomics."

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ment, the submitter disclose known conflicts of interest and indicate whether the researcher was free to publish the results without sponsor interference. In general, this proposal is sound. Indeed, the American Chemistry Council's Long-Range Research Initiative (LRI)—a multi-year, multimillion dollar program of research on basic questions underlying health and environmental risk assessment—has consistently followed such a policy. Research contracts require that investigators publish their results in the peer-reviewed literature regardless of the outcome, the LRI has no approval authority over publications, and investigators must abide by OMB Circular A-110 (5) (which requires data from federally funded research to be made public when used by the government). Disclosure of funding and of freedom to publish has the virtue of shifting debates from questions about sponsorship to more appropriate questions about underlying scientific merit.

CAROL J. HENRY

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References and Notes

- Section 8(e) of the Toxic Substances Control Act [U.S. Code (U.S.C.) 15, § 2607(e)], quoted above, addresses any chemical substance or mixture.
- Section 6(a)(2) of the Federal Insecticide, Fungicide & Rodenticide Act [U.S.C. 6, § 136d(a)(2)] requires reporting to EPA of "factual information regarding unreasonable adverse effects on the environment of [a] pesticide."
- Code Fed. Regul. 40, part 160.
- U.S.C. 44, § 3516 note, *Fed. Regist.* 67, 8452 (2002).
- Fed. Regist.* 65, 14406 (2000).

Response

ALTHOUGH HENRY AGREES WITH OUR solution, she is concerned that we have overstated the problem of conflicts in research. The fact that the American Chemistry Council (ACC) has chosen to incorporate protections against sponsor influence into the LRI supports our contention that the problems we raise are real and deserve attention.

Unfortunately, the laws and regulations cited by Henry do not provide adequate protection against sponsor control of research and reporting (1). Although the EPA has adverse effects reporting requirements, most of the regulations leave sponsors with considerable discretion to determine, on their own, when new information "reasonably supports the conclusion that [a chemical] presents a substantial risk of injury to health or the environment." Even more problematic is the difficulty in enforcing these reporting requirements. EPA acknowledged the limitations of "self-reporting" and offered an amnesty in the mid-1990s for chemical manufacturers who previously failed to report adverse effects. EPA received

11,000 adverse effects reports—four times the number submitted since passage of the statute 15 years earlier (2).

Furthermore, other agencies charged with protecting the public's health—including the Occupational Safety and Health Administration, the Mine Safety and Health Administration, the Consumer Products Safety Commission, and the National Highway Traffic Safety Administration—have no such rules. These agencies do not even have a formal mechanism to inquire who paid for a study submitted for consideration in rule-making, to say nothing of issues related to data analysis and sponsor interference.

The Information Quality Act also provides little protection in this area, because the White House's Office of Management and Budget has exempted from coverage most research produced by regulated parties, while the Data Access Act explicitly applies only to federally funded research, exempting all privately produced research (the source of much data submitted by regulated parties) from its disclosure requirements.

We are grateful for Henry's support of our proposal, and we hope the ACC will join us in suggesting that the protections

built into their LRI be extended to all research done by their member companies.

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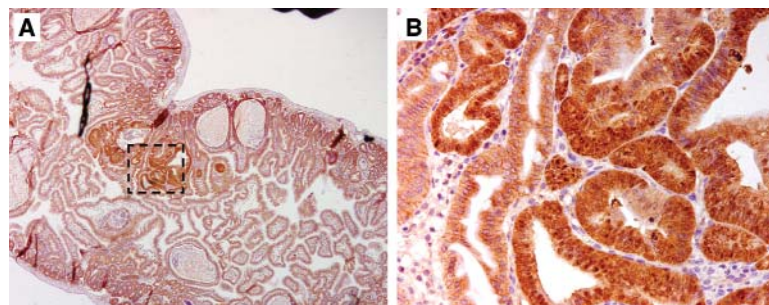
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CORRECTIONS AND CLARIFICATIONS

Reports: "Vortex core-driven magnetization dynamics" by S.-B. Choe *et al.* (16 Apr., p. 420). In the first full paragraph of the first column on p. 422, a negative sign was omitted from the description of vortex susceptibility. The corrected text should read "We considered a square vortex of length $l = 1$ mm, for which the vortex susceptibility has been determined by simulations to be $\sim 4 \times 10^{-5}$ henries per meter in agreement with experiments (14)."

Reports: "De novo crypt formation and juvenile polyposis on BMP inhibition in mouse intestine" by A.-P. G. Haramis *et al.* (12 Mar., p. 1684). There was an error in Fig. 3. Fig. 3B should be an enlargement of the area boxed in Fig. 3A. The corrected figure is shown here.



Perspectives: "After the toll rush" by L. A. J. O'Neill (5 Mar., p. 1481). In the figure, Porin (influenza) is listed as a virus, but it is actually a bacterium. In the figure legend, the acronym RSV should be defined as respiratory syncytial virus, not Roux sarcoma virus.