

The Unexpected Result of an Investigation of an Outbreak of Occupational Lung Disease

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The author describes the discovery of a cluster of cases of interstitial lung disease among employees of a textile manufacturing plant and the difficulties he and his university-hospital occupational medicine team encountered in attempting to identify the cause of the disease. At first accepted in a consultant capacity by the plant's management, the team met increasing resistance to its efforts as it uncovered evidence of a work-related cause of the disease and attempted to communicate its findings to both the workers and their union. Ultimately the plant's management dismissed the occupational medicine team and threatened legal action if it published or presented its scientific findings. Both hospital and university administrators attempted to thwart the team's efforts to publish their findings and colluded in summarily terminating the occupational medicine program. The author emphasizes the points actually at issue: the need to protect the freedom of scientists to communicate findings important to the health of the public, and the physician's overarching professional responsibility to his or her patients. *Key words:* public health; occupational disease; interstitial lung disease; conflicts of interest; ethics; professional responsibility; textile industry.

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For more than a decade, the Brown University School of Medicine in Rhode Island has had a program in occupational medicine within the Department of Medicine. In addition to providing electives for undergraduate students in environmental studies, medical students, and medical residents, and, until recently, mandatory experiences for both internal medicine and family medicine residents, the program has continuously provided required rotations for both the Brown University Pulmonary Fellowship Program and the medical students' Clinical Clerkship in Community Medicine. As a result of these teaching activities

and collaborative research efforts, the Program in Occupational Medicine has worked closely with Brown faculty based in divisions and departments of pulmonary medicine, infectious disease, community health, general internal medicine, family medicine, pathology, and environmental studies.

Always at the Program's core has been a hospital-based occupational health service, which has hosted a referral clinic for patients with suspected environmental/occupational illnesses and hazardous workplace exposures. Referrals have come from physicians, state and federal regulatory agencies, trade unions, employers, attorneys, and insurance companies. For the last nine years, the service has been located at the Memorial Hospital of Rhode Island, an affiliate of the Brown University School of Medicine. I am the founder and director of the Occupational and Environmental Health Service and, for the last 11 years, I have directed the Brown University Program in Occupational Medicine.

THE FIRST CASE OF MANY

On November 22, 1994, a pulmonary physician referred a 36-year-old textile worker to me at the Memorial Hospital of Rhode Island Occupational and Environmental Health Service for suspected occupational hypersensitivity pneumonitis. I had no idea that this case referral would ultimately lead to a battle over scientific integrity and bring into public discussion virtually every ethical issue in the practice of occupational medicine. The case was subsequently joined by others from the same company. The resulting outbreak of occupational lung disease eventually thrust me into an arena from which few occupational physicians emerge unscathed.

At the time of the first patient's evaluation, I had available a collection of Material Safety Data Sheets (MSDSs) covering chemicals in use at the patient's workplace. Under both state and federal right-to-know laws, physicians and employees are entitled to copies of all relevant MSDSs. Although the MSDSs did not list any chemicals known to cause hypersensitivity pneumonitis (HP), the patient's workplace, with its many wet processes and numerous organic materials, suggested conditions ideal for microbial growth and, in turn, HP; yet the patient's

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bronchoalveolar lavage had revealed findings never before reported in HP. This condition, then, was considered extremely unlikely; nevertheless, we attempted to arrange a worksite visit for the purpose of leaving no stone unturned while at the same time providing a learning experience for our medical students.

THE PLANT VISIT

I contacted the employer, Microfibres, Inc., a manufacturer of finely cut nylon (flock) and flocked fabric used in the upholstery, clothing, and automobile industries. I identified myself as Director of the Brown University Program in Occupational Medicine and Memorial Hospital's Occupational and Environmental Health Service and requested permission to visit the plant. I explained that if the employee were found to have the suspected occupational illness, it would be on the basis of allergy, not the company's violation of any specific law or regulation. I noted that our visit would serve a dual function in that every six weeks, our program's industrial hygienist and I would bring a different group of Brown University medical students and physicians-in-training to a specific worksite as part of their required occupational health experience. Last, I explained that the treating pulmonary specialist, in his letter of referral, appeared certain that his patient's condition was work-related and was likely to take such a position before the Workers'

Compensation Court. Our objective assessment of the workplace, then, would appear to be in everyone's interest. The company agreed to a worksite visit.

On December 2, 1994, a few students, our industrial hygienist (Kate Durand), and I visited the plant. At the door, we were met by Donna Nadeau, the personnel director, who asked us each to sign an "Agreement of Secrecy & Confidentiality" [attachment 1], which we did. In the next 60 minutes, we were shown one production area, collected a few volumetric air samples for investigation for both viable and nonviable mold spores, and then left. In my detailed consultation report to the referring pulmonologist, I concluded that hypersensitivity pneumonitis was extremely unlikely and recommended an open lung biopsy to determine the nature of the patient's interstitial lung disease. A biopsy was not scheduled, the patient was removed from work, and over the ensuing 12 months while on corticosteroid therapy he gradually made a symptomatic, radiographic, and physiologic recovery.

More than a year later, a 28-year-old textile worker with symptomatic interstitial lung disease (ILD), confirmed by open lung biopsy, was referred to me by another community-based pulmonary physician for suspected occupational hypersensitivity pneumonitis. The clinical and pathologic findings were consistent with, but not specific for, HP. On learning of his employment at the Microfibres plant we had visited a year earlier, I became concerned. ILD in young men is unusual. Two such cases occurring within a year among a production workforce of 100–150 far exceeds the expected annual incidence rate (for all ILD) of one case per 3,000 persons per year.¹

NIOSH INVOLVEMENT

I contacted John Parker, MD, a pulmonary epidemiologist with the National Institute for Occupational Safety and Health (NIOSH), to discuss the possibility of NIOSH's conducting a health hazard evaluation (HHE) at the Microfibres plant. NIOSH is charged under its HHE program with investigating suspected outbreaks of occupational disease. Dr. Parker and I had been professional colleagues and friends for a number of years. I asked whether the HHE request would best come from the employer or from the union. Dr. Parker noted that NIOSH would almost certainly be willing to conduct the HHE. He indicated that the company would probably be more likely to fully cooperate with such an investigation if the company itself requested the HHE. We agreed that I would notify the union business agent of the situation, urge him to allow the company to request the HHE, and encourage him to submit his own request should the company fail to do so.

Dr. Parker and I agreed that the investigation would be enhanced by a formal collaboration between NIOSH and our Brown University Program in Occupational

Medicine. I was assured that if the company asked for our consultative assistance, we still would be able to collaborate on the project with NIOSH. Subsequently, I called the union's out-of-state business agent, who agreed to the plan.

NOTIFICATION OF THE COMPANY

In a letter of February 6, 1996, I notified the company's owner of my concern, asked to meet with him, and recommended that he request a NIOSH HHE. While awaiting a response, I reviewed the medical literature on occupational ILD. I found an interesting report of five cases of ILD occurring in 1990–91 among 88 textile workers at a Canadian plant that manufactured products similar to those being made at Microfibres.² (I would later learn that the Canadian plant described is owned by Microfibres.) One of the workers described had suffered acute respiratory failure and required prolonged mechanical ventilation. Two had been left oxygen-dependent permanently. The authors speculated that mycotoxins generated by molds growing in the facility's stored adhesives were responsible for the disease, a hypothesis for which there was little scientific support. The report noted that following interventions to limit mold growth, there had been no additional case of ILD.

I met with the company's CEO and management team on February 26, 1996. During the course of the meeting, I was told that in 1990–91 a cluster of ILD had been detected at the company's Canadian plant; moreover, in the spring of 1995, following the diagnosis of two additional cases at that facility, the company had hired a Canadian industrial hygiene consultant to investigate. After listening to my thoughts on the subject, the company formally requested both our consultative assistance and a NIOSH HHE.

I explained that in an investigation of this kind, I would be asking employees to trust me with their medically confidential information. To provide a foundation for this trust, it would be necessary for us to be able to communicate freely with both employees and their union and for the company to accept and post our program's "Operating Principles and Guidelines" [attachment 2]. The company agreed in principle with these terms while reserving the right to have its legal counsel review our operating principles.

THE CONSULTING CONTRACT

In a letter of February 27, 1996, Rick Dietz, assistant vice president at Memorial Hospital, reached an understanding with the company's executive vice president, James R. Fulks, that the hospital would be paid on an hourly basis for our services. Over the ensuing months, the hospital administrator's repeated requests for a more formal detailed contractual agreement were rebuffed by Mr. Fulks, who expressed a preference for verbal agreements.

Over the following eight months, our program personnel devoted approximately 900 hours to the project, leading the company to pay more than \$100,000 to the hospital. Four interim reports were submitted to the company. In the first eight weeks, we began to characterize the clinical and pathologic profile of the illness, the identity and potential toxicity of workplace exposures, and the temporal, spatial, and dose relationships between specific exposures and the risk of illness. We assumed that the illness occurring in Canada was the same as that occurring in Rhode Island and, consequently, focused on determining which potential etiologic agents could be eliminated from consideration by virtue of their not being present prior to the onset of illness at each facility.

On March 5, 1996, our industrial hygienist and I met with the company's CEO, James McCulloch, Mr. Fulks, and others, to discuss our planned educational presentations to the workers. By that time a pulmonologist had referred another affected employee from the plant to us and we had learned of the open-lung-biopsy diagnosis of ILD in yet a fourth employee who had retired in 1994. At the meeting, we reiterated the importance of the company's posting of our Operating Principles. I provided the company with copies of our operating principles and an outline of the planned presentations. The next day, we delivered hour-long presentations to five seatings of employees.

THE EMPLOYEES AND THEIR UNION

At the beginning of each presentation, I explained who we were, the nature of the Brown University Program in Occupational Medicine, the details of our Operating Principles, and the company's plan to sign and post the latter. I noted that while the company was paying the hospital for our services, we considered ourselves consultants to the company, its employees, and the union, in that the success of our investigation depended on the full cooperation of all three parties. In detailing the chronology of the illness outbreak, I made it clear that when we had first visited the plant in November 1994, we had been unaware of the 1990–91 cluster of ILD cases at the company's Canadian facility. I further noted, however, that at the time of that visit, the company had understandably believed that the problem at its Canadian facility had been eliminated in 1991.

Following the last of the employee meetings, I met with the company's CEO and executive vice president. While they agreed that the presentations had been well received, they had three concerns. First, they expressed discomfort that I had mentioned the occurrence of illnesses at the company's Canadian facility. Second, they were unhappy that I had mentioned the local union, the officers of which work full-time in the plant's production area. With regard to these concerns, I reiterated the need for both truth and openness if our investiga-

tion were to have any hope of success. Employees would eventually learn about the Canadian experience, at which point I would lose their trust if I had participated in the subterfuge. As for my referencing the union, I explained that UNITE (Union of Needletrades, Industrial and Textile Employees, AFL-CIO) was an involved party with responsibilities to its members. Were I to ignore the union, my objectivity and dedication to worker health and safety would be justifiably questioned.

The CEO's third concern involved the local union's out-of-state business agent, whom I had initially contacted in early February 1996 prior to my writing to the company. Allegedly, the business agent had reported that I had recommended that he, not the company, formally request the NIOSH HHE. This was the first of many ludicrous accusations the company's management personnel were to levy against me in an effort, apparently, to create distrust among the involved parties. Dr. Parker at NIOSH has confirmed the agreed upon strategy as the one he recommended in an effort to gain the company's full cooperation. George Cummings, the union's business agent, has confirmed that he never made the alleged statement.

THE NIOSH INVESTIGATION

I arranged for Dr. Rita Washko, the NIOSH physician working on the HHE, to meet privately in my office with the four individuals I had diagnosed to have occupational ILD and provided her with their clinical records, pulmonary function test results, and radiographs. Dr. Charles Kuhn, pulmonary pathologist at Memorial Hospital, reviewed the patients' lung biopsy specimens with her. Over the following months, however, it became increasingly clear that our planned collaborative effort with NIOSH was being frustrated. We learned that the agency would be unable to share the results of its planned medical testing with us in the absence of individually signed employee authorizations. As a consequence, we were precluded from working with NIOSH in a meaningful way. Although most employees eventually did authorize us to obtain from NIOSH their individual medical test results, the obstacles placed by NIOSH may well have undermined employee confidence in the competence and integrity of the entire investigating team. Furthermore, for unfathomable reasons, we were unable to access any meaningful information about NIOSH's environmental sampling protocol.

By the end of April 1996, we had identified two more cases of ILD, for a total of six at the local plant. Although we had yet to obtain the Canadian lung biopsy specimens, we had received narrative reports describing them. The combined American and Canadian pathology materials made it clear that we were dealing with the same medical condition at both plants and that it was not a granulomatous lung disease such as hypersensitivity pneumonitis. The pathology was most consistent

with nonspecific interstitial pneumonia. While we had substantially narrowed the list of possible etiologic agents, the company had yet to provide us with a detailed chronology of materials use and production processes for the two plants.

COMPANY RESISTANCE

On April 30, shortly after issuing our first progress report, I met with Mr. Fulks, the company's executive vice president, who expressed displeasure that we had copied the report to the local union. I reiterated our program's position on this issue and pointed out that we had specifically explained in advance that this would be our policy. When the vice president noted that we might inadvertently include trade secrets or other potentially damaging information in these reports, I offered to have the company review our future submissions before we copied them to the union, an offer he accepted. Aware that the NIOSH medical screening program was to begin the following week and that our Operating Principles had yet to be posted at the plant, I explained that for employees to authorize the release of their screening results to me it would be crucial for the company to sign and post this document. Mr. Fulks agreed to do so but only after making a few specified changes that had been recommended by the company's attorney. When I offered to amend the document and return it to him the following day, he declined the offer, indicating he would make the changes and return it to me.

Three days later, on May 3, with the company's CEO, executive vice president, and personnel director in attendance, I described the upcoming NIOSH medical screening program to employees at the plant. At the same time, I distributed copies of a medical information release form that I had created specifically for the investigation, which had been approved by NIOSH's lawyer. On May 6, a local union representative called to report that the union had halted the NIOSH medical screening program within hours of its initiation that morning because a company representative had been handing employees an additional consent form. This second consent form authorized NIOSH to release to the company "... results of any medical testing that can be used to assess my medical condition regarding my capability to wear a respirator" NIOSH personnel were counseling employees not to sign this form. I was told that some workers presumed that I was responsible for what they considered a personnel department plan to obtain copies of their confidential medical records. I explained to the union representative that I had no prior knowledge of the second consent form, that the company had erred in introducing such a form in this way, and that I would immediately discuss the issue with the company.

Upon calling the company, I was informed by the personnel director that it was her understanding that the form had been discussed with and approved by

NIOSH's Dr. Washko. I explained that this was impossible in that the form's use would be both illegal and unethical, in that medical information cannot be released to non-medical personnel. I expressed displeasure that our program's carefully organized plan to legitimately access the medical information database being generated by NIOSH was now in jeopardy. The personnel director was distressed by the turn of events, which she attributed to the union's grandstanding. Over the ensuing weeks, I wrote personal letters, providing results and recommendations, to each of the more than 100 Microfibres employees who had authorized the release of their NIOSH screening data to me.

On May 31, we issued our second report to the company, which noted: "There are a number of tasks for which company personnel have assumed responsibility, that have not been completed. It is imperative that the following be done in order for us to continue with our investigation in a timely manner. (1) At the beginning of the investigation, we asked that our Operating Principles be posted at the plant in a place accessible to all employees. As far as we know, this had not been done. It is important for employees to understand these principles in order for us to gain their trust and participation. (2) We have asked

for a complete chronology of materials and production processes for both the Canadian and the U.S. facilities from the mid-1980s to the present. This has not yet been provided to us and is of utmost importance in assessing exposures in an attempt to identify the cause of the illness."

THE COMPANY'S ULTIMATUM

Three weeks later, still waiting for the company's comments on our second report before we could forward it to the union, I called Mr. Fulks, who asked us to meet with him. I had a premonition that the company might demand that we have no further direct contact with the union; earlier, Mr. Fulks had explained that for years the company had been following a successful strategy to marginalize the union but that, in a matter of months, we had completely undermined the status quo. I called the local union's president and explained that should the company issue such an ultimatum, we were prepared to sever our consulting relationship. I noted, however, that even with such restrictions we would prefer to continue serving as the company's consultant and would be willing to do so given one extenuating circumstance: I was providing medical care to three of the union's officers who had either known or suspected ILD. Consequently, I would be compelled to share with them, as patients, information that the company would not allow me to convey formally to them as union representatives. After discussing the matter with the other officers of the union, the president requested that we remain in the consulting relationship even if the company issued the anticipated ultimatum.

On June 21, our program's industrial hygienist, Kate Durand, Rick Dietz, and I met with Mr. Fulks, who explained that if we wished to continue as consultants to the company, we could no longer copy our reports to the union, have any formal contact with the union, or expect the company to sign and post our Operating Principles. He acknowledged the high quality of our consulting work with the company, the fact that we currently enjoyed the trust of both the workforce and the union, and the fact that management had been intentionally withholding information from us while deciding whether to allow us to continue to serve as the company's consultant. He explained that Microfibres could not afford to have us recognize the union as a party to the investigation but had no objection to my continuing to see the union officers as patients. Having argued in vain that such a policy was likely to erode employee trust and, in turn, undermine our ability to successfully identify the cause of the disease outbreak, we agreed to the stipulated terms.

FURTHER OBSTRUCTION BY THE COMPANY

By the time we issued our third report in early August, we had diagnosed a total of seven cases of ILD at the local facility. Each of the six biopsy specimens showed

nonspecific interstitial pneumonia. We continued, however, "... to be hampered by the absence of a detailed chronology of materials in use at the company's Rhode Island facility."

In mid-September, a company employee whom I had previously evaluated called to report that, having recovered from a work-related injury, he would soon be returning to work. He was concerned, however, that the nausea and vomiting he had previously experienced at the plant would recur upon his resuming work. Consequently, he was requesting permission to use a respirator. Given that the employee had indeed complained of these symptoms during his previous evaluation, that any one of a number of volatile organics in his immediate work area might cause nausea on the basis of odor alone, that he was otherwise threatening to complain to OSHA, that his request seemed reasonable, and that his co-workers assigned to jobs requiring respirators were resisting their use, I believed that honoring his request would benefit everyone. Consequently, I wrote a letter to the personnel director recommending that the employee be provided with a simple half-face negative-pressure air-purifying respirator.

When the personnel director called to express her displeasure, I listed all the above reasons other than the employee's threat to call OSHA. The personnel director remained unhappy, explaining that she would leave the matter to the company's executive vice president. On October 11, Mr. Fulks called in anger to say that you can't give people everything they ask for and that this employee did not require a respirator. I was informed that in agreeing to the employee's request for a respirator, I was legitimizing his claim of work-related illness and in turn providing the foundation for a workers' compensation claim. Mr. Fulks went on to inform me that he had just learned that the company was at risk of losing its workers' compensation insurance coverage and implied that I was to blame; just as I was coddling the employee who wanted a respirator, so was I coddling employees who had been found to have ILD, all of whom, I was told, should have been back to work long ago. When I responded that no doctor would ask these individuals to return to work at the plant at this time, he retorted, "That's not true ... I've spoken to a number of doctors all of whom say these people can return to work at the plant." When I said that "No ethical, knowledgeable doctor would say this," he disagreed. Our conversation ended with him telling me that he would not authorize a respirator for the employee. (The employee experienced recurrent episodes of nausea on each of his first five days back at the plant and was hospitalized the next day for chest pain that began at work.)

THE STAKES RISE

In our fourth report, issued in September, we reported both another newly diagnosed case of rapidly progressive biopsy-confirmed ILD and the identification of an-

other employee with previous biopsy-confirmed ILD, who had retired in 1989. The former employee was particularly worrisome in that he had been found to have normal NIOSH screening studies in May and July 1996, at which time he was already symptomatic. Given his normal test results, both the worker and his family believed that he "... was going crazy ..." as his respiratory symptoms progressively worsened. When he finally came to see us in September 1996, we found that his lung function had declined 50% during the preceding four months.

We had finally obtained four of the five Canadian lung biopsy specimens, each of which revealed the same abnormalities we had observed in the affected Rhode Island workers; one Canadian biopsy specimen also showed findings of acute lung damage. We also had finally received the information we had requested long ago regarding processes and materials use at the company's Rhode Island plant; we still had not received any information about the environmental sampling conducted by NIOSH.

In mid-September, Kate Durand, our program's industrial hygienist, participated in a first and only telephone conference call with the company's Canadian industrial hygiene consultant, the company's midwestern indoor air quality consultant, the corporate environmental director, and NIOSH's industrial hygienist. When the NIOSH industrial hygienist was asked for copies of his sampling protocol and detailed results, he indicated that for him to be able to comply with this request, it would be necessary for the company to write a letter requesting him to do so. This led us to conclude that NIOSH finally was going to provide us with the sampling data we had long been awaiting. A month later, however, it was hinted that NIOSH's refusal to provide us with its sampling data might have come at the insistence of a highly-placed member of the corporate management team. We dismissed the allegation, finding it difficult to believe that the company would want to conceal such results from its own consultants. Shortly thereafter, a different reality was suggested when the final version of the conference call minutes was distributed by the company's management. Next to the phrase describing the letter the company would write to NIOSH appeared the hand-written words, "...this will not be done ...".

A FIRST MEETING BETWEEN ALL THE COMPANY'S CONSULTANTS AND NIOSH

A week later, on October 28 and 29, the company hosted a two-day meeting with the participation of the company's corporate engineer, environmental director, and consultants, NIOSH's HHE team, and the president and vice president of the local union. At the first coffee break, I was informed by Joe Burkhart, the NIOSH industrial hygienist, that the company had been

insisting all along that he not provide any of the company's consultants with the sampling data. Because he had signed the company's "Agreement of Secrecy & Confidentiality," he had felt all the more restricted. It remains a mystery why NIOSH had not told us previously of the company's deception.

The meeting was surprisingly collegial and productive. We divided up the tasks and planned to reconvene in six weeks. The participants, however, began to question the wisdom of distributing the tasks if they were again to be forbidden from sharing information with each other. When the company indicated that it would take the matter under advisement, I stated that the Brown University Program in Occupational Medicine would no longer be willing to serve as the company's consultant unless a policy of open communication between the consultants and NIOSH was established.

THE CONSULTING RELATIONSHIP ENDS AND THE COMPANY THREATENS LITIGATION

At the close of the meeting, I provided the company with a draft of a scientific abstract, describing the clinical dimensions of the ILD outbreak, which I was planning to submit to the American Thoracic Society for presentation at its annual international conference in May 1997. Two days later, Mr. Fulks called to say that I could not submit the abstract and, that if I did, the company would take legal action against both the hospital and me. The next day, Rick Dietz, Kate Durand, and I reached an understanding that our continued collaboration with NIOSH and the company's other consultants was more likely to have a beneficial effect on employee health than would our submission of an abstract at this time. Consequently, when we met later in the day with Mr. Fulks, we offered to forego submission of the ATS abstract and to refrain from all public presentations or publications on the subject for at least one year if the company was willing to proceed with a policy of open communication between its consultants and NIOSH. We explained that there were two major reasons we wished to submit the abstract. First, colleagues elsewhere might be able to either shed light on the health effects of the plausible etiologic agents or suggest further methods of analysis. Second, we wished to advise colleagues to be on the lookout for this condition elsewhere.

We provided Mr. Fulks with another version of the abstract, free of any references to Canada and the nylon flocking industry. Mr. Fulks found both the revised abstract and our reasons for wishing to submit it unacceptable. Moreover, he indicated that we would never be allowed to present or publish on the matter unless we both found a correctable cause of the illness and had the company's approval. Last, he indicated that even before he had reviewed the abstract, the company had already decided to reject our call for a policy of open com-

munication between the company's consultants and NIOSH. In light of the above, we terminated our consulting relationship with the company at the closure of the meeting on October 31, 1996. Rick Dietz asked me to draft a letter both to formally terminate our consulting relationship and to inform the company of our intention to discuss the disease outbreak with the professional community.

Following discussion with my co-authors, I submitted the abstract with the knowledge that I would retain the option of withdrawing it through January 15, 1997. In an effort to minimize the likelihood of provoking retaliatory action from any quarter, we submitted the aforementioned watered-down version of the abstract.

THE MEDICAL SCHOOL ADMINISTRATION'S FIRST STRIKE

During the following week, I contacted the University Grants Office and was referred to Peter Shank, PhD, Associate Dean of Medicine and Biological Sciences (Research). By telephone, I briefly explained the situation and the threatened litigation. After reviewing both the "Agreement of Secrecy & Confidentiality" that Kate and I had signed 15 months before beginning work as the company's consultant and our program's "Operating Principles and Guidelines," which I had provided to the company when we began working as its consultants, Dr. Shank wrote to me, stating: "I see no way in which you can publish results of your studies at the company without their written approval . . . you should immediately withdraw your abstract to the national meeting." He copied his letter to both Rick Dietz and H. Denman Scott, MD, Physician-in-Chief at Memorial Hospital. Upon receiving his letter, I immediately called Dr. Shank to schedule a meeting.

Shortly thereafter, Charles Kuhn, MD, Chief of Pathology at the hospital, Kate Durand, and I met with Dr. Shank to discuss the issues of academic freedom, professional responsibility, and the suppression of scientific findings of imminent public health import. We explained that the outbreak at the company appeared to represent the largest unexplained outbreak of nongranulomatous interstitial lung disease under investigation, that one worker in Canada had almost died of the illness, and that two others had been left seriously impaired. We questioned whether anyone would have advised us to remain silent if the illness had been bacterial meningitis.

We pointed out to Dr. Shank that the "Agreement of Secrecy & Confidentiality," even if valid, specifies that "All information . . . shall be maintained in strict confidence . . . to the extent that such information remains unpublished, provided, however, that nothing shall prevent you . . . from using or disclosing to others any information which you can prove by documentary evidence was already known to you at the time of our disclosure, or which is hereafter lawfully obtained by

you at any time from some other source other than directly or indirectly from us.” We explained that in our scientific and public health communications we would not be divulging any trade secrets and, moreover, that a combination of both state and federal right-to-know laws, our knowledge of processes and materials use generic to the industry, and details previously published in *Chest* provided all the background information we needed. Last, we articulated the position that while lawyers can provide us with guidance as to the probabilities of our both being sued and successfully so, we have a professional responsibility to do what we believe is right. Dr. Shank explained that while he understood our concerns, he felt constrained by the document we had previously signed. He indicated that he would review the matter with the university’s legal counsel.

THE HOSPITAL’S SHIFTING SANDS

The following week, I gave Rick Dietz a draft of the letter I had written at his request to formally sever ties with the company. He approved the final draft, which I then forwarded to Dr. Scott, Physician-in-Chief at Memorial, for his review. Next I drafted a letter to the company’s employees, something I had been planning to do since the end of September following my identification of the most recent case of ILD at the local plant. In the early months of our investigation, we had found a number of symptomatic employees to have biopsy-confirmed diagnoses of ILD in the face of both normal conventional chest radiographs and either normal or minimally abnormal spirometry. Subsequently, NIOSH’s medical screening program utilizing the same type of testing identified no new case of ILD; at the time, in writing to employees who had authorized the release of their NIOSH test results to me, I had urged more sophisticated evaluation for those having persistent respiratory symptoms. The employee found to have ILD in September further justified this heightened concern. He had begun to experience persistent respiratory symptoms prior to NIOSH’s medical screening tests of May and July. His results at that time had been normal. Thus reassured, he had done nothing. In early September, progressive shortness of breath prompted him to seek my assistance, at which time he was found to have lost approximately half his lung function. Initially, I had planned to communicate both this incident and a recommendation for influenza vaccination at the end of September to employees who had previously authorized me to review their records. I had delayed writing, however, in the belief that there would be additional information to relay following the scheduled October meeting between the company’s consultants and NIOSH personnel.

Dr. Scott asked that I delay communicating with the company until he and Rick Dietz’ father, hospital president Frank Dietz, had an opportunity to meet with the company’s owner. When I explained the timeliness of my

plan, specifically, that I would be recommending influenza vaccination in my letter to employees, I was told there was no rush in that flu season was not likely to really start until either the end of December or early January.

During the first week of December, Dr. Scott, Rick Dietz, and Frank Dietz met with the CEO/owner and executive vice president of the company. On the afternoon of December 9, Dr. Scott met with me to report that I had been vilified at the meeting and that our consulting relationship could not be salvaged. When I asked whether I could now send the previously drafted letter to the company, Dr. Scott told me that the hospital administration would take care of this. Finally, I was told that the hospital’s legal counsel had been asked to review the matter, specifically the advisability of my withdrawing the submitted abstract, and that an answer was expected within 48 hours. When I asked for the opportunity to speak to the attorney before he arrived at his decision, Dr. Scott suggested that I put this request to Frank Dietz, which I did.

The following day, Frank Dietz told me that he would arrange for me to speak with the hospital’s legal counsel. He then went on to say that given the absence of any public health concern it seemed to him that I should withdraw the abstract. When I asked him why the disease outbreak did not pose a public health concern, his response was that no other company in the world makes what this company manufactures and that NIOSH personnel were already conducting an investigation at the company. I explained that this is not the only company in the world manufacturing these products, to which he replied, “Yes it is.” I noted the existence of two other companies in Rhode Island, a considerable number of business competitors throughout New England, and an international trade organization having at least 50 member companies. With that, he became somewhat agitated, stating that I was going to destroy the company, that both he and Dr. Scott were in agreement that this was not a public health issue, and that Dr. Scott was to have made this point clear to me. I explained that Dr. Scott had neither stated nor intimated any such thing. When I suggested that he and I sit down to review the whole story, he told me to clarify matters with Dr. Scott.

Perhaps worthy of note is that Microfibres is one of eight benefactors responsible for construction of the hospital’s histology laboratory. Three members of the company owner’s family serve as members of the Memorial Hospital Corporation. More troubling, however, is that the company was asked to contribute to the hospital’s Primary Care Center Capital Campaign at approximately the same time as Frank Dietz and Dr. Scott were attempting to allay the company owner’s anger about our having submitted a scientific abstract on the disease outbreak. Moreover, the solicitation was made jointly by Rick Dietz and the Chairman of the Capital Campaign. The Chairman of the Capital Campaign also serves both as Vice Chairman of the hospital’s Board of Trustees and as hospital attor-

ney. In the latter role, he has provided guidance to Frank Dietz on how to deal with the confidentiality agreement, the submitted scientific abstract, and me.

PROFESSIONAL RESPONSIBILITIES

Two days after my discussion with Frank Dietz, I had yet to hear anything further about my meeting with the hospital attorney. By then, seven weeks had passed since the termination of our consulting relationship with the company, yet the hospital was continuing to frustrate my efforts to communicate with more than 100 workers who had entrusted their health care to me. I had learned from NIOSH personnel and others that the company was continuing to insist that nothing had changed and that the Brown University Program in Occupational Medicine was still serving as its consultant. Also, having spent the prior two weeks as medical service attending physician, admitting patients to the hospital, it was clear to me that influenza season was upon us. I had professional responsibilities that I could no longer defer. Therefore, on December 13, I mailed the previously drafted letter to all company employees who formerly had authorized me to review their medical test results and to whom I had previously sent written interpretive reports.

THE OCCUPATIONAL AND ENVIRONMENTAL HEALTH SERVICE IS TERMINATED

Five days later, on December 18, I was summarily called to a meeting with Frank Dietz and Dr. Scott. The former angrily berated me for vindictively sending the company's employees such a frightening letter, which I was told had both infuriated the company's management and agitated the union. I responded that nothing in my letter was new other than my recommendation of influenza vaccinations and the severance of our consulting relationship.

The hospital president went on to say that he was formally requesting me to withdraw the submitted abstract. Furthermore, I was told that our industrial hygienist's position had been eliminated, that, in fact, there no longer was an occupational health program at Memorial Hospital, and that I was to have nothing further to do with the company's employees. Dr. Scott, who is both Physician-in-Chief at Memorial and Associate Dean of Medicine for Primary Care at Brown, said essentially nothing. Several days later, Mr. Dietz reiterated all his points in writing.

THE MEDICAL SCHOOL ADMINISTRATION'S SECOND STRIKE

On December 20, I asked Dr. Scott for clarification of two points. When I asked what would happen if I refused to withdraw the abstract, I was informed that if the company sued the hospital, the hospital would in turn

countersue me. When I explained that what I had really been asking was what would happen to my job, he answered that he did not know. When I asked what Frank Dietz had meant in stating that our occupational health program no longer existed, Dr. Scott answered that I could not have any contracts with industry. When I asked if I would still be allowed to teach occupational medicine to students and housestaff, he said "yes." When I asked if I would be allowed to continue seeing patients with suspected work-related illnesses, he said that he would have to check with Mr. Dietz. When I asked whether I would be allowed to do research on matters related to occupational health, he said that he would have to ask Mr. Dietz. I stated that while I understood Frank Dietz's perspective, I had difficulty understanding how he, Dr. Scott, could support such a perspective given the issues of academic freedom and public health, given his previous position as Director of the Rhode Island Department of Health, and his current academic positions. Dr. Scott responded that from his perspective there were two issues. First, I had lost the confidence of the company's management as a result of the way that I had handled the non-scientific aspects of the investigation. Second, my academic freedom was not being taken away from me but rather I had given it away in signing the company's secrecy agreement.

In response, I noted that there were three mutually exclusive ways one could characterize what had happened. First, I was a well-intentioned but bumbling scientist. Second, I was a scientist who intentionally had attempted to harm the company. Third, I was a well-intentioned scientist who had been as accommodating to the company as was reasonably possible and who had 15 years of experience successfully investigating suspected outbreaks of occupational and environmental disease, a full awareness of the non-scientific pitfalls inherent in such investigations, and the knowledge that a fair number of my occupational health colleagues had at one time or another suffered similar threats during their careers. I stated that the third scenario was, in point of fact, the truth; moreover, I had the documentation to support my claim that it was not a matter of failed interpersonal relationships but rather the company management's ineptitude in responding to the disease outbreak, its intentional efforts at deception, and its articulated need for complete control that were collectively responsible for the debacle. Finally, with respect to the issue of academic freedom, I expressed the opinion that the company's secrecy agreement had little if any relevance to the current situation and that, moreover, it should not be allowed to deter us from our professional responsibilities.

COLLEGIAL SUPPORT

In the ensuing few weeks, I discussed the situation with and sought advice from hospital-, university-, and public health agency-based colleagues both locally and na-

tionally. All were extremely supportive. Those not working in occupational health were nearly unanimous in recommending first that I withdraw the abstract to avoid the risk of being simultaneously sued and fired from my hospital-based position and second that I focus thereafter on bringing the issues to the attention of Brown University's administration and faculty. They expressed concern that there was not enough time to mobilize support at Brown University before the ATS's January 15 abstract withdrawal deadline. My occupational health colleagues, however, felt strongly that I should not withdraw the abstract. Moreover, they indicated their readiness to initiate a national letter-writing campaign under the auspices of both the American Public Health Association and the Association of Occupational and Environmental Clinics. In mid-January 1997, I received a letter from Dr. Robert Vanderslice, Chief, Office of Environmental Health Risk Assessment, Rhode Island Department of Health. In his letter, Dr. Vanderslice requested, under the state's Rules and Regulations Pertaining to the Reporting of Communicable, Environmental and Occupational Diseases, that I provide him with details of the cases of interstitial lung disease occurring at the plant. I drafted a response, which I reviewed with Dr. Scott before forwarding it on to the Department of Health. Dr. Vanderslice subsequently wrote again to say that both he and the editor of *Mortality and Morbidity Weekly Report (MMWR)*, a publication of the Centers for Disease Control (U.S. Public Health Service), had concluded that our findings should be published in *MMWR* given their broad public health significance.

THE MEDICAL SCHOOL ADMINISTRATION'S THIRD STRIKE

Although two associate deans, by then, had demonstrated what at best can only be considered poor judgment, the Dean of Medicine continued to remain silent. At my request, I finally met with him in early February. He acknowledged not having read the 25-page chronology and supporting documents that I had left for him in advance, explained that there was little he could do given the relative independence of the affiliated hospitals, and referred repeatedly to the "risk-averse stance" that the university must take in all such matters. In March, six courageous Brown faculty members—Kim Boekelheide, MD, PhD, Professor of Medical Sciences (Pathology and Laboratory Medicine), Lundy Braun, PhD, Associate Professor of Medical Sciences (Pathology and Laboratory Medicine), Dan Brock, PhD, Professor of Philosophy and Biomedical Ethics, Charles B. Sherman, MD, Associate Professor of Medicine, Harold Ward, PhD, JD, Professor of Chemistry and Environmental Studies, and Sally Zierler, DrPH, Associate Professor of Medical Sciences (Epidemiology) and Women's Health—submit-

ted to the Faculty Executive Committee (FEC) a list of charges against Memorial Hospital's President and Physician-in-Chief. At the urging of its vice-chair, James C. Baird, PhD, Professor of Chemistry and Physics, the FEC expeditiously notified both the Dean of Medicine and the President of the university of its concern that my academic freedom was being violated. In response, the Dean of Medicine convened a Committee of Inquiry, comprised of two Associate Deans of Medicine; one of the two, Peter Shank, PhD, had previously written that ". . . you should immediately withdraw your abstract to the national meeting."

Over the following month, the actions and statements of both Dean Marsh and the Committee of Inquiry made it clear that a search for truth was not in progress. In response, the six Brown faculty members who collectively had submitted charges to the FEC formalized their complaint; a letter-writing campaign, the brainchild of Howard Frumkin, MD, DrPH, an alumnus of Brown and Chair of the Department of Environmental and Occupational Health at the Emory University School of Public Health, was initiated by the Association of Occupational and Environmental Clinics; and Donald K. Milton, MD, DrPH, Associate Professor of Occupational and Environmental Health at Harvard, disturbed by the ignominy of the situation, forwarded details to a reporter for *Science*, whose news story on the matter stimulated further attention from the print and broadcast media.

Shortly thereafter, Dean Marsh issued a public letter of apology to Memorial's President Frank Dietz, retracting his statement that the hospital had closed our program without first consulting the university's administration; in fact, as the dean acknowledges, the hospital had acted following a meeting at which he had offered "no objection" to Frank Dietz's plan to terminate our occupational medicine program. In Brown's haste to distance itself from the controversy, the dean has publicly stated that: "Neither the School of Medicine nor the Department of Medicine has formally created a Program in Occupational Medicine." This statement is contradicted by my appointment in 1986 to direct such a program by the Chair of the Brown University Department of Medicine (Department of Medicine Reference Manual, July 12, 1989), the contents of my 1994 promotion dossier, and my submission of an institutional grant proposal on behalf of Brown University to the National Institute of Environmental Health Sciences. The proposal lists my title on the face sheet, was authorized by the University's Office of Research Administration, contains a letter of support from the dean's office, and notes that "For the last six years, Brown University has had an active Program in Occupational Medicine that crosses division lines within the Department of Medicine."

THE UNIVERSITY PRESIDENT AND THE AMERICAN THORACIC SOCIETY

Apprised of the Dean's deception, I wrote to Brown University's President Vartan Gregorian: "Given that there is no longer any recognizable moral authority within the current medical school administration, I turn to you for a final hearing." Almost simultaneously, the dean's Committee of Inquiry released its report. While the committee concluded that my academic freedom had been violated, it reached this conclusion on the basis of tortured legalistic reasoning and all but ignored the truly compelling facts and issues. It is difficult to imagine how anyone can take the report seriously given such conclusions as: "The company's attempt to have the abstract withdrawn is not considered by the Committee to be an attempt to compromise the health of its employees but rather an effort to avoid bad publicity and to protect its economic position."

The following week, my wife, Robin (who previously practiced labor law and currently sings) and I met with President Gregorian, who asked for time to review the situation. My colleagues and I then left for the American Thoracic Society's International Meeting, where we presented our findings on May 21, 1997.³ By the end of the meeting, the Association of Occupational and Environmental Clinics, the American College of Occupational and Environmental Medicine (ACOEM), the American Thoracic Society (ATS), the Harriet Hardy Institute, and both the Occupational Health Section Chair and the President of the American Public Health Association had all issued clear statements supporting our stance. The ACOEM warned: "History is replete with examples where delay or suppression in the reporting and dissemination of health risks led to serious human and financial consequences." The ATS admonished: "Barriers to the open communication of scientific information must be resisted. In particular, the threat of litigation and/or elimination of financial support to prevent the open communication of scientific information is abhorrent." Subsequently, both the Rhode Island Medical Society and the RI AFL-CIO added their support.

A FURTHER ALIGNMENT OF FORCES

One week after returning from the ATS meeting, I received letters from both Memorial Hospital President Frank Dietz and Brown University President Vartan Gregorian. The letters informed me that my five-year employment contract with the hospital would not be renewed upon its expiration in 1999 (but that it could be extended by one year), that both the hospital and the university recognize the importance of academic freedom, that in the interim I was free to continue my research (although the issue of resources was not adequately addressed), and that if I were to find

employment elsewhere, the hospital would assume responsibility for my salary for up to two years through the year 2000. Whether the hospital/university affiliation agreements allow for the non-renewal of an associate professor's employment contract in such a situation was not addressed; with chilling effect, the university administration has continued both to refuse to answer this question and to deny its faculty access to these agreements. While some have praised the university president for making the best of a difficult situation, especially given his lame-duck status (becoming president of the Carnegie Foundation on October 30, 1997), I feel far less charitable. A university president must know when it is more important to be a standard bearer than an architect of compromise.

On the very day I received the hospital president's letter, Microfibres, Memorial Hospital, and Brown University received notification from the federal Occupational Safety and Health Administration (OSHA) that I had filed a complaint alleging that they had violated my section 11C rights under the OSHA Act. Section 11C prohibits discrimination against employees for asserting their OSHA rights.

Following a relatively quiet month of June, there was a renewed burst of print and broadcast media activity. In early July, the hospital's president and physician-in-chief became so exasperated by the media blitz that they told one reporter it might be necessary for them to fire me before my contract expires. The media accounts commented on the recurrence of illness in a previously affected employee after his return to work, OSHA's ongoing investigation of my charges that the company, the hospital, and the university had violated my section 11C rights under the OSHA Act, the notion that the integrity of the physician-patient relationship rather than academic freedom is the real issue, and the recent occurrence of additional cases of flock workers' lung disease at plants owned by other companies. The hospital and the company intensified their smear campaigns. Mr. Dietz distributed a misinformation packet to physicians throughout the state as well as further afield. Dr. Scott sent the same mailing to all 1,500 Brown University faculty.

RESPONDING TO THE PUBLIC HEALTH

On September 26, our findings appeared in *Morbidity and Mortality Weekly Report*, a publication of the Centers of Disease Control and Prevention (CDC) of the U.S. Public Health Service.⁴ In October, OSHA completed its investigation of my claims of discrimination under Section 11C. Finding merit in my claims against the company, the hospital, and the university, the agency forwarded its case records for further legal analysis to the Solicitor's Office in the U.S. Department of Labor, where the matter remains under review.

COMMENT

Representatives of the company, the hospital, and the university have gone to great lengths to distort the truth. Yet, even were their claims true, their points of contention are irrelevant to the critical issues in this matter. That is, whether or not our occupational health program was generating or losing money, whether or not the occupational health program was a duly constituted university program, and whether or not the confidentiality agreement in question has any legal standing in no way either excuse or account for their (a) attempts to suppress the dissemination of scientific findings critically important to the public health, (b) interference with my professional responsibilities to care for patients, and (c) immediate termination of our occupational health program.

We are left confronting arrogance, dishonesty, and a callous disregard for the health of workers. While our medical school and university administrators continue to proclaim a dedication to truth, to the search for knowledge, and to the advancement of civilization, it is all pretense as wordsmithing triumphs over truth and as knowledge is buried. What makes such pretense infuriating goes beyond hypocrisy to the failure of these administrators to realize that people's lives hang in the balance. They either fail to appreciate or are unwilling to acknowledge that their words and actions have jeopardized

the health of individual workers, have contributed to the potentially irrevocable loss of an opportunity to advance both scientific understanding and the public health, and have undermined the collective sense of trust and mission in this academic community.

The saga will continue. My colleagues and I will remain forever grateful to those who have seen past the diversionary tactics and acted. Physicians, university faculty, public health practitioners, medical students, physicians-in-training, lay people, labor unions, professional organizations, and others, here in Rhode Island, nationally, and internationally have seen the issues clearly and formally registered their outrage. In sharp contrast to the situation depicted in Ibsen's "An Enemy of the People," I am not alone.

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