

BIO-MEDICAL RESEARCH
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NEW ETHICAL PROBLEMS RAISED BY DATA SUPPRESSION

The scientific community in the past has been a leading example of the success of ethical self regulation. While it is true that there is an occasional case of fraud or falsifying data, by and large the system has been effective. Whether because of the integrity of scientists or because of the fact that most important findings are re-tested and verified, scientists seem to have had fewer major scandals than many professions.

Now, however, a new set of ethical problems is raised by the withholding of data on industrial products or conditions from regulatory agencies. The scope of law setting standards for industry now includes environmental and occupational conditions as well as consumer products, food and drugs. Most such legislation was passed over the intense opposition of industry, which often must perform the tests, pay the bills, and sit out the expensive delays while Federal agencies make up their minds. It is no surprise that companies sometimes seek to circumvent their legal obligations to meet standards.

Pressures on Industrial Scientists Have Increased

The pressures on scientists have increased for these reasons and because research has become a larger component of the competitive edge in many industries. Their tacit approval is implicit in deceiving a regulatory agency, and how many industrial scientists can resist the pressures that can be brought to bear by management? Still rarer is the scientist who can bring himself not only to refuse to be a party to the suppression of data, but also bring his results to the public's attention.

One of the greatest sins in science has always been the deliberate falsification of data. Those who commit it are subject to ostracism and other informal but devastating sanctions. Sins of omission are just as culpable in law and common morality as those of commission; they can rouse even more contempt because of the cowardice they show. Yet industrial scientists who fail to challenge conspiracies of silence within their firms are not rebuked; rather, they are often quietly rewarded for their loyalty.

The ethical issues raised by acts of omission which result in falsification of data needed by a regulatory agency have been brought to the fore by the case of vinyl chloride. Simply put, Manufacturing Chemists Association members, including scientists, possessed data as early as November 1971 that vinyl chloride caused cancer in rats, especially the exceedingly rare and incurable angiosarcoma of the liver. This data was kept from the appropriate authori-

ties at the National Institute for Occupational Safety and Health (NIOSH) at least until July 1973, and probably until February 1974. Vinyl chloride is used as a feedstock for polyvinyl chloride products, which range from car interiors to phonograph records; until recent months it was also used as an aerosol propellant. Polyvinyl chloride (PVC) is the number two U.S. plastic in tonnage production (4.4 billion pounds annually); about one fourth of the world supply is made in this country.

What harm was done by the suppression of data in this instance? Workers were exposed longer to higher concentrations of vinyl chloride than they would have been if NIOSH had had full information. Those affected include about 6500 people who produce and manufacture vinyl chloride, and about 1.5 million who process it. People who live near plants where it is used may also be harmed as a result; two have already been identified as victims of angiosarcoma, which is a red flag indicating exposure. According to Dr. Joseph Wagoner of NIOSH, the occurrence of cancer in fabricating plant workers "points to the probability of low level exposure being obviously very hazardous." (Sixty per cent of the air samples NIOSH took in fabricating plants showed concentrations of less than one part per million (ppm) vinyl chloride. The standard for workers was 500 ppm until April 1974.) Consumers might even be affected by seepage of vinyl chloride from polyvinyl chloride products.

What follows is a rough chronology of some aspects of the vinyl chloride controversy (in bold face) with an accompanying discussion of some ethical and practical considerations. (This Bulletin deals primarily with the second phase of the controversy, after Mahon's data were revealed to the industry's Manufacturing Chemists Association, MCA, because the facts are more fully known and thus the issues are more clear cut.)

In May 1970, preliminary findings by an Italian investigator, Dr. P. L. Viola, were presented at a U.S. International Cancer Congress. He showed that extremely high concentrations of vinyl chloride (36,000 ppm) caused cancer in rats. These results were published in an American journal in 1971.

Even prior to these findings, it was a serious caution on the part of the plastics industry that vinyl chloride was never tested for carcinogenic and other properties, despite the fact that tens of thousands of workers were routinely exposed to it. MCA did solicit research proposals on VC

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1970, but no contracts were let until 1973. If strong provisions for pre-testing of possibly toxic substances are enacted by Congress (as discussed in the last Bulletin), and if they are strictly enforced, there should be no more similar oversights. This incident is one of the best arguments for such legislation.

Given the fact that no testing had been done previously: industry scientists would have immediately followed the European lead and tested vinyl chloride at lower concentrations—or at least sought to confirm Viola's findings—had they been thinking only of the public interest. But other factors prevailed. The route to advancement in industry is often what one author describes as "aggressive self-effacement." Scientists are relatively low in the organizational hierarchy; if they want to get ahead, they must play by the rules.

The counterweight of informal control by the wider scientific community is often weak in industrial settings. Although scientists are now considered to be responsible to society for the foreseeable consequences of their work, the industrial scientist has little or no control over the uses of his research. In this way, he is almost as isolated as an assembly line worker. For the scientists in question, the issue of their responsibility to society was blurred by the fact that they were faced merely by an expectation of non-action; the same people might react very differently if ordered by a vice president to falsify vinyl chloride data. But, to the worker with angiosarcoma, it makes little difference whether the act is one of omission or commission.

A year after the Cancer Congress, the Manufacturing Chemists Association brought Dr. Viola to this country. He revealed that other European studies were in progress, but refused to divulge the details according to MCA.

Any scientist in the field could make the educated guess that they involved graduated smaller doses of vinyl chloride. But in terms of scientific ethics, Viola's refusal violated his obligation to the scientific community and to the public. He failed to honor one of the oldest and most firmly held norms of the scientific community, freedom of information. This failure can probably be explained by the fact that Viola was and is an employee of the plastics industry.

No consideration should, however, have prevented Dr. Viola from disclosing at least the nature of the European studies. Even if he were willing to ignore his clear obligation to share data with other scientists, he should have thought of the thousands of people routinely exposed to a substance he knew to be carcinogenic. Other scientists could have, and apparently did not, bring these points to his attention; their influence would probably have been fairly strong, since Viola had published in an American journal and presumably would wish to again.

The analysis above assumes that Viola remained silent. There is evidence that he told MCA that concentrations of 5000 ppm or less could cause cancer in lab animals. Ethical implications of withholding this data will be discussed below.

In any case, MCA decided to undertake its own research, and in October 1972 plastics manufacturers who

sponsored the European research offered to share information—with strings attached. It was agreed that an MCA task group would reveal no information to anyone without the consent of European manufacturers.

MCA should never have made such an agreement. It flies in the face of its responsibilities to protect workers and the public and limits its scientists' rights to full and free information. Had the Association undertaken its own tests in May 1970 at the first sign of trouble, it would have had no need to obtain the results of European experiments under unethical strictures. It probably would have been possible to force release of the information simply by making the attempt at an undercover agreement public; but MCA apparently was prompted by fellow feeling for sister industries and its need for data which it should have collected itself in the first place.

Meanwhile, in August 1972, Dr. Cesare Maltoni of Bologna found angiosarcoma in experimental animals, and discovered that various tumors were produced at levels as low as 250 ppm. At that time the U.S. ceiling for human workers was 500 ppm. There is reason to

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FAS Fund

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believe that this level was exceeded in some plants. Dr. Maltoni later said that he believes that the results of these and other tests were predictive of the later discovered effects on humans.

Here the issue of sponsorship of research arises. While Dr. Maltoni is an academic, his research was paid for by the plastics industry. Had he been acting on his own, it seems very likely that he would have hastened to reveal and publish his data. Because he knew that humans were being exposed to levels of vinyl chloride higher than those which produced cancer in animals, he bore a heavy ethical responsibility to make the facts known.

One of the present difficulties in getting research on hazardous substances done is that only industry now has the resources necessary to perform it. Academically, measuring dose response to a substance is often not very interesting. In industry there is almost no incentive to test hazards unless it is feared that information will otherwise be disclosed to the detriment of the company. If a strong version of the Toxic Substances Control Act, discussed in the last Bulletin, is passed, then industry will be required to do such research by the Environmental Protection Agency.

On January 17, 1973, U.S. scientists representing the vinyl chloride and polyvinyl chloride industries visited Dr. Maltoni's laboratories to hear about his experiments in detail. They also spoke with the European sponsors of his research.

These scientists had the opportunity to insist that the European companies reveal Maltoni's data, and, if they refused, to blow the whistle. The scientists claim that they had doubts about certain of Maltoni's procedures: for example, food was left in the cages, and they thought that a substance formed by vinyl chloride and food might be responsible for the results rather than vinyl chloride itself. This would not be unreasonable except that, in Viola's findings, vinyl chloride was the culprit; in that light it seems a somewhat shallow objection. Even if the scientists took it seriously, they could have presented NIOSH with the data they had, along with a discussion of what they considered weaknesses in the experimental procedures.

If the scientists had decided to take that step, or to make the data fully public, what would the likely results have been? First and worst, they would probably have been fired. While the principle of due process (including hearings) in firing of state employees was affirmed in the case of three scientists who turned to FAS for help, it does not yet apply broadly to corporations. Finding other jobs in industry would be difficult or impossible for scientists with records of "disloyalty." Realistically speaking, even whistle blowers who manage to avoid firing—or to be reinstated—"must anticipate that the employers will find some way to make them scramble for a living—and pay—after their treachery" (*Blowing the Whistle*, 1972, Charles Peters, ed.). The scientists would probably have found little meaningful support in the scientific community; however much praise they received, it could not have been turned into a livelihood.

Their legal position would have been precarious. As Professor Arthur Miller has emphasized, generally "the law at present provides very little protection to the person who would blow the whistle; in fact, it is more likely to assess him with criminal or civil penalties."

The scientists could have taken the risks of firing and legal action to protect the public health, but they did not. The confidentiality agreement with European manufacturers may have constrained them, but it should not have prevented their acting as responsible scientists should. The agreement was made in violation of common scientific ethics, and the scientists should have felt no more bound by it than a person who is told about illegal activities in secret should feel obliged to keep his word.

No Censure by Scientific Community

Instead, they chose the path of least resistance, and as a result have grateful employers and continue in their jobs. If the scientific community feels any outrage now that the case is widely known, it has not expressed it in any kind of censure. A civil suit for damages will never be brought against the scientists by a worker who alleges that he got cancer as a result of their withholding data from NIOSH. It could simply never be proved, especially since cancer takes decades to develop. Yet the moral fact remains that people were exposed for longer than necessary to a substance which harms health more as the dose increases. (In fact, cancer can be initiated by exposure to a single molecule of a carcinogen.) Under the law, however, an individual could not make a case. Indeed, even if he could, he would sue the company, which is insured and able to pay; the scientists themselves would not be punished. This discussion applies to civil cases; the legal position of these scientists with respect to possible violation of the law will be discussed below.

Less than two weeks after the MCA visit to Maltoni, NIOSH requested (in the Federal Register) "information on potential hazards associated with occupational exposure to 23 chemical substances and physical agents," including vinyl chloride. On the same day an MCA meeting was held at which, in MCA's words, "a brief oral progress report was presented on Prof. Maltoni's work by those who had visited him. It was reported that, in experiments with rats, in addition to tumors of the ear canal, tumors of the kidney and liver were observed at concentrations as low as 500 and 250 ppm, but not at 50 ppm nor in the controls."

This meeting widened the circle of scientists and others who could have blown the whistle and did not. The fact that their information was clearly covered by NIOSH's specific request makes their remissness in not furnishing it all the more reprehensible. At this stage, it would not even have been necessary for a whistle blower to reveal his identity. He could have simply alerted NIOSH to the fact that something shady was happening, and leave it to them to discover the details. Apparently no one made even this timid gesture.

On April 9-12, Dr. Maltoni discussed his results publicly at the International Symposium on Cancer Detection and Prevention in Bologna. As it was a very minor

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conference, no one from the U.S. government attended, and publication was still far off.

On March 7 MCA responded to the NIOSH request for information with a recommended precautionary label which made no mention of toxic effects on animals or people.

Up to this point, the only harmful acts were those of omission; in making this response, however, MCA crossed the line into commission by deliberately misleading a Federal agency. The most that has happened as a consequence are some embarrassing moments at public hearings—hardly a deterrent when hundreds of thousands of dollars can be saved by inaction or deception.

Under the Occupational Safety and Health Act, those who mislead the government in a document "filed or required to be maintained pursuant to this Act" may be prosecuted. But the NIOSH request was merely an "invitation" to "submit" data; thus it seems unlikely that MCA's omission is covered. If not, this is a real gap in the enforcement provisions of this law, since the quality of standards promulgated depends heavily on having full information. Another major loophole is the lack of any clause that would have required MCA to submit the Maltoni data to NIOSH for review even before the Federal Register request. A case might arise, for example, in which industry discovered that a common substance could be hazardous, although no standards applied to it and it was not under investigation. As the law now stands, industry would not be required to submit such unsolicited data.

On July 17, 1973 the Director of NIOSH and some of his staff met with an MCA delegation at their request. There is much dispute over what was and was not said at the meeting. The gist of the quarrel is that NIOSH says no mention was made of angiosarcoma. Dr. Maltoni or his work; MCA says that, "NIOSH was told that vinyl chloride caused multi-sited primary tumors in rats at concentrations down to 250 ppm."

Even if the latter allegation is true, the fact remains that MCA suppressed the Maltoni data for six months. They have attempted to explain this delay by saying that, in accordance with the confidentiality agreement with European manufacturers.

"We wanted their participation in the release of the information to the government, and it was a matter of working out the schedules and the date of meeting turned out to be July, whatever it was, in 1973. It is not true that there was a period of inactivity."

If MCA had been more forthcoming with the Maltoni data, the Director of NIOSH has said that his agency would have "taken an entirely different course of action [in setting standards for vinyl chloride] in view of the widespread use of this material."

The Association received another progress report on Maltoni's research in November 1973.

Then, on January 22, 1974, B. F. Goodrich announced that three polyvinyl chloride workers had died of angiosarcoma of the liver since 1971—from only one of its plants.

That same day MCA revealed the Maltoni data to NIOSH; on February 15 it was made public.

The Occupational Safety and Health Administration lowered the permissible worker exposure level to 50 ppm from 500 ppm vinyl chloride on April 5, in an emergency action.

A less black picture is painted in the case of data suppression on the drug Slow-K, entirely due to one conscientious scientist and an FDA Medical Officer. In hearings before Sen. Kennedy's Health Subcommittee on September 25, 1974 it was revealed that a major company suppressed experimental results obtained in 1965 in order to push through a new drug application in 1972. The drug in question, Slow-K, was originally developed almost purely for reasons of convenience and palatability. It is necessary for persons taking diuretics or with certain medical conditions to supplement their potassium (K) intake. This may be done through changes in diet, a liquid, or an effervescent tablet containing potassium.

However, because these methods can be inconvenient and unpleasant, a pill called Esidrix-K (forerunner of Slow-K) was developed for the same purpose by Ciba-Geigy Pharmaceuticals. When it was discovered in late 1964 that it was associated with ulcers, most Esidrix-K was voluntarily withdrawn from the market. Dr. F. Gilbert McMahon, a vice president of Ciba, was put in charge of a team of 9 or 10 scientists whose job was to find a substitute for Esidrix-K which would not cause ulcers. Generally speaking, the method was to test all available potassium salts for ulcer-causing properties.

Among the compounds researched was Slow-K, a drug then in very wide use in other countries. Ulcers were indeed produced in monkeys, and shortly thereafter reports of human cases began to reach the U.S. from Australia and Europe. Unsurprisingly, Dr. McMahon advised against using Slow-K in this country. In 1967 he resigned from Ciba, but continued to warn against the use of Slow-K, particularly in the British journal *Lancet*.

In 1972, greatly to his surprise, Dr. McMahon heard that Slow-K was being tested in the U.S. He immediately wrote FDA and advised that they contact members of

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A MODEL WHISTLE BLOWER CLAUSE

(b) (1) No person shall discharge or in any other way discriminate against or cause to be discharged or discriminated against any miner or any authorized representative of miners by reason of the fact that such miner or representative (A) has notified the Secretary or his authorized representative of any alleged violation or danger, (B) has filed, instituted, or caused to be filed or instituted any proceeding under this Act, or (C) has testified or is about to testify in any proceeding resulting from the administration or enforcement of the provisions of this Act.

Public Law 91-173, Sec. 110 (b)
Coal Mine Safety Act

WHAT CAN BE DONE ABOUT DATA SUPPRESSION?

In cases of vinyl chloride and Slow-K cited in this Bulletin, purely practical considerations such as fear of job loss seem to have determined the outcome of the ethical decision whether or not to call important scientific data to the attention of the government or the public. Would Dr. McMahon have stopped the new drug application for Slow-K if he had still been working for industry? Would Dr. Maltoni have publicized his data if he had not been?

As matters stand, no practical argument can be made in favor of whistle blowing, which can cause job loss and lawsuits, rather than going along with the organization and probably advancing in it. It is impossible, and probably undesirable, ever to equalize the desirability of the two alternatives. But the factors should at least be adjusted to the point where no scientist fails to take his case to the public or government *solely* for economic or other pragmatic reasons. A good beginning would be for universities to strengthen the preventive measure of education for ethics; for professional societies to help and encourage members to make ethical choices, and to censure those who do not; for Congress to reform the law along previously established lines both to deter those who would withhold data from regulatory agencies and to protect those who do not; and for the courts to extend the principle of due process after firing to corporate employees.

Alertness to ethical dilemmas should be part of every scientist's professional training. To help universities meet this goal, scientific societies would do well to follow the lead of engineering groups by compiling a basic text to use in such courses. In 1965 the Ethics Committee of the American Society for Engineering Education produced *Ethical Problems in Engineering*. It deals with dozens of concrete problems, including a variety of viewpoints on each. The topics range from the relatively trivial—using a Society emblem for promotion—to more substantive problems such as conflict of interest. There is no reason why the same approach could not be used in scientific ethics; many dilemmas apply to all fields, and even those which do not would be useful in training any student how to recognize and think about such issues. Once such a basic text had been written, it could be made an indispensable part of graduate education in science.

Another measure societies could take to prevent ethical abuses would be to improve contracts to protect members from unreasonable consequences if they did need to make confidential data public or reveal it to government. Unfortunately, industry has legions of lawyers and acres of fine print to pit against the often paltry legal knowledge of a prospective employee. He may later be threatened with unrealistic lawsuits by his employer, for example, or loss of his pension rights. Scientific societies could review contracts for their members to explain the legal implications; most could probably be covered by a booklet explaining standard phraseology. In addition, the society could pioneer in developing model contracts which would protect the employee's right to due process, i.e., hearings, if he is fired, much as is possible in the public sector. (Other issues which might be incorporated are

the right to publish and attend professional meetings.)

For scientists who are already on the spot, such as those in the vinyl chloride situation, a major problem is that there is no one to turn to for impartial advice, much less to support them if they defy the rules of organizational behavior. Scientific societies could alleviate this problem by extending responsibilities of their professional ethics committees to include problems involving the scientists' responsibility to society. The committees could be available for anonymous consultation by members who were deciding what to do with important data affecting the public interest.

Impartial Advice on Options

The committees could advise scientists about the options available to them inside their companies, their industries, the press, and society generally. This could be invaluable to people with little experience outside the laboratory. An ethics committee for this purpose would have to be interdisciplinary, including both scientific experts and at least one lawyer with experience in ethics and related areas.

The scientist could, in some cases, achieve his goal of changing company policy about certain data by letting it be known that he was consulting his society. In other situations the society could make quiet representations through its committee. Sometimes it would recommend that the member appeal to the public, when other possibilities were ineffective or too slow and when important principles were at stake. The society could agree to back its member in several ways, including a declaration of support; providing legal assistance if necessary, perhaps appealing to its members for a defense fund in extreme cases; and, if a new job were required, help in finding one.

Adopting a plan like this one would serve scientists who wish to consider the public interest well. What of those who do not? The scientists in the vinyl chloride case knew that, whatever problems they might encounter as a result of going along with their companies, censure from the scientific community would not be one of them. A moderate proposal which would avoid witch hunting would be for ethics committees to investigate the facts in cases when members appeared to have shirked their obligation to the public interest. Such an investigation could be prompted by request of a certain number of society members, by press reports, or by some other established means.

Findings Should Be Published

When the facts were collected, the committee would of course give the person(s) accused the right to defend themselves. The committee could then reach a judgment of whether or not the member had breached common scientific ethics. It should be obliged in any case to present the facts in its journal, along with the committee's opinion and a refutation by the person accused if desired.

The closest approach to the roles for professional societies discussed above is the American Chemical Society's Membership Assistance Program. It provides an informal procedure for arbitrating and assessing situations in which

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WHAT CAN BE DONE—Continued from p. 5

member feels unprofessionally treated and asks the Society's help. Most cases involve termination in one way or another, including such problems as derogatory letters of reference, inadequate or improper severance pay, and reimbursement for travel or moving expenses. When it is required, ACS may write an employer requesting a certain action; if he does not comply, ACS informs its Council and publishes the information in Chemical and Engineering News. One measure of the program's success is the fact that only four of about 25 cases in the last year had to be cited in this way. In addition to these informal procedures, qualified members and other chemists can participate in a Legal Aid Loan program.

Congressional legislation also has a role to play. Regulatory legislation should automatically contain "whistle blower clauses" like that of the Coal Mine Safety Act. It prohibits discharge of or discrimination against a miner because he has notified authorities of possibly dangerous conditions, or because of testimony given or proceedings instituted under the act. (See the box on page 4 for the full text.)

In addition, regulatory legislation should make it possible to prosecute individuals as well as companies for withholding data pertinent to fulfilling its objectives. In the case of vinyl chloride, such a provision would have encouraged MCA scientists to reveal the Maltoni data to NIOSH as soon as they received it. It would also cover cases where a substance to which no standards applied was found to be harmful.

Due Process in Firing

The courts could alleviate one of the potential whistle blower's worse fears, unfair job loss, by holding that due process must be followed when a corporation discharges an employee. (This was pointed out at the Nader Conference on Professional Responsibility.) The law specifically provides that, in a few narrow areas such as auto franchises, employees cannot be discharged without following certain procedures. This principle was upheld recently in the case of three scientists employed by a state who turned to FAS for help when they were summarily

discharged. It seems that due process in firing could also apply to private corporations if the courts chose to interpret it that way. Several authorities including Prof. Miller have argued that Fourteenth Amendment protection could be extended, on the basis that corporations are like government in many ways; thus, they argue, citizens should enjoy the same protections from the former as they do from the latter. Also, the very existence of corporations is a manifestation of the government's power, since they are made possible only by charter. This view has not yet been generally accepted by the courts.

In conclusion, data suppression should be viewed as a kind of scientific malpractice. The public has been disturbed enough about the failures of the medical profession, for example, to regulate them somewhat through Professional Standards Review Organizations as well as the courts. Data suppression is potentially far more damaging than medical malpractice; if it continues, it invites the same public reaction of outrage.

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the Ciba task force he had headed for their test results. The FDA Medical Officer assigned to the case recommended that Slow-K not be approved as a new drug for three reasons:

- it was shown to cause ulcers in animals and humans;
- the labelling was deficient in that it did not specify that only patients who could not tolerate other forms of potassium should use it;
- the name was misleading.

Also, in 1973, the FDA General Counsel's office was informed that Ciba had suppressed data, but the matter is still under study. For reasons which are unclear, an FDA Advisory Committee overruled the staff opinion on Slow-K, and the agency was on the verge of approving it. Without Dr. McMahon's intervention, Slow-K might well have been on the shelves of American pharmacists. While a cynic would say that he had little to lose since he had left industry, Dr. McMahon's effectiveness leaves little doubt that one person's action can counteract the omissions of those who are more numerous and powerful.

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