Professional Sanitarians and the Law

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ABSTRACT

Increased communications between sanitarians and lawyers are important as the public becomes more conscious of sanitation matters, the food distribution chain lengthens, and governmental budgets increase. Federal and state laws prohibit shipment of “adulterated” food, including food packed or held under insanitary conditions, even though the food itself is perfectly clean. Penalties for violation are seizure, injunction, and criminal prosecution, including prosecution of “responsible” individuals. In addition, recalls, which are not mentioned in the federal law, are frequently used. All of these actions require close cooperation between sanitarians and lawyers, whether on the industry side or the governmental side. Preparation for, conducting, and following up on inspections by FDA or other governmental agencies also require cooperation between sanitarians and lawyers.

Our two disciplines — yours as sanitarians and mine as a lawyer — have been coming into contact more frequently and more intimately in recent years, and it is extremely important that we open the door to further communications between us. Incidentally, it is much better for us to communicate on your grounds — in a manufacturing plant or warehouse, or even better at a meeting than it is to meet on my grounds — at an administrative hearing or worse yet in a court room.

REASONS FOR COMMUNICATIONS

In analyzing why it is increasingly important for us to have good communications, it appears to me that there are three reasons.

First, our country — including particularly the consuming public — has become increasingly conscious of sanitation and related matters. The recent “Philadelphia incident” was a dramatic example which captured public imagination and focused attention on the necessity for perpetual environmental vigilence, including sanitation. As we learn more about bacteria, yeasts, molds, and other even more exotic instrumentalities which are perpetually ready to assail the food supply of the human race, it becomes increasingly clear that sanitarians have an enormously important role to play. And it is also clear that the significance of this role is going to increase in the future. As it increases, I suspect you will be dealing more and more with lawyers, and I know from my own experience that lawyers are going to need you more and more.

Second, the role of sanitarians, and our mutual need to cooperate, seems to increase as the length of the food distribution chain increases. When food was produced primarily for home consumption on the farm a sanitarian would not have been a particularly welcome visitor. But as the producer and consumer have moved further and further apart, both in terms of geography and of middlenmen, the role of the sanitarian has become a vital factor in protection of the public health.

Third, FDA, and other federal and state agencies have greatly increased budgets, which means that sanitarians and lawyers will be working much more closely together either for the government or for industry, and hopefully in solving mutual problems before they get to the litigation stage. FDA’s budget, for example, was $5,000,000 in 1955; Commissioner Schmidt estimates that by 1980 it will be $500,000,000. This means more scientists, including sanitarians, working for the government; it means more comprehensive and intensive statutes, like the impending bill, S. 641; it means more knowledgeable and technical inspections at food plants; and it means more and better equipped FDA inspectors.

I cannot overemphasize to you the importance which professional sanitarians are going to be playing in food, milk, and environmental matters in the immediate future. The public health needs you, and we lawyers view you and your burgeoning profession with a great deal of respect.

REVIEW OF FOOD LAW

I would like to give you a brief review of food law as it applies to your profession. For some my comments may be quite elementary, while for others they may be exposure to a new field and new ideas.

The basic concept of the Federal Food, Drug, and Cosmetic Act (although this is an intentional over-simplification designed to let us zero in on our specific topic) is that adulterated food may not be shipped or received in interstate commerce. The word “adulteration” has several very specific definitions in the Act, but the one which is most important for us is in Section 402(a) (4) (21 U.S.C. 342(a) (4)) which provides:

“A food shall be deemed to be adulterated — (a) . . . (4) if it has been prepared, packed, or held under insanitary conditions whereby it may have become
contaminated with filth, or whereby it may have been rendered injurious to health . . . ."

The importance of this section is that a food is adulterated under this definition if the plant or warehouse in which it is packed or held is insanitary, even though the food itself is perfectly clean. And Section 402 (a) (4) is one of the sections of the Act most frequently by the FDA in its enforcement proceedings.

**PENALTIES FOR ADULTERATION**

Next, let's take a brief look at the penalties for violating this adulteration section. Three remedies are provided in the Act:

(a) Seizure of the adulterated goods. This is by far the most common remedy used by FDA, and by state agencies enforcing state laws similar to Section 402 (a) (4). The maximum penalty in a seizure action is loss of the goods which have been seized, although of course there may be sequential problems such as what to do with similar goods not seized.

(b) An injunction against the firm and/or individuals to restrain them from some form of future action. For example, FDA has exercised this authority to effectuate closing of plants which it deemed to be so insanitary that they could not be corrected.

(c) Criminal prosecution against the offending firm and/or its individual officers or other responsible individuals. This is an extremely serious remedy, which involves a fine of $1,000 on each count for the firm and individuals, and/or a maximum of 1 year in jail on each count for individuals for a first offense, and more serious penalties for subsequent offenses.

Last year the United States Supreme Court decided the case of U.S. v. Park, 44 L.Ed. 2d 480 (1975), in which the president of Acme Markets, a large retail chain in the East with 16 warehouses and 874 retail outlets, was found guilty of violating the Act because of insanitary conditions in the firm's Baltimore warehouse. While the case involved only a misdemeanor, and the court assessed only a $250 fine, the principle was so important that Mr. Park appealed the case all the way to the United States Supreme Court which affirmed his conviction on the ground that Mr. Park was a responsible official, and was not "powerless" to have prevented the violation.

One effect of the Park case has been to get the very clear attention of corporate officials all over the United States. They are more than ever, and some for the first time, looking to sanitarians and lawyers to assure them that they are not in serious jeopardy of a jail sentence. If you ever had the slightest doubt about the importance of a sanitarian, you can now erase it. If you are a sanitarian in private industry or a consultant to private industry, the president of your company is in jeopardy of a criminal prosecution if you do not do your job properly; if you are a sanitarian for a governmental agency, the success of your agency's prosecutions may very well depend on the accuracy and detail of your work.

Let me be more specific. Just last month (July, 1976), I defended a criminal prosecution against a partnership which operated a food wholesale warehouse. Three of the four individual partners were also defendants. The government had charged each of the four defendants with eight separate violations of the Act, which could have resulted in a $32,000 fine and 8 years in jail for each of the three individuals. Five of the counts charged all four defendants with holding food which itself was contaminated, but the other three counts charged only that the food was held under insanitary conditions at the warehouse. Indeed, the government's own tests showed that the food involved in these three counts was not itself contaminated in any way. Thus Section 402 (a) (4) was the sole charge in these three counts.

You can imagine the importance of sanitarians in a case like this, both before the case was filed and as witnesses. I am pleased to say that the jury found the three individual defendants not guilty on all eight counts, and vindicated the warehouse's sanitation practices by finding the partnership not guilty on the three counts which involved Section 402 (a) (4) alone. The government prevailed on the five counts for which FDA had photographs taken by the inspectors 2 years and 1.5 years before the trial.

(d) A fourth remedy used with increasing frequency, although it is not mentioned in the Act, is a recall. FDA has recently published, in the Federal Register for June 30, 1976, a comprehensive proposal concerning recalls in which you may be interested.

**INSPECTIONS**

Finally, I would like to discuss inspections by federal and state officials, again an area in which sanitarians and lawyers must cooperate. If you are a sanitarian working with an inspected firm, it is crucially important that you work with your firm's lawyers in designing a suitable protocol covering preparation for the inspection, conduct of the inspection itself, and followup on the inspection. Obviously legal questions are involved in each of these three steps, so your profession and mine will again be working together. Let me emphasize particularly the importance of proper followup after the inspection is concluded. This followup should include not only internal changes, but also a thorough report to the inspecting agency. Again, a job for sanitarians — who are the experts in knowing what must be done to effectuate necessary changes — and lawyers, who hopefully are the experts in translating action into words which will be persuasive to the regulatory agency in its decision as to whether further regulatory action is needed.

If you are a sanitarian working for a governmental agency, you must of course be thoroughly prepared for the inspection, know how to conduct the inspection, and help carry out your dedication to the protection of public health by sharing your views with the firm at the conclusion of the inspection. If the firm fails to carry out what you believe to be necessary steps, you will undoubtedly be talking to lawyers who will be preparing a case, and again our two professions will be working
One potential bone of contention in the handling of inspections is the taking of photographs. FDA inspectors are instructed to attempt to take pictures of any violative condition which they find, and they have authority to do so unless the inspected firm requests that the pictures not be taken. In other words, the inspected plant has the option of prohibiting the taking of pictures, and because pictures can so distort a condition, it is my strong recommendation that the inspector be requested to leave his camera in the car — politely but firmly.

I hope that these comments have reaffirmed your awareness of the importance of sanitarians and the work which you do. You are absolutely essential not only to the protection of public health, but your role is becoming increasingly important as technology develops. As a lawyer, I particularly thank you for the expertise which you have brought to the field of food technology, and look forward to working with you in the protection of the public health — hopefully on your field of battle but if necessary also on mine!

ACKNOWLEDGMENT