

[CELIA WEXLER COMMENTS]

Subject: Comments from the Center for Science and Democracy at the Union of Concerned Scientists

We appreciate the effort by the committee to revise these recommendations, in the light of comments and discussion at the Oct. 21 meeting.

However, we continue to be very disappointed that ACUS has expended staff and resources on a “problem” which cannot be substantiated by evidence. The report, “Agency Publicity in the Internet Era,” offers only three specific examples where businesses were harmed by agency communications, and one of those examples dates back to 1959.

In contrast, the report does not address the well-documented harms that occur when agencies fail to inform the public about dangers that could have been prevented.

- An estimated 55,000 heart deaths occurred because the drug maker, Merck, failed to report troubling heart problems in clinical trials of Vioxx, and because the Food and Drug Administration failed to heed the warnings of its own scientist and even attempted to suppress his research.
- FDA enforcement actions and warning letters did not do enough to prevent New England Compound Center for selling tainted pain injections until more than 30 patients had died and more than 400 were injured.
- The Consumer Product Safety Commission failed to adequately warn the public even after CPSC staff were aware that at least two children have been seriously injured from swallowing the small aspirin-sized magnets in a Magnetix toy. As a consequence, one child died, and 26 more children were seriously injured. CPSC’s failure to warn was prompted in part by statutory restrictions on what the agency may report about consumer products and the company that makes them.
- General Motors failed to notify regulators of a defective ignition switch that caused at least 100 deaths.

As a consequence, the recommendations, although improved by revision, continue to be weighed far too heavily in favor regulated industries that wish to avoid adverse publicity, even for defective products, shoddy business practices, or environmental violations that harm the public.

We would urge ACUS to further revise its recommendations so that agencies are not discouraged from informing the public about unsafe products, environmental violations, or investigations into a company’s poor worker safety performance.

We would urge ACUS to narrow the scope of its recommendations:

Retain **Recommendation 1. A and B.**

Retain **Recommendation 2 a.**

Cut recommendation 2b. There is no evidence that any federal databases have behaved irresponsibly in the handling of consumer complaints or other data that concern individual companies. This recommendation is written far too broadly. It may capture databases of relatively trivial consumer complaints.

For example, the FDA's device complaint database includes complaints concerning serious injury, harm or death from medical devices, and the FDA informs companies about these reports. But contact lens solution is considered a medical device. Should the FDA be required to notify the manufacturer about a trivial complaint, such as difficulty opening the box, or the solution caused some type of temporary irritation? ACUS simply lacks the information to write such a broad recommendation.

This recommendation also fails to acknowledge that in the era of the Internet, companies are fully aware of the plethora of consumer review and complaint sites, and yet they have managed to monitor them and to respond to any information or opinions they feel are inaccurate or misleading. A site such as TripAdvisor receives far more traffic than any federal website. Yet there is no obligation that TripAdvisor or Yelp notify a hotel, restaurant, service business, or other tourist destination each and every time the business gets a negative review. As long as agencies carry appropriate disclaimers, and businesses have the opportunity to refute complaints, agencies should not have the additional burden of notification.

Cut recommendations 5 and 6. These recommendations are overboard and are not evidence-based. They also include terms, like "where practicable" or "in circumstances supported by the public interest," that are vague, and again send a signal to agencies to release less information.

7. Eliminate the phrase, "when practicable." It is not clear what that means.

Cut recommendations 8 and 9. There is no evidence that agencies issue press releases that are inaccurate or fail to correct mistakes when they occur.

The IQA was not designed to include agency press releases, and should not include them. All press releases presumably contain new and substantive information, so this recommendation, again, would be both vague, overboard and unnecessary.