A USDA investigator seals a sample of an agricultural chemical to be sent to the laboratory to determine conformity of label and contents to regulations

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The Interdependence of Science and Law

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Our society operates on the basis of two sets of laws—the laws of nature and the laws of man. One is recorded in scientific writings, the other in our statutes and codes. But the two sets are correlated and interdependent since no social order can exist except in the natural universe and it would be futile to establish legal dicta contrary to physical or biological facts. The infusion into the laws regulating society of the beneficial patterns of nature and the exclusion of harmful patterns are necessary conditions for the realization of a stable and salutary society. Hence it is inevitable in this technological age that scientists are called upon to cooperate in the writing and administration of man-made prescriptions for social behavior. On the measure of these concerted, cooperative efforts of scientists and lawyers depends the security of every citizen and the welfare and progress of our nation.

ONE MAY WONDER why these rather obvious remarks need emphasis. Unfortunately, it has been suggested that there has been too much interference on the part of scientists with the promulgation and interpretation of food and drug laws; furthermore, it has been seriously recommended that the testimony of scientific witnesses at administrative hearings be sharply restricted to the methods and results of their experiments without allowing them to express their views as to the commercial or social effects of any new proposals. On the opposite side, the complaint has been made that there has been too much "lawyering" in the conduct of administrative hearings. Some scientists who have appeared as witnesses at these hearings have resolved never again voluntarily to permit themselves to be subjected to the indignities of cross-examination by industrial lawyers. Hugo Mock has reminded us that "every craft and profession is jealous of its prerogatives." I can think of no area, however, where such jealousy is more out of place than that of public health and, I am convinced, this is only a minority attitude albeit not one to be ignored.

Although English is our common medium of expression, the language habits and technical jargon of both scientists and lawyers are not infrequently responsible for misunderstanding and perhaps for a subconscious unwillingness to agree on matters outside their own province. "Words have a penumbra of uncertainty," to quote Dr. Glanville Williams (*Law Quarterly Review*, April 1945) who writes:

"A chemist does not need to answer the question, yes or no, does a rolled-gold watch come within the description gold. Biologists may find difficulty with their classification, but nothing turns on the question whether they classify a creature under one head or another: it is simply a question of verbal expediency. With the lawyer it is different. The lawyer, like the theologian, is faced with a number of texts that he regards as authoritative and that are supposed to settle any question that can conceivably arise. Each text was once drawn up by someone who presumably meant something by it; but once the document has left its author's hands it is the document that matters, not any unexpressed meaning that still remains in the author's mind. For the lawyer the words of the document are authoritative as words and there is no possibility of obtaining further information from the author, either because the author is dead or because of the rules of evidence precluding reference to him."

An illustration of the confusion which has arisen under the Food, Drug, and

...nd the Law

Inspection of food handling equipment for conformity to sanitary laws is a part of the work of the Food and Drug Administration

As dynamic factors in social progress, scientific-legal interrelationships are very important—conspicuously so where agricultural and food sciences are concerned. Here a scientist and a lawyer present their views

Cosmetic Act is the recent decision revolving around the chemist's colloquial use of the term "fluorine" for the more precise "fluoride". Another is the legal characterization of substances as "poisonous or deleterious" without specific relation to dosage, mode, and frequency of administration. While this may have involved little uncertainty when applied to compounds of mercury, lead, arsenic, and similar acutely lethal substances which were encountered in the early days of food law enforcement, the definition of "poison" has become complicated since the introduction of substances whose effects may be slight, chronic, or even uncertain, and is now left largely to administrative discretion. These examples show, in the words of Sir Ernest Gowers ("Plain Words—A Guide to the Use of English," London, His Majesty's Stationery Office, 1948)

"how hard it is for the draftsman to foresee every possible path down which the judicial mind may be led by what he writes, and also provides another illustration of the truth that legal ambiguities are caused more often by over-simplicity of diction than by over-elaboration."

Lawyers themselves have been quite concerned with the need for clarification of such expressions as "reasonable," "purports to be," "substantial evidence," "harmless," "fair dealing". All are terms which have a direct concern to those who are responsible for conformity to the Food, Drug, and Cosmetic Act. So perhaps it is true, as Sir Winston Churchill is said to have remarked, that we have a common language that divides us.

The need for close cooperation between law and science is clearly and convincingly demonstrated by the recent history of our food and drug laws. At the turn of the century the manufacture of foods and medicines was predominantly local. When the industrial revolution invaded the field of food and drug production, the emphasis shifted from the kitchen and the corner drug store to large-scale manufacture. The many advantages of mass production and distribution became available, including better sanitation, purity, and quality, year-round availability, variety, economy, convenience, and the like, but along with them certain risks were increased. While an error on the part of the housewife or the pharmacist might have had only limited significance, mass production brought with it the possibility that variations in the composition or production of foods and drugs, whether intentional or unintentional, might have more far-reaching and even serious consequences. Furthermore, scientific advances, especially in the fields of chemistry and microbiology, as well as developments along the lines of engineering and processing, resulted in many new food products and synthetic drugs for which no criteria of purity or efficacy hitherto existed. Several decades' experience in the enforcement of the Food and Drug Act of 1906, as well as the need to adjust to these technological advances, gave rise to the recodification of the basic food and drug law under the present Food, Drug, and Cosmetic Act of 1938.

Scientist's Role Predominant

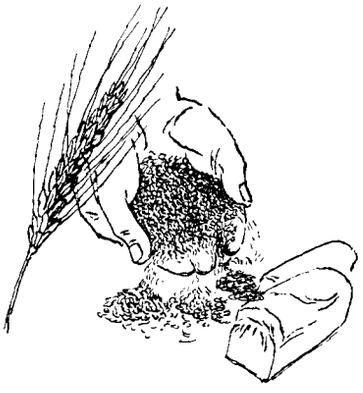
The predominant role assumed by the scientist in the operation of this law can be well exemplified by the activities of the Food and Drug Administration. This agency exercises control over the products of industries whose total retail value is approximately $50 billion per year. One fourth of the national income is spent on commodities dealt with under this law, yet the cost of enforcement to each individual is only about 3.25 cents a year. As of 1953, the total personnel of the Food and Drug Administration (exclusive of the rather specialized certification and sea-food services) was 792 of which 234 or roughly 30% were professional laboratory personnel and medical officers, and 193 or 24% were field inspectors; the total number of administrative personnel was 67.

In passing it may be mentioned that it is a sad commentary on Congressional recognition of the importance of the Food

and Drug Administration that the size of its staff has actually diminished over the past five-year period. At a time when increased demands are made upon its scientific staff, curtailment of the budget of this administration to the extent that its professional personnel are unable to attend scientific meetings would appear to be contrary to public interest.

One is impressed with the array of scientific disciplines called upon in the enforcement of the Food, Drug, and Cosmetic Act which, it will be recalled, controls devices as well as food, drugs, and cosmetics. To establish standards of identity and quality, to detect adulteration, to prove misbranding, the services of chemists, bacteriologists, microscopists, and nutritionists are of course essential. Medicine, both human and veterinary, and its various specialized branches also occupy important positions in the rank of sciences concerned with food and drug laws. Less obvious but no less vital are the services of immunologists for the serological identification of adulteration of meat products; of toxicologists and pharmacologists for the determination of the potency or safety of drugs or of the harmlessness of proposed food additives; of entomologists for the detection and identification of the source of insect infestation; of horticulturists and food technologists to establish the requirements of production or "good manufacturing practice"; and of physicists and engineers for providing essential scientific and technological information particularly concerning devices which come under the act.

Special mention should be made of statistics and biometrics which are playing a new and ever increasing role in the scientific work demanded under the Food, Drug, and Cosmetic Act. Needless to say all inspections are based on samples, and the adequacy of sampling is of obvious significance in seizure proceedings. However, there is need to apply statistical procedures in determining the representative character of samples whose compositional or dimensional properties are used to establish the norms for setting up standards. Statistical principles are invoked in the development and adoption of analytical methods as well as in the design and interpretation of biological and pharmacological tests, inasmuch as the significance of individual observations often requires a knowledge of the normal variance and the factors that control it. Certain types of subjective reaction such as taste, odor, and similar organoleptic properties are susceptible of measurement on a highly objective basis by means of properly designed experiments.



In recent years standards hearings have brought out the inadequacy of our knowledge of "what the consumer expects." Various agencies, some public, others private, have been called upon to supply such information and, indeed, this branch of statistics has attained the dignity of a name, psychometrics. Reliance should not be placed on the views and preferences of "representative" individual consumers. There is a genuine necessity for the application of scientific and objective sampling or polling techniques as a basis for ascertaining authentic information about consumers' habits, expectations, and preferences with regard to the composition and properties of various commodities. It remains to be seen whether the recent designation of "consumer consultants" in each of the districts of the Food and Drug Administration can satisfy this need.

Laws Have Been Stimulus

Many scientific advances have been made, particularly in the field of analytical methodology, under the stimulus of our food and drug laws. Standards of identity and purity are difficult if not impossible to establish in the absence of objective analytical data or where chemical, physical, and microbiological testing methods have been lacking or insufficiently advanced to meet the challenge. The vast amount of effort that has gone into this work has led to the establishment of such orgnizations as the Association of Official Agricultural Chemists and the Association of Feed Control Officials and has prompted a continuous search for newer and better methods among food and pharmaceutical chemists working independently and through their various professional organizations, trade associations, and Pharmacopeial committees. During the past half century while our food and drug laws have reached their present state of maturity, analytical chemistry as a profession has come of age.

The last decade has witnessed a rapid and almost universal realization of the great benefits to be derived from many new insecticides, fungicides, rodenticides, herbicides, antiseptics, and preservatives. These products present the possibility of saving many billions of dollars worth of agricultural products from the ravages of pests. Desirable though such developments may be from the standpoint of world nutrition and economy, they pose serious problems for the food industry and the regulatory agencies. This situation has given impetus to the entire field of toxicology with particular respect to the acute and chronic effects of exposure to or consumption of these substances. Experimental toxicology makes use of new techniques and instrumentation and the opportunity is being afforded to learn more about the responses of laboratory animals over longer periods of their normal life cycle than was hitherto considered necessary.

At the same time these developments have given rise to serious doubts as to whether the Food, Drug, and Cosmetic Act can cope properly with the problem of protecting the consumer against subtle or uncertain hazards. The question is a highly complex one involving, as it does, moral and social considerations that are not exclusively within the province of either the lawyer or the scientist. To quote one of our great modern philosophers: "No body of experts is wise enough, or good enough, to be charged with the destiny of mankind." Regardless of his specialty, it behooves any professional man to maintain a spirit of humility and not to confuse his learning with wisdom in the affairs of life. So often the specialist, be he a doctor, lawyer, merchant, or chief, is blessed with such concentration and intensity of purpose as to deprive him of the sense of perspective essential for a balanced judgment affecting public policy.

By stressing the activities of scientists in the Food and Drug Administration I do not mean to underemphasize the part played by lawyers. While the Administration itself does not have any lawyers on its payroll, the Department of Health, Education, and Welfare has a General

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Counsel's office in which 10 attorneys are assigned to food and drug work. The intricacies of modern technology and the great diversity of production subject to the Act requires a high degree of professional skill on the part of the legal officer. He should have the capacity to move with firmness and assurance in a difficult and unfamiliar terrain. He should have the capacity to understand and cooperate with his scientific associates in the exercise of the balanced judgment necessary for the formulation of standards of identity, purity, and fill. He should not be so bound by tradition as to be incapable of interpreting the intent of the law within the limitations of changing technological requirements. He should be able to distinguish fundamental facts from specious arguments advanced in support of conflicting commercial interests. This type of specialized legal work must hold a particular fascination for those dedicated to it in the federal service, since the financial rewards and the security of tenure can hardly be considered attractive.

Law Affects Scientific Development

Many industrial and institutional scientists contribute to the large body of data on which regulatory action is based. It is a specific function of the Food and Drug Administration to select from the ever-increasing mass of scientific knowledge the pertinent facts and figures, to verify them, to adapt them to enforcement needs, and even to supplement them by original research in fields which have not yet been explored.

Industrial and academic scientists are similarly engaged. The law has a profound effect upon the scope and direction of scientific research, particularly as applied to the development of new food and pharmaceutical products. It is essential that scientists working in these fields be aware of the limitations which control such developments as new drugs; pesticidal agents, residual traces of which may be present in foods or feeds; the limitations which govern the introduction of new preservatives and antioxidants; the necessity for developing accurate and precise analytical methods for the determination of quality, purity, and freedom from adulteration; restrictions imposed by judicial construction on developing foods resembling those for which standards of identity exist; and the different labeling requirements for various types of foods, drugs, and cosmetics.

It is not intended to imply that the scientist must function in the professional capacity of a lawyer, but rather that he should be cognizant of any laws which determine the direction or affect the progress of research especially in the applied field. Laws should be understandable and understood by all concerned with their operations. Nevertheless scientists cannot expect to become conversant in all phases of law, any more then lawyers, however expert they may be in food and drug law, can substitute their judgment on scientific matters for that of specialists in fields beyond their ken.

Administrative hearings to establish tolerance limits for added poisonous and deleterious substances or hearings to establish standards of identity, purity, and fill, provide common ground on which legal and scientific specialists meet with representatives of government and of trade and consumer organizations. The requirement that rulings be based on substantial evidence in the record makes it essential that considerable latitude be allowed in assembling all pertinent facts and opinions. It is unfortunate that controversies of a commercial nature have sometimes been injected into these hearings to the extent that their fact-finding, legislative character is sacrificed, and they assume the aspect of criminal proceedings about which some scientific witnesses have complained. It is to be hoped that the amendment to simplify standards procedure (H. R. 6434) which was proposed at this meeting last year will help to alleviate this situation.

The degree of expertise presumed to be necessary in certain administrative hearings sometimes verges on the absurd as when a physiological chemist was required to establish his familiarity with rabbit urine. A competent chemist should be able to give admissible testimony on the composition of a food product even though he may not be as familiar with it as the chemist working in the manufacturer's control laboratory; a statistician should be able to give admissible testimony on the validity of data regardless of his knowledge of the particular product involved; an anthropologist should be able to give admissible testimony on the eating habits of various races of man regardless of whether he likes fried locusts or not. The idea of restricting the testimony of scientists to their methods and results fails to take into account the fact that they too are "common people" form part of the consuming public; the fact that they have specialized knowledge, background, and competence should lend particular validity to the informed opinions they are able to render.

Science and Law Evolving

Just as science is in a constant state of evolution, laws are ever in need of revision, expansion, or reinterpretation to conform to the changing needs of society. Recent discoveries of physicists, chemists, and biologists have disclosed the relevance of atomic events to natural phenomena. The law cannot disregard these discoveries inasmuch as they affect the social order, the well-being and security, and even the economic prosperity of people everywhere. The health and indeed the survival of people and of nations may depend on scientists working not only in the field of atomic physics but with viruses, toxins, radioisotopes, trace elements, and with the living cell. It is inconceivable that discoveries in these fields will not influence future legislation. It is the professional duty and the moral responsibility of the scientist first to make the most accurate observations compatible with his present facilities—in fact to find ways and means of improving these facilities—and then to judge the relevance of his findings against the background of his knowledge and experience, applying to this task the same critical objectivity as he is trained to employ in the laboratory. This is not to say that his judgment at the social level need be accepted as final; but it would be folly indeed to deny him the right to express it.

Undue risks are never justified in matters affecting public health. The burden of responsibility upon the scientist is great, as it is also upon lawyers and legislators. The public generally may be ignorant of the scientific background which forms the basis of the decisions reached by government administrators and the courts, but scientists and lawyers can join in the effort to bring understanding to the average man so that the consequences of these acts and decisions appear reasonable and right.

Respect and Understanding Between Science and Law

This is an age of merging fields of specialization. Just as in the field of science there are all varieties of hybrid chemists, in the field of law we have patent lawyers who are not necessarily engineers or chemists; tax lawyers who are not necessarily accountants; admiralty lawyers who are not necessarily sea captains; and food and drug lawyers who are not necessarily food technologists or pharmacologists. This serves only to emphasize the need and in fact the inevitability of fusion of specialized knowledge and for cooperative effort among different scientific and professional disciplines. It does not mean that the scientist must be a lawyer, nor the lawyer a scientist. Just as the former has no monopoly on natural laws, the latter has no monopoly on statutory laws or on the exercise of judgment regarding moral or sociological values. But no cooperation is feasible without mutual respect and understanding. There should be no rivalry or competition between the professions of law and science, but rather a friendly collaborative relationship which should serve not only in the public interest but as a mutually inspiring experience and a source of intellectual reward.

Presented before the Food, Drug and Cosmetic Law Section of the New York Bar Association, New York, Jan. 27, 1954.