

## LETTERS

### Public Health Issues:

#### Bendectin, Love Canal

Reputable scientists have different points of view about a number of issues that have an impact on public health and safety. The AAAS Committee on Scientific Freedom and Responsibility (1) has taken the position that such controversial issues should be aired with the fullest possible presentation of the scientific evidence and that *Science*, because it is so widely read both inside and outside the scientific community, should be a major channel for this.

*Science* has fallen short of this role by failing to provide factually accurate and balanced reporting of two important and controversial public health issues with which I am familiar—the extent of health hazards at Love Canal and the safety of Bendectin, a drug prescribed for nausea in pregnancy. Some clarification of the record is essential.

#### Bendectin

1) Gina Bari Kolata, in the article "How safe is Bendectin?" (Research News, 31 Oct. 1980, p. 518), refers to several of the witnesses, including myself, who testified at the Food and Drug Administration (FDA) hearings on Bendectin as witnesses of "the flamboyant lawyer Melvin Belli." In fact, the hearings were organized by the FDA, who chose the witnesses and invited them. In my own case, the invitation to testify came from A. T. Gregoire of the FDA, and I have never had any professional relationship with Belli.

2) In the same article, the substance of the issue is missed because the epidemiological problems involved in detecting a weak teratogenic effect are not discussed. Several scientists who believe that Bendectin may be a weak teratogen have estimated from the available studies that it may produce from one to five additional congenital malformations per 1000 live births against a much higher background frequency of malformations (2). As was thoroughly aired at the hearing, detection of teratogenicity at this level requires a population study with a very large cohort or a case control study. The FDA committee recognized in its conclusions that none of the cohort studies examined were large enough to detect a weak teratogen. However, three of the four case control studies described at the hearing showed a statistically significant association of Bendectin usage with specific deformities. This leads to a very different assessment of Bendectin's safety from the impression given by Kolata's article.

3) Kolata reports that the study by Smithells (3) involved "2000 women who took the drug as compared to 11,000 women who did not." This is incorrect. Smithells himself made clear at the hearing that his "controls," which apparently included all live births in the cities of Leeds and Liverpool, contained an appreciable but unknown percentage of Bendectin users. These points are of some significance since, despite its insufficient cohort size and lack of appropriate control, Smithells' study has been widely quoted as indicating Bendectin's safety.

#### Love Canal

There has been a continuing focus of controversy over the health effects experienced by the Love Canal population. Because there are no other epidemiological studies of health effects available except for the single study by Vianna *et al.* on adverse pregnancy outcomes (4), my own early survey (5) still remains a primary source of data, despite the fact that it was never intended as a definitive epidemiological survey. Since it is one of the few studies publicly available, I would like to point out several important facts not mentioned or incorrectly reported in *Science*.

1) The *Science* articles do not mention the report (6) of the panel of epidemiologists and other scientists from the Department of Health, Education, and Welfare and the Environmental Protection Agency chaired by David Rall which was convened in 1979. They reviewed my data and that of the New York State Health Department on possible health effects at Love Canal and concluded that the concerns and questions raised by my data merited serious attention; they recommended establishing a registry, initiating epidemiological investigations, and taking action to minimize the exposure of residents.

2) There has also been no mention in *Science* of the fact that the only portion of my data which has been subjected to independent verification, the portion concerning adverse pregnancy outcomes, was replicated by the New York State Health Department (3), who considered the evidence strong enough to issue an order (7) on 8 February 1979 evacuating pregnant women and children under age 2 from the entire Love Canal neighborhood.

3) Independent evidence concerning the other health problems whose incidence was elevated in my study (asthma, urinary system problems, and symptoms of central nervous system damage) have not appeared in the 2 years since I reported my results to the New York State Department of Health. I may be

mistaken about these health effects, but that can be determined only by a study designed to test the hypotheses.

4) Contrary to the article in *Science* by Constance Holden ("Love Canal residents under stress," News and Comment, 13 June 1980, p. 1243), I have never claimed that cancer, liver disorders, or emphysema are elevated in the Love Canal population.

5) Recently a new factor in the controversy was introduced by the release of the Thomas committee report, which was widely covered by the public press and reported by R. Jeffrey Smith in the News and Comment briefing "Love Canal reviewed" (31 Oct. 1980, p. 513). Some background information is appropriate. A New York State legislator, supported by the press, was calling for an independent investigation of the health effects at Love Canal. Instead, New York State Governor Hugh Carey appointed the Thomas committee, composed of medical faculty at New York institutions. The Thomas report strongly criticizes the former New York State Health Department administration and all other agencies and individuals, including myself, who have worked at Love Canal except for the current Health Department administration. A major recommendation of the report is that all future studies of the Love Canal population be organized and controlled by the New York State Health Department. This recommendation appears unrealistic in light of the antagonism that now exists between the New York State Health Department and the Love Canal population, who feel that the state agency has been dilatory and unduly secretive in failing to release any of their previous health studies except for the long-delayed report by Vianna *et al.* (4).

More important, the report's conclusions regarding the lack of health effects at Love Canal have been widely quoted and are likely to become a basis for public policy despite the fact that, unlike a conventional scientific document, the report does not reference the specific facts or documents from which the conclusions are drawn. What the report does provide is a very briefly annotated bibliography. This deficiency is serious. For example, the Thomas committee claims that there has been no excess of cancer, asthma, or epilepsy at Love Canal, although the appendix study listed as providing evidence for this claim is actually on adverse pregnancy outcomes and contains no information about cancer, asthma, or epilepsy. No other studies on asthma or epilepsy are listed, and the study on cancer is listed as "in progress." Similarly, the Thomas committee

concludes "it is clear enough" that there are no reliably documented cases of acute health effects. No study on acute health effects is listed in the appendix, nor does one exist to the best of my knowledge. There do exist documented cases of acute health effects. During the remedial construction phase in 1979, a temporary mechanism was set up to verify acute health effects. During those months it was in effect, there were more than 125 cases of physician-verified acute physical health effects. The physicians signed a form saying "this illness appears to be coincident in time, and in my opinion, may be causally related to excavation of lateral trenches at the Love Canal."

6) Smith reports as a conclusion of the Thomas committee that "hysteria was fueled by the congressional testimony in 1979 of Beverly Paigen." This statement is untrue. My testimony did not fuel hysteria nor did the Thomas committee reach that conclusion. Rather this is an editorial opinion of Smith which is incorrectly ascribed to the Thomas committee. Even as an editorial opinion, such a view indicates a serious lack of information about the events which did trigger hysteria at Love Canal. Had Smith checked with one of the organizations active in the community, he would have found that hysteria occurred on those occasions when government agencies failed to provide factual information or to deal realistically with the people's concerns.

I believe the *Science* articles on Bendectin and Love Canal contain additional factual errors, but I have only pointed out those of which I have firsthand knowledge. Even though I was mentioned by name in these stories, I was not called by a *Science* reporter to check the facts, a standard journalistic practice.

In both of these situations, *Science* has failed to provide balanced coverage and accurate reporting of controversial issues. I trust that *Science* readers will reserve their judgment on these issues until more information is presented. I suggest that *Science* publish articles from other scientists familiar with the Bendectin and Love Canal issues which present a point of view different from those reported so far.

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#### References

1. Committee on Scientific Freedom and Responsibility, *Scientific Freedom and Responsibility* (AAAS, Washington, D.C. 1975).

2. Fertility and Maternal Health Drugs Advisory Committee meeting, 15-16 September 1980 (Food and Drug Administration, Washington, D.C., 1980).
3. R. W. Smithells and S. Sheppard, *Teratology* 17, 31 (1978).
4. N. J. Vianna *et al.*, in preparation.
5. B. Paigen, in U.S. House of Representatives, Committee on Interstate and Foreign Commerce, *Hazardous Waste Disposal*, Part 1 (Government Printing Office, Washington, D.C., 1979), p. 60.
6. Subcommittee on the Potential Health Effects of Toxic Chemical Dumps, Committee to Coordinate Environmental and Related Problems, D. Rall, chairman, "Report of meetings between scientists from HEW and EPA, and Dr. Beverly Paigen and scientists of the New York State Department of Health concerning Love Canal" (Department of Health, Education, and Welfare, Washington, D.C., 26 July 1979).
7. D. Axelrod, "Supplemental Order: State of New York, Department of Health, In the matter of the Love Canal Chemical Waste Landfill Site Located in the City of Niagara Falls, Niagara County" (Department of Health, State of New York, Albany, 8 February 1979).

The Thomas panel noted the fear and anxieties that have beset the Love Canal residents for 2 years, explaining that many of the residents believe their health is irreversibly damaged—that they are at future risk of cancer, birth defects, miscarriages, and abortions. Paigen had reported, based on anecdotal information gathered by the homeowners, on an increased risk of these and other ailments, including central nervous system disorders, urinary disease, suicides, epilepsy, skin disease, heart disease, and "a definite impairment of the blood-clotting system in these people." The Thomas panel said that this report "cannot be taken seriously as a piece of sound epidemiological research, but it does have the impact of polemic."

Thus the briefing does report, admittedly in abbreviated form, the panel's view on the substance of Paigen's testimony. No one disputes her sincerity and goodwill in bringing the homeowners' difficulties into public light.

—R. JEFFREY SMITH

*Science* published a brief account by R. Jeffrey Smith (News and Comment, 31 Oct., p. 513) of the report on Love Canal research issued by a panel chaired by Lewis Thomas. Smith quoted the panel's view of research by Beverly Paigen and others but without providing background essential to an understanding of the Thomas panel's report, a document widely distributed to the press and to every New York State legislator.

The Thomas panel was established by New York's Governor Carey at a time when the Department of Health (DOH) was under political attack in the New York State legislature. On 27 April 1980, State Senator Thomas Bartosiewicz, ranking member of the state senate's standing committee on energy and utilities, wrote to Governor Carey requesting

that the governor initiate an investigation of DOH activities at Love Canal. He called for an independent, outside commission with subpoena powers. On 17 May, the chromosome breakage fiasco dominated the news. On 28 May, Senator Bartosiewicz distributed a resolution to all his colleagues in the legislature asking their support for the resolution to initiate an investigation. Governor Carey appointed the Thomas panel on 4 June 1980. The panelists were all physicians, and with one exception, administrators at New York State institutions. While the panelists are all eminent, their appointment raises a question of a conflict of interest.

The New York State health commissioner must approve every capital expenditure for construction and equipment in all public and private medical facilities (N.Y. Public Health Law, sections 2801[5]; 2802). The New York health commissioner also participates in setting rates for hospital services on an annual basis (section 2807). The commissioner has discretionary power in setting rates. "The commissioner shall exclude costs for research, those parts of the costs for educational salaries which the commissioner shall determine to be not directly related to hospital service, and allowances for costs which are not specifically identified" (section 2807[3], effective 1 April 1978). The Thomas panel was evaluating the work of a department whose commissioner has extensive powers over their institutions.

The report omitted any criticism of DOH activities past the initial Love Canal time bomb report of August 1978. Its criticisms of DOH were limited to actions taken by the former commissioner. The New York State DOH has spent \$3.2 million on health studies at Love Canal, and it has produced but a single report, rejected for publication by *Science*. The Thomas panel did not discuss the antagonism DOH activities have created in Love Canal residents toward DOH and other government scientists.

Research at Love Canal has gone on in a highly politicized atmosphere. Unwarranted ad hominem attacks undermine the basic social control of science, which depends on independent effort. The Thomas committee castigated Paigen and others. This was repeated by *Science* without adequate investigation. Rather, these scientists deserve public commendation for their bravery and persistence despite great personal cost and harassment.

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