"Ashamed" to Put His Name to It: Monsanto, Industrial Bio-Test Laboratories, and the Use of Fraudulent Science, 1969–1985

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One of the most well-documented episodes of scientific manipulation and overt fraud was the scandal involving Industrial Bio-Test Laboratories (IBT) in the 1970s and the chronic toxicity tests it conducted on behalf of Monsanto that ultimately led to the indictment and conviction of employees of IBT and the Monsanto Corporation. IBT, at the time the nation's largest private laboratory, served a range of industries and government agencies. IBT conducted about 22 000 toxicology studies for scores of corporations, representing between 35% and 40% of all tests conducted in private labs in the country. IBT has been justly condemned for its fraudulent activities in the 1970s, but no one has looked at the relationship between the corporate funders of IBT's research and its fraudulent practices. We use previously secret corporate documents that detail the role of IBT's largest customer, Monsanto, which used fraudulent data to influence government. This material, revealed through legal discovery proceedings now under way regarding polychlorinated biphenyls (PCBs) and Roundup, show the long-lasting impact of Monsanto's behavior on efforts to regulate large corporations as well as on the long-term effects on human health. (*Am J Public Health*. 2023;113(6):661–666. https://doi.org/10.2105/AJPH.2023.307247)

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For more than a century, organizations like the National Safety Council, the Industrial Health Foundation, and even the Manufacturing Chemists' Association representing the chemical industry, have pledged to test their products and guarantee the safety of materials introduced into the environment in exchange for limiting the reach of government regulators. If there were dangers, they promised to let users know what they were. Even after the establishment of the Occupational Safety and Health Administration (OSHA) and the Environmental Protection Agency (EPA) in 1970, the government largely depended on the integrity of industries to provide the necessary scientific data that could be used as the basis of relatively loose regulation.[1] This issue of the integrity of industry-sponsored science has become ever more important as discovery proceedings in court have released internal memos and studies revealing that industries—ranging from the tobacco, asbestos, and lead industries through the giant oil and chemical companies—have not been forthcoming about what they knew about the dangers of their products.[2] The creation of doubt in the science used to expose the danger, the hiding of information, and the misrepresentation of data to federal authorities have been the subject of numerous studies in recent years.[3]

One of the best-documented episodes of scientific manipulation and fraud was the scandal involving Industrial Bio-Test Laboratories (IBT), a private testing laboratory in Illinois, which in the early 1970s conducted long-term studies using rats on a variety of chemicals for various corporations, including Monsanto. In subsequent years, the uncovering of the corruption of these studies led to the indictment, conviction, and imprisonment of IBT and Monsanto employees.[4] In this article, we use previously secret corporate documents detailing the role of the

Monsanto Corporation, IBT's largest customer, in encouraging and engaging in fraudulent practices at IBT to thwart government investigations into the dangers of Monsanto's products on human health.[5]

In the late 1960s, Monsanto approached IBT to conduct chronic toxicity tests on polychlorinated biphenyls (PCBs) in response to growing national concern about the universal presence of PCBs in the environment. PCBs, a plasticizing and insulating agent widely used in paints, plastics, carbonless copy paper, adhesives, electrical transformers and capacitors, and numerous other products had been marketed by Monsanto for commercial use beginning in the 1930s. In the mid-1960s, it was identified in animal and human tissue, fish, waterways, and birds throughout the world, leading to demands for information as to its toxicity. Monsanto, which for nearly three decades had failed to test the long-term effects of PCBs on human health, turned to IBT to conduct chronic two-year toxicity testing on animals.[6] From the first, these studies were seen by Monsanto as part of a larger strategy to prove to the public and government—particularly the Food and Drug Administration (FDA) and the newly established EPA—that PCBs "do not constitute a serious threat to the public health" and specifically were not carcinogenic.[7]

Monsanto contracted with IBT in 1969 to perform two-year chronic toxicity studies and other studies, one of which did not meet the company's expectations as it did not turn out to be "as favorable as we [Monsanto] had hoped or anticipated. Particularly alarming is evidence of effect on hatchability and production of thin egg shells." Hence, Monsanto arranged with IBT to repeat "some of the studies" in order "to arrive at better conclusions."[8] They sent IBT new samples of their PCBs that they claimed were "clean[ed] up" and told IBT they hoped to "find a higher 'no effect' level," a potential "safe" level below which the experimental animals would not show symptoms of damage.[9] Indeed, their collaboration with IBT to downplay the hazards of PCBs appears to have been successful. By 1973, they claimed that "the most important data which has led the government agencies to permit the continued but constricted use of polychlorinated biphenyl are the extensive animal toxicity studies which we have completed in the last two years."[10]

FRAUDULENT LABORATORY PRACTICE

But the reliability of those studies was belied by two facts: first, the actual conditions in the IBT labs that tested PCBs for Monsanto were soon found to be compromised, and second, data were found to be fabricated and sent to the government as ostensible "proof" of their chemicals' safety.

Philip Smith, an assistant toxicologist in the IBT labs where PCB chronic toxicity studies were conducted, described the gross conditions under which the experimental animals were kept, which compromised the collection of reliable data: "[L]oose and wild [rats] . . . were in the rooms . . . chewing the feet off of the [experimental] animals that were in the cages." He explained it was "difficult to tell the difference between loose laboratory animals and loose [wild] animals that have been raised outside and gotten in," as interbreeding had occurred and technicians were not able to distinguish which rats were which. The poor professional standards maintained in the lab can be gleaned from Smith's description that "technicians . . . were caught burning rats' testicles with lit matches." Dead rats were often left to decompose so badly that they "would ooze through the bottom of their cages, and all their tissues would be at a total los[s] for any pathology work."[11] Animal caretakers reported "that there were many dead animals that were stinking so bad that [the] caretaker did not want to go into the room to change the water bottles" and new, live animals were substituted for dead ones with no acknowledgment.[12] Despite the obviously compromised test conditions, IBT produced seemingly scientifically rigorous reports on three of Monsanto's PCB products (Aroclor 1254, 1260, and 1242), claiming that testing proved PCBs were not carcinogenic.[13]

The second issue involved fraud: simply, IBT employees made up data. Otis Fancher, a toxicologist at IBT, wrote to his colleagues as early as 1972 that much of the work was so shoddy that he "was ashamed to publish the work done." He wrote that "much of the data are either fudged or collected with carelessness of incompetence, particularly the data for the supplementary studies of [PCBs]."[14] In fact, data reported were inaccurate or literally invented and the language was altered by Monsanto officials themselves. In 1975, IBT's Joseph C. Calandra sent a draft of their latest "AROCLOR 2-year Rat Feeding Studies" to George Levinskas, Monsanto's manager of environmental assessment and toxicology, listing Aroclor 1254 as being "slightly tumorigenic." Levinskas objected, asking that the phrasing be changed to "does not appear to be carcinogenic," a simple but important revision that avoided raising government concerns about cancer. Calandra complied.[15]

Central to these activities was Paul Wright, who was the link between IBT

and Monsanto. Wright was employed at Monsanto beginning in 1965 as a senior research chemist and from 1968 until 1970 as a research group leader. In 1970, as IBT began its two-year chronic testing of PCBs for Monsanto, Wright moved to IBT, where he directed the toxicology lab that oversaw these studies. In late 1972, he returned to Monsanto as the toxicology manager and stayed at Monsanto until 1984, shortly before his conviction for having conspired to use the US Postal Service to defraud the government was upheld, and he was imprisoned.

Philip Smith, the lab assistant in the IBT PCB studies, gave vivid descriptions of how Wright had falsified data that ended up in the report sent to the government. "The body weight data [were] non-existent," Smith testified in one deposition he gave years later. "For intervals it was not collected."[16] He knew that, "because under Paul Wright's instruction, I plotted out the body weight data that we had in the department and all of the data that we could find in the storage area of the department. Then he [Wright] plotted out and gave me body weight numbers to put into the report for all the spaces that we had no records for." Smith "watched him" "make up numbers" "out of his head."[17] In 1976, the FDA found inconsistent data in one of IBT's studies, leading it to scrutinize IBT's studies.

In 1977, as questions about its studies accumulated, IBT requested a meeting with Monsanto about the chronic toxicity testing that they had conducted on several different substances. In July, Monsanto officials, including M. C. Throdahl, the company's group vice president for environmental policy and member of the Board of Directors, and Paul Wright, now having returned to Monsanto and soon to be director of its Environmental Health Laboratory, met with officials from IBT, including A. J. Frisque, its president, and F. R. Current, IBT's legal counsel. The "reason for the meeting," according to an internal Monsanto memo, was the "recent actions by the FDA and the EPA (pesticides) in questioning the validity of toxicology studies performed by IBT." The FDA had specifically questioned the studies performed on trichlorocarbanilide (TCC), an antibacterial agent that, based on IBT reports, the FDA had approved for use in soaps and lotions.[18] IBT reviewed its operations and "discovered . . . major problems . . . at IBT's Northbrook, Illinois, facility," where their long-term PCB and other chemical rodent studies were conducted.[19] At the meeting, Monsanto Vice President Throdahl "asked specifically whether 'fraud' was involved in the twelve" Monsanto long-term rodent studies, to which the president of IBT "replied that 'extrapolation' and 'faulty interpretations' were part of the problems . . . and that he guesses this constitutes 'fraud.'" Monsanto's representatives called this "a very damaging admission [that] was made in the presence of a [IBT] lawyer who took no exception to the question or answer."[20]

INDICTMENT AND CONVICTION

In the late 1970s and into the early 1980s, the US government investigated the toxicological work that had been done at IBT. On May 4, 1981, a federal grand jury handed down an indictment focused on TCC, one of the 12 Monsanto chemicals then being tested in the rat toxicology labs. The indictment charged former IBT president Joseph C. Calandra, Moreno L. Keplinger, Paul L. Wright (now back at Monsanto), and James B. Plank with fraud. The indictment charged that between 1970 and 1977, Wright and the others had

> devised and intended to devise a scheme to defraud clients and government agencies by writing and distributing false and fraudulent study reports and false and fraudulent explanations of study reports, and by concealing the fraudulent nature of the study reports and explanations of studies and study reports.[21]

The accusations focused on Wright, Keplinger, Plank, and Calandra, who had represented that the studies had lasted 24 months when in fact the defendants "knew that the report included data from a substantial number of animals that had been on the study for significantly lesser periods of time." The defendants were also accused of falsifying the report they sent to the federal government, creating inaccurate mortality tables "which the defendants then knew to be false in that it substantially under-reported . . . the number of animals that died during the study," and thus "concealed . . . that the animal mortality . . . was substantially greater than reported in any version of the study report."[22]

The indictment detailed that Monsanto's Wright made "false, fictitious and fraudulent statements and representations . . . and concealed and covered up material facts" on the "Two Year Chronic Oral Toxicity with TCC, trichlorocarbanilide." Wright, who by 1976 had returned to Monsanto as the company's "toxicology manager," falsely predated the study by two years, to March 21, 1974,[23] showing that he was aware of, and continued to engage in, fraud after he had returned to Monsanto.[24]

In January 1978, the FDA and the EPA investigated three other long-term studies that IBT had conducted, including two that were done for Monsanto on Machete, another Monsanto herbicide, and monosodium cyanurate (ACL). The FDA concluded that in both studies there was evidence that Monsanto knew of "significant problems" at IBT "prior to submitting their [Monsanto's] report to the US Government." There was "strong evidence of client's being knowledgeable of inaccuracies in the final report," and in the other IBT study of ACL there was "strong indication of client's knowledge of the deficiencies before they issued their report to the US Government." The inspectors reported that "anticipated toxicity problems known to both the client [Monsanto] and test facility [IBT] were deliberately overlooked."[25]

The trial of the four defendants began at the United States District Court in Chicago in April 1983 and continued for several months. Almost immediately, national and local newspapers picked up on the significance of the case, pointing out that it raised many questions about the integrity and honesty not only of IBT but of Monsanto itself. Monsanto's press office denied that Wright was guilty of any fraud: "We think Mr. Wright is innocent and if his case goes to trial, the trial will vindicate him."[26]

Monsanto's statements were disingenuous at best. As we have indicated, four years prior to the indictment in 1977, Monsanto had been bluntly told by IBT's president that studies Wright had directed at IBT were fraudulent. Nevertheless, in 1977 Monsanto promoted Wright to director of the Environmental Health Laboratory, and in 1981, when Wright was indicted, he was assigned to work on special projects, including overseeing its Material Safety Data Sheets, the documents that OSHA demanded be available to warn workers about dangers of substances they were handling.[27] Far from being reprimanded or fired, Wright was given merit raises in 1977, 1978, and 1980. In 1982, a year after he was indicted,[28] Monsanto paid his legal defense to the tune of $1.4 million.[29] Monsanto continued to cite these studies well into the future as evidence of the safety of PCBs. In 1979, for example, a Monsanto publication cited the IBT studies of PCBs as "the most comprehensive safety tests of the time."[30] Further, in 1983 and 1985 Monsanto continued to cite the IBT studies in their Material Safety Data Sheets.[31] As late as 2018, one of their experts in PCB litigation depended on these fraudulent studies.[32]

In August 1983, Paul Wright, Moreno L. Keplinger, and James B. Plank, former assistant toxicology manager, were convicted of fraud and sentenced to jail.[33] But even following conviction, Monsanto gave Wright a "golden parachute," providing him with full retirement benefits, accrued vacation time, one month's severance, and the services of a recruitment specialist to help him find future jobs when he was released from prison.[34]

CONCLUSION

In the period following the expansion of government regulation in the early 1970s, the government depended on the integrity of industries and their private laboratories to provide them with information needed to establish new standards. Hence, the EPA, OSHA, and the Consumer Product Safety Commission, along with older agencies like the FDA—government agencies with neither the resources nor the inclination to test the myriad chemicals and synthetic products yearly produced by US industry—depended on companies' integrity. Following the revelations discussed here, "Good Laboratory Practices Regulations" were promulgated that were intended to guarantee the quality of research upon which federal regulations depend.[35] But the central tension between the interests of industries and the interests of public health remained. Here, we show that the influence of industry on laboratory practices made the corruption of science more likely. With or without regulatory standards, we need to maintain vigilance over companies whose self-interest has distorted science and may continue to do so. AJPH

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CONFLICTS OF INTEREST

Both David Rosner and Gerald Markowitz have participated as expert witnesses in lawsuits on behalf of the City of Seattle, the State of Washington, and individuals regarding PCB cases against Monsanto

ENDNOTES

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