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# Food Drug Cosmetic Law JOURNAL



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THE EDITORIAL POLICY of this JOURNAL is to record the progress of the law in the field of food, drugs and cosmetics, and to provide a constructive discussion of it, according to the highest professional standards. The FOOD DRUG COSMETIC LAW JOURNAL is the only forum for current discussion of such law and it renders an important public service, for it is an invaluable means (1) to create a better knowledge and understanding of food, drug and cosmetic law, (2) to promote its due operation and development and thus (3) to effectuate its great remedial purposes. In short: While this law receives normal legal, administrative and judicial consideration, there remains a basic need for its appropriate study as a fundamental law of the land; the JOURNAL is designed to satisfy that need. The editorial policy also is to allow frank discussion of food-drug-cosmetic issues. The views stated are those of the contributors and not necessarily those of the publishers. On this basis, contributions and comments are invited.

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# Food and Drug Regulatory Programs in England, Wales and Scotland

By JAMES R. WOODWORTH

The Author, Chairman of the Department of Government at Miami University, Based the Article Reproduced Below Upon His Research into the Food and Drug Programs in the United Kingdom. The Study Was Supported by a Fellowship from Miami University. Mr. Woodworth Has Also Been a Member of the Public Administration Service Field Staff Which Carried Out a Fifty-State Study of State and Local Food and Drug Programs.

PERHAPS THE MOST IMPORTANT OBSERVATION TO MAKE is that in its totality the British have a remarkably effective regulatory program. In our natural desire for improvement, we search for the weaknesses or inadequacies present in any program. Yet how does one judge regulatory programs? By the number of inspections or inspectors, the number of seizures, convictions or fines? No simple yardstick exists, but there is one obvious point which can be made. In spite of ever-increasing population, of growing complexity of production and distribution, of a startling rise of ingestion of food produced out of the home, fewer than 30 British people each year since 1958 have died of food poisoning.[1] While this is hardly reason for complacency, it does mean that some sort of perspective is necessary. For example, the annual death rate for typhoid in England and Wales in 1904 was 9.3 per 100,000 population.

[1] Vernon, Enid, "Recorded Food Poisoning," *Scientific and Technical Surveys*, Number 44, British Food Manufacturing Industries Research Association, Leatherhead, Surrey, March 1966, p. 33.

In Scotland it was 8.9.[2] In numbers, this means 3,162 people died of typhoid in England and Wales; 400 died in Scotland. Sixty years later, three people in England and Wales and three in Scotland died of typhoid.[3]

As might be suspected, this dramatic decline in death rates is clearly related to the remarkable improvement in sanitation and quality controls, from manufacturer to retailer. "It is reckoned that the adulteration rate detected by random sampling has been reduced from 20 percent to almost nil in the course of 50 years . . . ."[4]

In 1964, Scotland had a typhoid problem traced to imported corned beef. It made headlines and shook the entire British inspection program as any crisis does. Four hundred and fifty people were affected; one died. By way of contrast, 8,079 died in Great Britain as a result of traffic accidents in that same year. Regulatory people in the food field have some reason to view their record with pride.

## Organization of the Program

To the outside observer, the impression has been that Great Britain, or especially England, as a unitary government, is centralized in almost all aspects. As a matter of fact, however, the food and drug programs operate in a remarkably decentralized pattern. Parliament passed the present basic food and drug law for England and Wales in 1955, and a very similar (but not identical) law for Scotland in 1956. Since Northern Ireland has its own parliament, they adopted their own act a couple years later. Thus the United Kingdom (England/Wales, Scotland and Northern Ireland) has in fact not one, but three, regulatory programs in the food and drug area.

Even this, however, does not accurately picture the decentralization of the program. Theoretically, the central government possesses great power to direct affairs down to the local level, but in practice much has been delegated to the local authorities, particularly in the areas of education and health. Thus in England/Wales, and, to a lesser extent, in Scotland, there is a strict separation of roles between the ministry and the local government in the food and drug field. The primary task of the English Ministries of Agriculture, Fisheries and Food and of Health is regulation-making. There is no min-

[2] U. S. Department of Commerce, Bureau of Census, *Mortality Statistics 1905*, Washington, D. C. 1905, p. 21.

[3] Letter to author from Scottish Home and Health Department, dated 15 August 1966.

[4] *Annual Report* of the Public Health Department, City and Royal Burgh of Edinburgh, 1964, p. xx.

istry inspection program and no review or evaluation of local programs. There is even some doubt in the Ministry of Agriculture, Fisheries and Food whether they can advise a local agency as to the legality of a particular label or product. Indeed the local authorities feel quite strongly that giving legal opinions is a function limited to the courts, and Ministry officials seem to share this view. Enforcement is the responsibility of approximately 350 of the 1,500 local authorities—the counties, the urban districts, the rural districts and the city boroughs. The only coordination of these activities is accomplished by an extra-legal organization called Local Authority Joint Advisory Council (LAJAC), which represents all local authorities and has sub-units dealing with specific problem areas, like sanitary inspection and food and drug laws. Since LAJAC's members are agencies of equal authority, this means cooperation, but not necessarily coordination. Like much of British life, the food and drug field depends heavily upon personal ties and close friendships among regulatory officials to achieve program uniformity. In practice it involves varying interpretations of the laws and regulations.

Scotland, with its unique history, provides a variation from the English pattern. The separation of rule-making from enforcement seems, at first glance, to be identical. The Scottish Home and Health Department combines food and drug regulation functions which in England are divided between the Ministry of Agriculture, Fisheries and Food and the Ministry of Health. The Scottish program, like its English equivalent, can exercise no real control over local authorities, but Scotland does have regional food and milk officers. Their role is to advise and persuade local officials. To the extent they are successful, they not only provide liaison among the local enforcement men, but they also enable the Scottish Home and Health Department officials to be knowledgeable about the strengths and weaknesses of local programs.

## The Rule-Making Process

Generalizations are not easy, because the process varies somewhat depending upon whether the topic is food standards, food hygiene or drugs. Rather than describe each of these separately and in detail, it may suffice to submit what is typical, admitting that in individual situations there may be variations. It must be remembered that a ministry regulation approved in London applies only to England and Wales. It has no authority in Scotland or Northern Ireland.

The British make frequent use of the committee of experts. For example, in the area of food regulation, there has been established the Food Standards Committee. Appointed by the Minister of Agriculture, Fisheries and Food, the committee consists of three members drawn from industry, three from the technical field (non-industry), and three from the general public, plus a chairman who is a specialist in the field. Industry representatives are generally from the large-sized industries; the technical representatives typically include a public analyst. The public representatives at present are the president of the Federation of Women's Institutes, a woman trade union member and the editor of *Bell's Foods and Drugs.* The chairman is professor of food and leather science at Leeds University. Usually meeting once a month, the committee has this year held the 150th meeting in its history. Staff from the Ministry of Agriculture, Fisheries and Food serve as the secretariat. Since Scotland and Northern Ireland have no equivalent committee, they usually send representatives to the meetings, as does the Ministry of Health.

Whether a particular problem is identified by the committee or by Ministry staff, the initial stage in the rule-making process is with the committee. The secretariat prepares a working paper describing the present regulations, the previous reports and any representations they may have on the subject. Normally, by press release the committee notifies all interested parties in the trade, government, and consumer groups, and invites testimony. Should the problem be unusually complex, an outside expert or two may be invited to the meetings. All of this is handled in executive session and none of the testimony is published. In due time, however, the committee makes its report and sends it to the four ministries.[5] With the publication of this report, the trade and the public are officially aware for the first time of the committee's recommendations. Presumably the committee has operated free of trade pressure, although it faces the usual constraints present in a deliberative atmosphere which includes the representatives of competing interests.

Following the publication of the committee's report, the trade again responds, as will local government officials and consumer groups. The Ministry of Agriculture, Fisheries and Food, working closely with the Ministry of Health, and in constant contact with the Scottish and Northern Ireland representatives, will then issue

[5] Minister of Agriculture, Fisheries and Food and Minister of Health for England and Wales; Secretary of State for Scotland; and Secretary of State for Home Affairs for Northern Ireland.

draft regulations. Typically the draft follows the Food Standards Committee report, but not always. Some have argued that in the labeling regulations, for example, the Ministry went farther than the Food Standards Committee recommended.

In response to the draft regulations, there will be more representations and deputations to the ministry from the affected interests. Finally, the regulations are issued. Since Scotland has a marked degree of autonomy, the Scottish Home and Health Department may or may not recommend the regulations to its Secretary of State for approval. Likewise, it may or may not see fit to revise them. Similarly, Northern Ireland may or may not deviate from the ministry regulations, although it is highly unusual for both Scotland and Northern Ireland not to pass similar regulations, since their representatives have been part of the deliberative process from the beginning.

The Codes of Practice are another aspect of the rule-making process. There is no legal basis for these, rather they are guidelines worked out between LAJAC and appropriate trade associations to regularize trade standards where there are no ministry regulations. For example, there are proposed regulations to set a minimum for the amount of meat in a meat pie. What is not stated is the kind of meat. Thus a Code of Practice will stipulate the maximum or minimum percentages of pork and beef. Although these are not exactly enforceable, they are honored by reputable firms. Moreover they have been quoted in the courts to substantiate a charge that a product was not of the nature, substance and quality demanded.

## Personnel

Food and drug authorities everywhere tend to complain about understaffing. The problem in England and Scotland is complicated by a full employment economy, which causes shortages of trainees. As a consequence, the local authorities compete with each other for the available supply of manpower. Although the pay scales are supposedly standardized, the "scale" is in reality a floor standard. Local councils can and do add to the floor standard, with additional income of up to £150, with sizeable car allowances, or by combining positions and titles. Even public housing ("council owned housing") has been known to be used as an incentive. As a result of this

competition there is a noticeable migration of qualified inspectors from Scotland to England and from the cities to the suburban or rural areas. The city authorities uniformly report vacancies on their staff, running often as high as 25%! Rural areas, on the other hand, indicate they are up to strength, obviously because they are more able to offer meaningful incentives, especially those of good car allowances and combined functions. Rural inspectors also report that their work is more varied than it is on the urban scene, and this is an important fringe benefit.

To meet the staff crisis, some cities have assigned the more routine tasks to less well trained "technicians." While public health inspectors tend to criticize this move as a dilution of their profession, it does seem sensible to spare the trained inspector the less than challenging responsibility of checking the cleanliness of toilets in factories and offices.

A second method used by cities is to add apprentices. All too frequently the urban program loses the qualified inspector just as soon as the training period has been completed. Yet it is an enlightened viewpoint and certainly the chiefs who take their program time to train apprentices do get some benefit from the services of the young men during the training period.

The training program for inspectors seems to be fairly uniform throughout England, Wales and Scotland. It involves four years of a combination of on-the-job experience, plus formal technical courses which are taught by university approved staff. Naturally, the programs located closer to the universities are better able to take advantage of high quality course work. The gradual extension of these programs by the expanding university system will enable more trainees to take advantage of them. There are no complaints about inadequately trained staff, only about over-zealousness of the younger men. This is hardly a new phenomenon, nor one limited to Great Britain. No one has yet found a cure for youthfulness.

Staff size is always difficult to compare and evaluate. A suburban area will present far fewer potential food and drug problems than an urban area with considerable food manufacturing and catering premises, although the population of the two may be almost identical. A typical agency in an area with about 100,000 population will have an authorized staff of about 12-15 assigned to the overall sanitation field, with about half this amount representing the full-time equivalent manpower engaged in food and drug work. No local

agency chief complains of inadequate staff authorization; only of the staff turnover and the vacancies.

At the ministry level in London the staff is very small. The Food Standards Section (whose concerns cover additives and food standards) has a staff of twelve plus clerical help. Increasing interest in international food standards requires expenditure of staff energy on preparation of draft proposals, attendance at conferences, and discussions of ministry attitudes. This means less time for concern with the domestic program.

In Agriculture, Fisheries and Food there seem to have been leadership inadequacies in the past, but the blame may rest with the system rather than any individual. The English civil service offers advancement anywhere in the system. The turnover, which is really advancement, is thus startling. In the Food Standards Section, for example, only one man has had more than five years experience in that section, with three years being typical. The result is that these men, who are very able, competent administrators, rarely stay in one field long enough to carry out some of the needed imaginative changes. The present assistant secretary is a unique exception to the pattern. He is at present head of a division in which he has previously had experience. As might be expected, there is evidence that this is resulting in some fresh approaches to old problems.

The Scottish Home and Health Department is, comparatively speaking, in better shape. Their headquarters staff of seven is supplemented by five regional food and drug officers.

## Operation of the Program

It has already been noted that there are really 350 food and drug enforcement authorities in England, Scotland, and Wales. Inspection, sampling and enforcement are all local. There is no centralized authority responsible for maintaining supervision of a product from raw material through production to retailer. Enforcement is totally decentralized. Ministry of Agriculture, Fisheries and Food people describe the program as "consumer protection" rather than "industry supervision." Their argument is that it is industry's responsibility to maintain supervision of the hygienic standards and to assure compliance with the food standards. The same philosophy is applied by the Ministry of Health in its drug program. None of the programs is designed to supervise industry quality controls or manufacturing practices. Hygienic conditions in food, meat or milk plants might be checked, but the ultimate test, as far as

inspectors are concerned, is the final product. And it is the end product which the government has responsibility for checking, for this is what the consumer buys, consumes and may complain about. Thus a typical local food and drug authority will sample a fixed number of items each quarter, ranging from milk, meat pies, candy and drugs, to spirits. These samples are then turned over to "public analysts" who will be instructed to check chemically or bacteriologically. A public analyst is an officially designated person. Although he is appointed by local food and drug authorities, his qualifications are determined by Parliament. In practice the public analyst may be a private laboratory operation on a fee basis or, in the case of cities, a public program. The analysts are required by law to report quarterly to the central government in London or Edinburgh the results of their findings.

Local food and drug authorities differ in the mechanics of program operation, some dividing their problems geographically and some functionally. The risk in a district system is that food problems or store-plant hygiene may be pushed aside under the pressure of other tasks such as water, sewage, housing, air pollution. This danger is enhanced by the persistent staff shortages in the cities. As a partial remedy, some cities have combined geographic and functional systems. Thus Edinburgh has a well-known milk specialist whose concern is milk and food problems and who can provide expertise when the district men need help or spurs when there is evidence that the districts are slighting food problems.

Regardless of the mechanics, the programs have a two-fold objective: (1) constant checking on the state of hygiene of all food premises (from manufacturing to retailing) within the geographic area of the authority and (2) sampling from retailer stocks of *all* the food and drug products sold in the area, regardless of source.

The sampling technique, which is standard throughout England, Wales and Scotland, provides a useful, constant feel of the pulse of the food and drug artery flowing throughout the nation. It means that everywhere local authorities are sampling and public analysts are testing and checking the ingredients of foods, drugs and spirits for purity, label accuracy, etc. Milk, for example, is checked for butterfat content, antibiotics, cleanliness, water adulteration, bacteria count.

There is a major gap in the pattern in the English program. Due to staff shortages, the quarterly reports from public analysts are not normally summarized. Also there is no systematic collection of the annual reports of public analysts by the central government

in London. Thus there is no way anyone can know where problems are to be found. Local authorities, because of their history of independence and their legal autonomy, tend to contact each other only when it is necessary. Thus on a crisis or problem basis, communication will be good, but selective. On a routine basis, it will be negligible. The frequent meetings of the associations are useful communication devices, as are journals such as the *Public Health Inspector*. But there is no such thing as combined planning of inspections, nor even systematic information sharing, to assure total coverage of all types and brands of products. At the ministry level there is neither personnel nor authority to carry out program planning. Thus each authority determines what and how many items shall be sampled. One stresses milk, one drugs, another meat pies, and so on. In three counties, Berkshire, Staffordshire and Somerset, as many as three-fourths of the samples tested in 1965 were milk, with only one percent found to be unsatisfactory, the typical error being added water or fat deficiency. Local authorities argue that as a result of this random pattern, everything does get sampled. The great difficulty is that no one can prove whether or not this is actually true.

The lack of overall guidance in the English program is an important omission. There is awareness on the part of Ministry officials of the significance of this gap. The Ministry of Health, concerned as it is with the hygiene regulations, attempts to provide uniformity with persuasion and constant contact by the Food Hygiene Advisory Officer. Since the Food and Drugs Act has laid the duty of enforcing the Act and the regulations directly on local authorities, the Ministry of Agriculture, Fisheries and Food has limited scope for ensuring uniformity. It has, in the past, relied upon the associations (the County Councils Association, the Association of Municipal Corporations, the Urban District Association), or upon particularly knowledgeable local men. What has been lacking, however, is the assurance that there is a uniformity of enforcement, of interpretation of the wording of the regulations, of agreement on priorities. Ministry officials have even tried to persuade local officials to appeal some cases to higher courts, so as to have decisions made by courts of record. (Prosecutions made under the Food and Drug Law are handled by magistrate courts, which are not courts of record.) Neither local government nor industry is usually willing to appeal and the ministry is without authority to pursue the matter further.

In May of 1966 one step was taken as part of the search for a remedy. A meeting was held in London, the purpose of which was to begin discussions to identify troublesome questions. Aware of the real limits to their authority, the Ministry officials took particular pains to assure the local authority representatives that the purpose of the meeting was to assist the ministry in making sure the regulations were effectively written from an enforcement point of view. The meeting revealed that local enforcement men, as well as Ministry staff, were interested in a more structured method of sharing information. But, of course, local representatives were anxious not to call in question the responsibilities of their authorities. Ministry officials continually stress the intense concern felt by local governments in preserving their power over the remaining areas of responsibility: health and education in particular.

Scotland is in a somewhat better position. All the results from public analysts and sanitary inspectors are summarized and digested in the form of the Scottish Health Statistics. In addition, the regional food and milk officers of the Home and Health Department are in constant touch with officials in the local programs. As a consequence, the central officials in Edinburgh seem much more knowledgeable about people, programs and problems at the local level.

Perhaps the most notable factor at work influencing the regulatory program operation is industry. Increasingly a growing segment of the food and drug industry is demanding of itself higher standards of quality, purity and uniformity. The impact of a firm like Marks & Spencer upon hygienic standards of suppliers and competitors is indeed dramatic. In every local authority there exists a story of how Marks & Spencer forced upon a local firm an improved quality control standard. The impact of other giants can be noted: Lyons in baking, United Dairy in milk, Wall in ice cream, just to name three. As a result of this trend, local authorities spend less of their available inspectional time checking on such firms. They can still be certain that public analysts are testing the end products, at least on a random basis. And the internal controls of the large firms assure, on the whole, a more reliably standardized product without local authority inspection than the inspectors can assure among many smaller problem firms.

## Penalties

When the inspector discovers violations, hygienic or economic, he will use any one of a series of warning techniques, varying from oral

instructions to a formal note from the Chief Public Health Inspector. In England the decision to take a food/drug case to court is made, theoretically, by the elected council. In practice this power is delegated sometimes to the Health Committee, which is made up of a portion of the elected council members, or to the Medical Officer, or even to the Chief Public Health Inspector. No pattern seems to exist which enables one to predict where the authority will reside. Much seems to depend upon historic leadership patterns: a strong council, a strong Medical Officer, etc.

In Scotland, on the other hand, if the local authorities decide that a given violation requires prosecution, the case materials are turned over to the central government authorities, the Procurator Fiscal, who makes the final decision as to whether or not to take the case to court.

Persuasion, however, is the keynote of both English and Scottish programs. There are exceptions, of course, but they seem based on good political reasons, rather than the belief that prosecution improves food and drug standards. A total review of the local authorities might reveal a contrary pattern, but my sampling seems to show that the tendency to prosecute will more likely occur in urban districts dominated by the Socialist/Labor Party. Conversely, there is less interest in prosecution in rural districts or where the Conservative Party dominates.

By far the majority of local authorities are most reluctant to use prosecution as an enforcement weapon. Many express opposition to court action, viewing it as evidence of failure on the part of the educational program. While all agree that the incorrigible offender must be punished, there is at least one major city with an inexhaustible amount of patience. Officials of this city are reluctant to be specific, but indicate that there have been but two prosecutions in the past 30 years. More typically, prosecutions for poor hygienic conditions will average two to four a year, with fines amounting to £5-15. All authorities report a larger number of prosecutions each year for consumer complaints. However, the fine is consistently small, and this hardly acts as a deterrent for the chronic offender. Hence the dilemma of the authorities. For most violators, education and persuasion, plus patience, will suffice. Sooner or later, every enforcement program uncovers the uneducable violator, who seems to require fines so severe as to threaten bankruptcy.

It is for just this reason that local officials argue in favor of registration authority. The matter of registration, especially for restaurants, has been the source of disagreement between central and local authorities for some time. The milk and ice cream regulations do permit registration; however, no regulations have ever been promulgated to put this section into operation. Local enforcement people almost unanimously express the desire to possess registration as an additional weapon. Central authorities in London and Edinburgh argue that if local authorities will not prosecute, what assurance is there that they would deny registration? In addition, registration, which involves no fee, would be a costly financial burden on either local or national government. Local men answer with the argument that at present anyone can start a restaurant without getting approval from any health authority. What is more, restaurants are often opened in totally unsuitable quarters by people with totally inadequate financial resources and perhaps not even the most elementary knowledge of hygiene. Prosecution requires an offense, whereas the inspector would like to use prevention. Registration would enable the inspector to withhold permission until hygienic requirements are met. In addition, local officials argue, the Offices, Shops and Railway Premises Act of 1963 required registration of all premises *except* food manufacturing, retailing and serving, and thus the additional burden of registration of these latter places would surely be slight.

## Summary

There seems little doubt that the English and Scottish food and drug programs are good ones. At the ministry level, the staffs seem to be knowledgeable and very competent. The British practice of promotion within the civil service generally very likely improves morale, but works a hardship on innovation. In addition, the staff is much too small to carry out some of the essential review of the efforts of local programs. The remarkable lack of information possessed by the Ministry officials in Agriculture, Fisheries and Food about the efforts of local authority programs is regrettable, and seems to be attributable almost entirely to staff shortages.

The local authority inspectional staff is well trained and dedicated to the goals of public health. There do not seem to be complaints by agency chiefs that not enough staff has been authorized. Staff turnover and vacancies are an ubiquitous problem and will become even more acute. Pay differentials and fringe benefits cause qualified staff to leave Scotland for England and cities for rural areas. Industry is increasingly a new competitive factor, as trained men are

hired for the developing industrial quality control programs. The chronic nature of the problem has forced a search for solutions, one of which is the substitution of less well trained staff for the qualified inspectors on more routine tasks. In spite of the protests, the use of such techniques will probably be expanded, simply due to necessity.

It is impossible to ignore the revolution taking place in the sanitation and inspectional fields. Not only is industry more and more assuming the traditional public health department inspectional role, it is also establishing quality controls and hygiene standards which equal those found in governmental regulations. A curious role reversal can be observed. No longer must the inspector spend much of his time attempting to educate industry as to the nature of its responsibility. On the contrary, large food manufacturers and distributors are themselves hiring trained inspectors. The public health inspector is increasingly discovering that he has little to teach a growing segment of large industry. For the remainder of the trade, he is a substitute for internal controls not yet established.

Here is the greatest single weakness in the entire inspectional program. In a world of breathtaking technological change, of revolutions in packaging and manufacturing processes, the inspector, and the program he serves, is still geared to another world. Justifiably, much has been made of the dramatic decline in deaths attributable to food borne disease. Yet the record in food poisoning incidence is less comforting. From a high of 20,000 cases in 1955, there was a 50% decline by 1962. But the number of cases climbed again to 13,000 cases in 1963.[6] Rarely fatal, food poisoning fails to generate great public anxiety. But, occurring as it does with increasing frequency in mass feeding establishments, the poisonings are a cause for genuine concern.

What is needed is leadership at the ministry level to identify the issues for the 1970's, to initiate far more research on food poisoning, or to stimulate committee study of such new problems as shelf life of today's packaging, bacteria level of frozen food at retail level, or to suggest local authority sampling priorities. These, of course, are just a sampling of the questions. The basic problem is apparent: as mass feeding becomes an increasingly common phenomenon in the United Kingdom, as it already has in the United States, and as pre-cooked and partially-cooked products attain wider consumer acceptance, the inspectional programs must take cognizance of these changes. **[The End]**

[6] See footnote 1; p. 38.

# FDA—Management Cooperation

By WINTON B. RANKIN

The Following Article Was Delivered as a Speech at the Proprietary Association's Third Manufacturing Controls Seminar on October 25, 1967, at Saddle Brook, N. J. Mr. Rankin Is Deputy Commissioner of the Food and Drug Administration.

THE RESPONSIBILITY FOR MAINTAINING quality in drugs too often has been left solely to the quality control profession —a profession that frequently operates in quiet isolation. Occasionally, this isolation explodes; and then there is trouble. And the trouble is likely to stem from a firm's failure to safeguard against product contamination, defective packaging, deviations from potency requirements, or labeling errors. Obviously, such problems could and should be avoided. That is why we are here today.

Food and Drug Administration (FDA) and management cooperation is but a part of the whole picture. We must recognize the requirement for increased cooperation within the firm's own organization to keep pace with increasing production demands and product complexity. The independent operation of research, development, production, advertising, and other departments can be an exercise in futility. It can cause a breakdown in communication within the firm and with the FDA, as well as a breakdown of the public trust in the integrity of the nation's drug supply.

This is why the subject of FDA-management cooperation must extend beyond the Quality Control Department and above the middle management level. Departmental isolation must be penetrated. The concern with quality control must extend to the top of the corporate organization, where the return-on-investment decisions are made. And this concern must be reflected in consistent support for quality control personnel and an open receptiveness to their recommendations.

The significance of our meeting today—beyond the objective of finding ways to improve drug quality—is that it marks another step

in the cooperative effort by industry and the FDA to find better ways of "building in" drug quality.

Since the publication of the Good Manufacturing Practices Regulations in June 1963, the FDA has sought through various channels to encourage industrial compliance measures, and thus to assure the consumer that the drugs he buys are safe and effective. One such channel is the voluntary compliance program; another is the greater utilization of self-inspection. These programs, of course, require that industry and FDA frankly discuss problems of quality control.

As an indication of our interest, I might point out that during the last fiscal year, our District Offices sponsored 22 regional seminars and workshops to promote Good Manufacturing Practices. In 1965 there were only two such meetings. An indication of your interest was the attendance by representatives of 912 firms at last year's meetings.

Most of those who have participated in these workshops have been from middle management. This year, however, we set up a workshop for first-line supervisors of several firms in Memphis, Tennessee. This provided a more direct line of communication with hourly employees of the participating firms.

Another aid in educating employees in the importance of Good Manufacturing Practices is our color slide show. It is flexible, easy to use, and inexpensive. By adding slides of your own, you may readily adapt the series to meet the particular conditions in your own plant.

Our Bureau of Education and Voluntary Compliance, in addition to coordinating the workshop programs, is expanding its operations in other ways. It is developing programs on analytical testing, and soon will provide a continuing analysis of the basic reasons for drug recalls.

We would like to see the day when voluntary programs can be substituted completely for regulatory activities. This is not possible now and probably will not be within the next several years. But there is every reason to believe that wholehearted participation by industry in voluntary compliance programs will bring about a very significant improvement in drug quality. This we all seek.

In the meantime, FDA inspections continue. Deficiencies in processing or packaging found by our inspectors, or by the firms involved, continue to result in recalls. During the fiscal year 1967,

there were 651 drug recalls, compared with 446 the previous year. Excluding veterinary drugs and medicated feeds, 10 percent of these involved non-Rx drugs, 54 percent Rx drugs, 15 percent antibiotics, 7 percent vitamins, and 13 percent bulk, new or investigational drugs. The 10 percent on non-Rx recalls is still 10 percent too much. Approximately three-fourths of the recalls resulted from failure to apply Good Manufacturing Practices.

To provide a better measure of the quality of the Nation's drug supply, we established the National Center for Drug Analysis in St. Louis last July. When it is in full operation, we expect that the Center will be able to analyze 300,000 drug samples a year from the retail level. This surveillance program, new though it is, resulted in a major recall of an anticoagulant earlier this month. But is this the ideal way to deal with product deficiencies? Obviously not. We must devote greater attention to correcting weaknesses at the source.

There will be many suggestions as to worthwhile ways to increase the ability to meet Good Manufacturing Practices. There are several thoughts I would like to present by way of introduction.

We still encounter some manufacturers who deprive themselves of the advantages of having a complete inspection of their operations. These firms want our inspectors to advise them of deficiencies in their operations, yet, at the same time, they may try to limit the inspectors' opportunity to evaluate their total operation.

There are firms that refuse to permit review of batch production and master-formula records. Others may not permit us to trace the complete history of any specific batch of a drug, including information from complaint files and in distribution records.

Other firms do not take full advantage of their own data. For example, a batch sheet should contain both theoretical yield and actual yield. We find batch sheets where such data are not recorded and others where there is no attempt to determine the cause of significant differences between actual and theoretical yields.

Often a manufacturer relies on the ability of other firms, such as a repacker, to competently perform part of the job necessary to market a drug. Our experience shows that competence should not be taken for granted. We have even found a firm which was committed to manufacture an injectable for another company, that did not have the equipment necessary to do the job.

Subcontracting does not relieve you of the legal responsibility for the quality of your product. In fact, the firm whose name appears



on the label bears an additional burden. It must assure that the subcontractor's plant, as well as its own, is operating under Good Manufacturing Practice.

Looking beyond your own industry for a moment, there is another program which should be of interest to you. The FDA and the General Foods Corporation recently agreed to a pilot plan for industrial self-certification covering certain products made at the General Foods plant in Dover, Delaware. Briefly, the plan calls for sharing all records pertinent to the quality of the products, including the firm's manufacturing evaluation and performance records, as well as formulas. It is a plan that may well be applied to the drug industry, and one that we would like to see advanced.

The development of a program is time-consuming, and I must caution you that we are not prepared today—and will not be prepared for many months—to begin working with the drug industry on self-certification. If the General Foods test turns out well, as we expect, then the idea of self-certification will be extended to a number of other food firms before we try it in the drug area.

I am aware that a number of manufacturers have already informed General Delmore of their interest in self-certification for drugs. The timing I have just estimated should not discourage you; you can start right now to develop self-inspection programs which should be of material value in insuring Good Manufacturing Practice. Self-inspection is a simple procedure in which a firm's own specially trained quality control people inspect all operations listed under the Good Manufacturing Practice regulations. We will help you set up such a program, if you desire.

The airing of mutual problems that confront industry and the FDA at meetings such as this has accomplished, and will continue to accomplish, a great deal. We welcome your cooperation and offer our continued support to help you carry out the tremendous responsibility of supplying our Nation and the world with drugs of unquestioned quality.

I do not need to remind you that today's consumer is more sophisticated than ever before. He is alert to considerations of product quality, packaging, and advertising. And he will continue to insist that the government provide the protection beyond his own means. The consumer is entitled to confidence in the products and services he purchases. We must work together to assure the confidence is not betrayed. **[The End]**

# Government and Consumer Protection — Drugs

By IRVING H. JUROW

The Following Article Was Delivered on May 9, 1967 as a Speech at the Conference on Business-Government Relations Sponsored by the National Association of Business Economists. Mr. Jurow Is Vice President and General Counsel of the Schering Corporation.

THE PROLIFERATION OF CONSUMER PROTECTION AGENCIES at every level of government does not promise to abate. The 89th Congress considered a proposal to establish a Cabinet-level department of consumers. Although the bill failed to get out of the House subcommittee, and despite the strong opposition voiced by both the Department of Justice and the Federal Trade Commission, the idea still germinates. Who knows, perhaps in 1984 —Orwell's 1984—or perhaps sooner, the idea may bear fruit.

Meanwhile, the 90th Congress has established a permanent subcommittee on consumer affairs, a new subcommittee of the Senate Commerce Committee. Even fashion has gotten into the act; the President's personal advisor on consumer affairs, Mrs. Esther Peterson, has been succeeded by Betty Furness.

## More Consumer Protection

Why this unmistakably accelerated trend toward more and more "consumer protection" by government? Why this apparent disenchantment with the business community, this amorous alliance with bureaucracy? And, more to the point, what does this mean for our American economic system?

Regulation by government and consumer protection are neither new, nor modern, topics. In every organized society in recorded history one finds some attempt by the governing body to regulate economic activity for the protection of the consumer. It is only a bigger and more complex problem today. That the problem is bigger

and more complex is not an indication of greater business dishonesty; it is a reflection of a larger, more complex, and more sophisticated society.

In considering the subject of drugs in the context of the government's role in consumer protection, I propose to focus on the Food and Drug Administration (FDA), a component of the Department of Health, Education and Welfare. Although that Administration has, in enforcing the Federal Food, Drug and Cosmetic Act, regulatory powers over the food industry and the cosmetic industry, in addition to the drug industry, I must of necessity narrow that vast field. I propose, therefore, to consider but one segment of the pharmaceutical industry, that sector which produces and markets medications for the consuming public.

Broadly speaking, these medications fall into two categories, prescription drugs, that is, drug products which, under Federal law, may be dispensed only by, or on the prescription or order of, a physician, and secondly, proprietary drugs (sometimes referred to as "over-the-counter" drugs), that is, drug products which may, under our law, be dispensed to, and purchased directly by, the consumer without any professional order.

Since recent government inquiries, legislative proposals, and media attacks with "scare" headlines, not to mention some half dozen full-length books, have concentrated upon the "ethical," or prescription, pharmaceutical industry, I have chosen that as the relevant market for this discussion.

The history of the past fifty years is one of increasingly greater government participation in the production and marketing of prescription drugs through extended and detailed regulatory activity.

## First Legislation

The first Federal legislation concerned with the drug industry, the act of 1890, prohibited merely the *importation* of adulterated or unwholesome foods and drugs, the theory being that regulation of the drug industry on the domestic scene should be left to the states. A little more than a decade later, the Federal Government extended its regulation of the industry by the Food and Drugs Act of 1906, which prohibited the introduction into interstate commerce of adulterated or misbranded foods and drugs. Enforcement under that Act was accomplished by seizure and confiscation of the products found to be in violation of the law. The mission of these earlier laws was to assure the wholesomeness of our food and drug products.

The real thrust of government regulation came, however, as a part of the New Deal legislation of the 1930's. It was then that the basic framework of our present law was enacted. Because it is a fascinating example of history repeating itself, and because of the interesting parallel between the events of 1938 and those of 1962, I shall briefly comment on that event which stimulated the passage in 1938 of the modern Federal Food, Drug and Cosmetic Act.

The New Deal food and drug legislation had been slumbering in the Congressional committees for several years when the country was shocked and aroused by the so-called elixir-sulfanilamide incident. The death of over one hundred people, before that newly marketed "miracle drug" could be recalled and discontinued, stirred the Congress into speedily adding to the proposed legislation a novel provision requiring government review before a "new drug" could be commercially marketed.

Prior to the enactment of the 1938 Act, no provision existed for testing and examining drugs before they were marketed. Indeed, that Act was the first law requiring a drug to be adequately tested before it could be introduced into regular trade channels. The apparent lack of demand for such regulation, and of purpose to require such procedure, was evident from the fact that at no time during the five-year period of legislative gestation through which the 1938 leigslation passed did anyone suggest such a requirement. It was only when the elixir-sulfanilamide incident presented Congress with tragedy that broad and sweeping proposals for the control of drugs, designed to prevent the recurrence of such a calamity, were speedily advanced. With little analysis, without Congressional committee hearings, and certainly with less thought as to its implications, the proposal was enacted into law.

In addition to subjecting cosmetics to regulation and greatly strengthening the power of the government over the labeling and the requirements for the identification and purity of all food, drug, and cosmetic products, the law, more importantly, adopted the concept of a "new drug." This proved to be the most significant innovation in the regulation of drug products.

The phrase "new drug" is one of legislative art. In 1938 it meant any drug product which was not generally recognized by qualified experts to be safe for use under the conditions set forth in the label of the product. Such a "new drug" would now require an "effective" new drug application before it could be marketed. For the first time a government agency had the power to prejudge a drug product and to block its introduction into the marketplace. This meant that the

manufacturer had to produce and submit to the government agency adequate data to satisfy the agency that the drug product could be safely used under the conditions of use spelled out in its labeling. Obviously, the purpose was to assure the consumer adequate protection against unsafe drug products by authorizing and empowering the government to prevent their marketing.

The next twenty-five years saw the 1938 Act amended to add a further, somewhat technical, regulation in the interests of consumer protection. The insulin amendment of 1941, which requires the government to certify every batch of insulin before it is marketed, and the several antibiotic amendments, which require every covered antibiotic and antibiotic-containing product to be similarly certified by the government before introduction into the marketplace, were essentially predicated on the fact that then existing technology could not assure consistency in the product.

Nevertheless, it was during this twenty-five-year period, when government restrictions and limitations were minimal and research, production, and marketing of drug products was somewhat narrowly regulated, that the greatest advances in drug therapy occurred. Even a casual review of the record of those years establishes this beyond peradventure of doubt. These were the years of the many miracle drugs, the sulfas, penicillin, the antihistamines, the antibiotics and the hormones, and these advances in drug therapy kept pace with important advances in medicine and in surgery.

During this score of years government regulation was, in the main, a policing activity; consumer protection in the pharmaceutical field consisted essentially of government action more frequently *after* the fact than *before* the fact. Except in limited fashion under the new drug procedure, pharmaceutical manufacturers were usually brought to book after the drug product was found to be violative and after it had actually been marketed.

## Second Milestone

The second milestone in government regulation of the drug industry came with the passage of the Drug Amendments of 1962. These resulted from the long and intensive investigation of the drug industry by the late Senator Kefauver. Once again, as in 1938, the many legislative proposals embodied in the Kefauver bill were proceeding at a snail's pace in the Congress when another tragedy occurred which impelled the Congress into action. You all remember the thalidomide story. A

product which had been extensively sold in European markets for a number of years, and which was under clinical investigation in this country, was discovered to cause serious birth defects. Despite assurances that our laws were adequate to avoid similar tragedy, the public was sufficiently alarmed to demand Congressional action. What the Congress might not have done under considered and calm reflection, it was stirred to do under intense media pressure. And, consistent with our American tradition of not doing things by half measures, the regulatory power vested in the government over the affairs of the pharmaceutical industry was enormously increased.

The regulatory authority was so broadly expanded, that to this very day the implications and reach of that authority remain unclear and uncharted. Indeed, disputes between the government and the industry remain to this day unresolved and several major lawsuits are now pending seeking interpretation of the new amendments.

As the law now stands, the regulatory agency has vast and exceedingly tight controls over the investigation, the manufacture, the distribution, the labeling, the packaging, the advertising, the use, and the method of sale of all pharmaceutical products. So, too, is its power and authority over the manufacturers of drug products.

As to "new drugs," government control is, for all intents and purposes, complete. The government must be informed immediately when anyone intends to investigate the potential use of a new drug in human therapy. The government must be furnished a complete and detailed plan for investigating and testing the drug and a complete list of everyone concerned with that investigation. The care and the use of experimental animals in the investigatory phase is controlled by legislation and by government supervision. Moreover, any "new drug" must now not only be completely established as safe, but must also satisfy rigid requirements of proof of its effectiveness for its recommended uses. Detailed reports must be furnished periodically, sometimes immediately, to the government during the period of its investigation and after it has been marketed. Specific government approval is necessary before it may be made available for public use. The manufacturer is subject to registration and to mandatory periodic inspection, and his records and facilities are open to complete and thorough review by government officials without prior notice and at any reasonable time. Virtually no change in the manufacturing methods, the composition of the drug product, the label or labeling of the drug, or even the location of the manufacturing facility, may be made without submitting the information to the regulatory agency and receiving its approval. All

labeling, all promotional material and all advertising are subject to the minutest scrutiny on the part of government officials.

## Further Regulatory Requirements?

One could hardly imagine that there remains any room for further regulatory requirements. Even so, there is at present an alarming amount of proposals for additional controls. There are those who wish, for example, to destroy patents and trademarks in the pharmaceutical industry; there are those who propose that every single batch of a drug product be checked, approved, and certified by the government before it may be released to the market; there are those who propose that the government dictate every word on every label of every drug, old or new, such as the size of the type, the placement of the text, the very phrases to be used; and, there are, of course, those who even postulate that there should be price controls.

Because of the very nature and importance of drugs, these proposals are probably more extreme than what is faced, at least for the present, by other industries. Nevertheless, many of our problems in the drug industry find their counterparts in others. The current dialogue on automobile safety standards and the complications arising out of the recently enacted Fair Packaging and Labeling Act provide somewhat analogous problems. The bitter attack on advertising in many government quarters has presented that industry, and indeed all business, with new battle fronts.

This is about where we are today. How did we get here? Where are we going?

Consumer protection is a marginal concept. In the main, laws governing the protection of the consumer historically have been, and still are, directed to the fringe operator found in every era and in almost any industry. This is not unique. The reputable business, large or small, plans to be a growing enterprise. It hopes to be operating not only this and next year; it fondly hopes to be bigger, selling more, and making greater profits. It can only do so if it has created a body of satisfied consumers who return again and again to buy its products. To that extent the consumer, through his purchasing power in the marketplace, protects himself. By repurchasing the meritorious product, by ignoring the poor one, the consumer rewards the one and punishes the other. No business, certainly not the pharmaceutical business, can long survive with shoddy merchandise. No amount of legislation or government regulation will eliminate fringe activity or produce perfection. "... But a man's reach should exceed his grasp, or what's

a heaven for?" Even in the highly crucial field of aerospace research, attainment of "zero defects" can no longer be assured.

## Wisdom of Government Regulation

Our experience during the past five years, since the passage of the 1962 Amendments, justifies our reflecting upon the wisdom of the breadth of government regulation over the pharmaceutical industry brought on by those amendments. The scientific community, the medical profession, the pharmaceutical industry all entertain serious doubts as to whether we have not embarked upon a period of overregulation and overachievement. The complexity of the rules under which research must now be done in the field of new drugs, the minutiae of requirements in the care of experimental animals, in the employment of volunteers and patients in clinical human testing, in the types of technological procedures that are required, many of which have not yet even been fully perfected, and the heavy involvement of time and of money in bringing to market new drugs have all produced during this period a substantial increase in the reluctance of investigators to test and experiment with new medicaments and a substantial lag in the development and marketing of new drug products. The age of the many miracle drugs seems to be giving way to a period when similar advances cannot be hopefully anticipated. Even government expresses its concern. Recently a science adviser to the President observed that the drug industry was operating under government regulations that could hardly be regarded as providing adequate incentives for innovation in the field of medicine. And he apparently deplored the fact that these regulations had been so sharply reinforced as to dissuade many researchers from undertaking such studies.

In our democratic and free enterprise society, we still, I believe, wish to live by the principle that we maximize free choice and minimize government coercion. This is not to say that there is no necessity for government regulation to protect the consumer. The basic issue is not between *caveat emptor* and total government control; both are unreal extremes. Realistically, one must say that the fundamental issue is between more or less governmental control. To "prevent the government from wasting the labor of the people under the pretense of caring for them," as Thomas Jefferson admonished, remains today, as we press on to achieve a society of abundance, a valid precept. In this age, when the compelling slogan seems to be "protect the consumer," we tend to forget that our business economy and our industries have not, in the main, been unmindful of this essential. We seek to solve all our problems by hurried legislation, by more and more

expensive and extensive regulation, which frequently is an unjustified burden on industry to the detriment of the public.

We sometimes forget that our free enterprise system has produced for us the standard of living which is the envy of the world. Do we wish to exchange it, discard it, for the illusory security of a corporate state? Despite the fact that we have achieved a society of complexity and sophistication, is it not evident that ever-increasing government involvement is incompatible with the fundamental objectives of a free democratic society?

Government regulation exacts a heavy price in terms of money and in terms of liberty. It imposes heavy costs on industry to comply, and it costs the government tax money to administer. Where regulation is necessary and efficiently administered, it is money well spent; where it is not, it is "wasting the labor of the people under the pretense of caring for them."

Let me refer, briefly, to two examples in the pharmaceutical industry which I believe are indeed a waste of the people's money. There is now pending for decision before the Supreme Court of the United States a test case under the 1962 Amendments to determine whether it is necessary under that law to state, each time a trademark for a prescription drug is mentioned, its so-called "generic," or common, name.[1] This would mean that in any statement of directions to the physician as to how to use the drug, or in any advertisement or promotional literature where the trademark for the drug is employed, the generic, or common, name of the product must also be employed with each mention of the trademark. In other words, if the product is identified by its trademark name twenty times on the same page, its generic name, in precise juxtaposition, would also be repeated twenty times. Since these statements of directions and these advertisements are directed to the medical profession, a profession of intelligence, skill, and sophistication, it seems to me not only unnecessary and redundant, but downright silly, to remind the doctor of the common name each time you name its trademark.

Another example arises out of the law's requirement that medical journal advertising for prescription drugs contain a brief summary

[1] Following the decision by the Supreme Court in favor of the industry (*Abbott v. Gardner*, CCH Food Drug Cosmetic Law Reports ¶ 40,258, 387 U. S. 136), holding that the litigation was ripe for decision on the merits, and remanding the case to the lower court for that purpose, the FDA stipulated with the industry to withdraw its original proposal and to promulgate a new one (CCH Food Drug Cosmetic Law Reports ¶ 40,280, 32 *Fed. Reg.* 14898, October 27, 1967), abandoning its contention that the "generic" name has to be stated "each time" a trademark is employed.

describing the precautions, the side effects, and the efficacy of the product for the uses mentioned in the advertisement. Under the government's current interpretation of this provision of the law, one can hardly distinguish between an advertisement and the full and complete information that is available to the physician in the official, government-approved statement of directions, a document that must be inserted with every package of the drug. This misconception on the part of the government of the role of advertising in our economy is basic to the dispute. And until the government adopts a more realistic view, one consonant with the common understanding of the function of advertising, we will continue to have misunderstanding and irritating argument. For it strains my belief that any reputable physician would prescribe potent drugs for his patient, relying only on an advertisement without fully understanding and carefully reading the official statement of directions.

## Conclusion

The apparent disenchantment with the business community to which I have alluded has come about, in my opinion, because *all* industry, and in recent times particularly the pharmaceutical industry, has been subjected to blunderbuss attack based upon isolated examples of dishonesty, or fraud, or ineptness, which, for a variety of reasons, some well-meaning, others ulterior, have been expanded into baseless, but attractive, generalities. The public's amorous alliance with bureaucracy stems, I suggest, from the understandable human desire to get more for less, to achieve a society of abundance without the diligence and effort that is essential. What effect this disenchantment and this alliance will have on the future integrity of our way of life will depend upon what you do in providing the public with the essential facts, in alerting the public to the implications of these expanded governmental authorities, in eliminating the "economic illiteracy" that threatens our economic well-being.

It is the responsibility, the obligation, of business leaders and of business economists, hardy exponents of our American economic system, to speak out so that the people may know where they are going and what is ahead of them on that road. The academicians—the theorists—and the bureaucrats continue to mount their attacks. The business community must stand up to these and make reply. In historical perspective it is but a stone's throw to 1984, and we have precious little time. If today's theme is government's protection of the consumer, tomorrow's should be protection of the consumer from the government. **[The End]**

# Pharmacy and the Future

By JAMES L. GODDARD, M.D.

The Following Address Was Presented at the Convocation of the College of Pharmacy, University of Michigan, at Ann Arbor, Michigan, on October 18, 1967. Dr. Goddard Is the Commissioner of the Food and Drug Administration in the Department of Health, Education and Welfare.

THOSE OF US IN THE HEALTH PROFESSIONS are acutely aware of the changes wrought since the founding of the University in 1817. One hundred and fifty years ago, life expectancy was short. Smallpox, diphtheria, typhoid and other diseases were anticipated in dread by every family.

In the years since then, particularly in our own lifetime, we have seen remarkable progress in science and medicine, in disease prevention and in successful therapy when disease does strike. This process of change is apparent, moreover, not only in professional abilities, but in public attitudes. We now see a broader awareness of health needs and a deep-running demand for quality health care for all Americans, wherever they may live or whatever their financial circumstances may be.

This attitude, this demand, underlies the many-faceted, far-reaching health programs which the Congress has enacted in recent years. Medicare and Medicaid; training assistance for health professionals; new programs to combat cancer, heart disease and stroke; funding for community mental health centers; the expansion of immunization programs—all of these enactments and others respond to the contemporary public view that our health problems must be solved through a common public effort—which is what a Government program really is.

The field of pharmacy has not been unaffected in these years of change. Far from it! The nature of the profession has been, and is being, altered by many forces—scientific, economic, demographic and political. I do not intend to offer you an analysis of why and how

these alterations have come about. But I would like to share with you my views of how the patterns of professional practice we can now discern, may shape the pharmacy of the future.

First, however, let me confess that my views may be conditioned, perhaps prejudiced would be a better word, by my own profession and by the job I hold. As a physician, I see the pharmacist as a professional resource person whose full potential is not being realized at the present time. And as Commissioner of Food and Drugs, I see the American pharmacist as a necessary and valuable ally in protecting and improving our national drug inventory.

I realize, of course, that what I say here today, or what I do in my office tomorrow, will not determine the future of pharmacy. Only you and your colleagues across the country can do that. But I strongly believe that the manner in which you respond to change will affect not only your own profession, but the total health community—and thereby the Nation as a whole.

## Challenge to the Pharmacist

What is the nature of the challenge that faces the pharmacist? Most fundamental, perhaps, is the task of defining his role as a professional in contemporary terms, including his relationship to other health professionals. Part of that task, I maintain, is the shedding of outmoded concepts of the pharmacist's contribution to health care.

For example, we must concede that the neighborhood drugstore isn't quite the same anymore. And that's because the "neighborhood" isn't the same anymore. We can no longer describe the pharmacist's professional contribution in the context that he knows all his customers, their varied ailments, and their doctors. There are advantages to this kind of intimacy. If the pharmacist knows that Mrs. Smith is careless about reading label directions, he can take extra pains in telling her how to use her medication. If he knows what prescription drug Mr. Jones is taking, he can offer some reasonable choice on over-the-counter (OTC) products that have caught Mr. Jones' attention. This setting still exists in some towns, in some neighborhoods. But I believe it is foreign to most pharmacists practicing today.

Our population has shifted, first into the cities, and then, in large measure, out again, into the suburbs. And we are a mobile people now, no matter where we may live. Instead of having the family doctor drop by the house, make a diagnosis, and write a prescription to be filled at the corner drugstore, we are more apt to visit a specialist

downtown and have the prescription he writes filled at any one of a dozen pharmacies that may be convenient.

In the suburbs, the cozy corner drugstore is a rarity. Instead, we more commonly have a pharmaceutical supermarket, located in a shopping center and staffed by shifts of pharmacists whose only contact with the customer may be a passing glance as he hands a prescription to the sales clerk, who rings up the sale and dispenses the premium stamps. Sales of the most common OTC drugs are handled at a check-out counter along with candy, shaving gear, flashbulbs, and magazines.

I do not mean to imply that we should try to unscramble this new environment and return to the little neighborhood drugstore as fast as we can. It would clearly be impossible, even if it were desirable. And I'm not sure at all about its desirability. But I do think it is important that the professional practice of pharmacy is not obscured by the practices of merchandising. Certainly, the prescription counter is still the economic focal point of the drugstore. One survey, for last year, reported that drugstore sales for the first time had passed the 10-billion-dollar mark—and prescription drugs accounted for 32 percent of that impressive figure. Other drugs and health aids made up another 18 percent of over-all sales. So the drugstore is still living up to its name, even though it may not seem that way to the casual shopper.

There has been another significant change in the practice of pharmacy which we also must bring into our reckoning today. And this is the obvious fact that the pharmacist, by and large, has traded off his mortar and pestle for the convenience of "packaged" preparations. Some pharmacists may compound as little as five percent of the prescriptions they fill. And the public is well aware that the pharmacist behind the counter is more likely to be counting out pills or capsules than blending exotic chemicals to match an exacting formula prescribed by the physician.

Does all of this mean that the pharmacist will eventually fade away, replaced by an automated dispensing machine busily filling punched card prescriptions? I hope not. There is a greater need for the drug specialist today than ever before. And I strongly believe that the modern practice of medicine demands greater utilization of the knowledge and skills which only the pharmacist can offer.

We all know how difficult it is for the practicing physician to keep up with the wide range of drugs available today. The supply is vast,

running to some 7,000 now and growing constantly. In his office practice, the physician tends to use only a fraction of the drugs available. But in the hospital, medical requirements that are more varied and complex demand a highly selective, sophisticated use of drugs. This demand can best be met by greater utilization of the pharmacist. There is a compelling logic for bringing the pharmacist out of the drug dispensary, so that he may serve beside the physician as a Therapeutic Advisor. Why should he not be a regular member of the team making hospital rounds? This would give the physician a broader range of therapeutic choice, for he would have a drug specialist at his side. The pharmacist, in turn, would gain a broader understanding of the uses of the different drugs and their effects.

The role of Therapeutic Advisor has a potential beyond the hospital. The practice of medicine is changing, not only in method but in organization and structure as well. We can expect to see new forms of group practice and new variations of community and regional medical facilities to meet the ever-widening demand for comprehensive health care for all our citizens. The pharmacist must have a responsible role within these new structures, too, if we are to make the most of the array of drugs at our disposal now and in the future.

I believe there is a growing awareness of the need for a closer partnership between physician and pharmacist. At the National Conference on Medical Costs in Washington this past summer, the discussion covered the full range of how we are organized to deliver medical service to the public today. One of the points made was that, for the sake of efficiency as well as economy, the physician should know more about the pharmacist's knowledge, and vice versa. And it was suggested that a good starting point would be at our universities, where a stronger relationship ought to be established between the Colleges of Pharmacy and Medicine.

The rationale for this closer working partnership becomes more insistent with every new breakthrough achieved in our pharmaceutical laboratories. The remarkable era of drug development that began after World War II has not ended. The years ahead promise to be as fascinating as those just gone by in the biomedical field. Anti-cancer agents; anti-arthritics; drugs that alter the genetic code; drugs for the menopause; new psychopharmacologicals; synthetic hormones; radiopharmaceuticals; immunochemistry; drugs for aging: all of these and more are on the horizon. And the specialist who knows these drugs, their capabilities and their shortcomings, will be even more essential tomorrow than he is today.

The contemporary pharmacist, whether he is practicing in a hospital, behind the prescription counter of a giant chain store, or in a not-yet-extinct corner pharmacy, also faces other challenges and responsibilities which flow from our now firmly established national commitment to quality health care for all.

## Government Involvement

We have witnessed a growing state and federal involvement in the provision of this care, and this involvement seems certain to expand in the months and years ahead. As you know, President Johnson this year asked Congress to include prescription drugs under Part B of Medicare. At the same time, he directed Secretary Gardner to initiate a study of the impact and implications of prescription drugs under Medicare.

The Task Force on Prescription Drugs was established by the Secretary to carry out this assignment, and, as a member of that Task Force, I can assure you that the assignment is not an easy one. While the Task Force is carrying on its deliberations, Congress is pursuing its own studies of drug prices, generic equivalency, drug distribution patterns and related questions.

What we are witnessing is the development of a new national policy. From a distance, it may appear to be a disjointed and cumbersome effort; but all the relevant facts and opinions are being assembled and assimilated, and a number of decisions will emerge.

These decisions may not, and probably will not, please everyone. On the other hand, they will not be immune to criticism and change either. I believe that the development of our Nation's health policy follows the traditional guidelines of the democratic process.

I am willing to discuss the future, but I will not be so rash as to predict the eventual outcome of the "generic versus brand-name" debate that is so much in the news these days. The question of therapeutic equivalency of drug preparations from different manufacturers is one of the more difficult issues before the Task Force. Ideally, the Food and Drug Administration (FDA), through its enforcement program, should be able to guarantee that all drugs from all manufacturers and repackers meet exacting quality standards. I'm frank to admit that we cannot make that kind of unqualified, blanket guarantee at this point in time, but I promise you that we are moving toward that goal as fast as we can.

There is still the question, however, of whether two drug preparations, with the same active ingredients and both meeting U. S. P. or other specifications, have the same therapeutical effect when administered to the patient. I believe that the great majority of drugs do, but we need clinical studies to be sure. The pharmaceutical industry has not produced this kind of data, nor has it been required to do so by law. The FDA is sponsoring such studies and the Public Health Service is also contributing extensively to this effort.

Regardless of the conclusions to come, we are certain to see changes in the drug price structure and in prescribing patterns. Without any change whatsoever in law, if more physicians write generic prescriptions, and I believe this is happening now, the pharmacist will carry a larger responsibility in drug selection. Does he choose the least expensive preparation, regardless of how much, or how little, he may know of the manufacturer? Does he choose a more expensive product because he's pricing on a mark-up basis and a cheaper brand would not provide what he considers a "fair return"? Or does he choose something "in between," balancing his doubts about price quality ratios with deference to the customer's pocketbook?

It is less difficult, certainly, to have the physician make the choice when he writes the prescription, but I believe this responsibility will be coming to the pharmacist more and more. And if this results in greater pressure from your profession for the FDA to assure the quality of all drug products, I will welcome it. Your support is vital to help our Agency carry out the responsibilities Congress has given us.

I believe the pharmacist and the FDA also have a common interest in the efficacy of drug products in general—that is, that the drug will actually live up to the therapeutic claims in its labeling. As you know, since the Kefauver-Harris Drug Amendments became law five years ago this month, sponsors of new drugs have had to present substantial evidence of efficacy as well as of safety. You may also be aware that a little more than a year ago, the National Academy of Sciences-National Research Council (NAS-NRC) agreed to undertake for FDA an evaluation of the efficacy claims of some 3,000 drug preparations marketed between 1938 and 1962.

The first recommendations coming from this far-reaching study were submitted to me last week and are now under consideration within our Bureau of Medicine. These NAS-NRC reports will be coming to the FDA in a steady stream in the weeks and months ahead and they will be acted upon as promptly as possible by our Agency.

The National Academy, which has established 29 panels of distinguished physicians and scientists to carry out this most difficult assignment, anticipates that few drug preparations will be found to be totally ineffective. But it is probable that modification of labeling claims will be required for a great many products.

Carrying out these changes will tax both the FDA and the drug industry. Learning a new set of efficacy values for many preparations will draw heavily upon the time and energies of all physicians and pharmacists. But the result will be worth it. We will know more about our drug supply, its capabilities and its limitations, than ever before in history. And this knowledge will benefit the public whom we all serve.

## Master Bank of Drug Data

All drug knowledge being accumulated from one source or another has only a limited utility unless it is efficiently assembled and easily accessible. This is now possible with automatic data processing. The prospects are exciting. Some of your professional groups have given considerable attention to the development of a program that would provide uniformity among institutions utilizing automatic data processing to handle drug data. The FDA, along with other agencies of government, is also concerned with the development of a uniform data system, one which would have national utility. We have had fruitful discussions with other groups concerning this endeavor and I believe we can move forward together toward our common goal.

The first step in establishing a workable, uniform data system must be the coding of drug preparations into an alphanumeric language the computer can assimilate—a language that will say the same thing to a hospital computer in Ann Arbor as it does to the FDA computer in Washington. This, in itself, is no small project. But I'm confident it will be accomplished. And I'm equally confident that we will build a master bank of drug data that can be utilized by Government, industry, hospitals, medical schools and others.

One of the first applications of automatic data processing within FDA has been in our drug experience reporting system. We receive such reports from government and private hospitals, from physicians, and from drug manufacturers. Frankly, the system still is not what it should be to provide a continuing, reliable check on the way drugs are used and the effects they bring about. This is not because of built-in deficiencies of the computer. No, the reliability of the system

depends on the source of the data, the initial reporting point of a drug experience. This is where we must seek further improvement, and I believe the professional pharmacist can make a vital contribution to this reporting system.

I received a letter some days ago from a hospital pharmacist in the Midwest who was aware that his drug reaction reports had been coming to the FDA for several years. He wanted to know what became of his reports and why there was no feedback to him. The system, of course, doesn't operate so simply or so directly. One adverse reaction of a drug, or two, or three, don't mean very much in themselves. These may represent patient idiosyncracies. It is when similar reactions to a given drug are reported in greater numbers that we can begin to see a pattern emerge. Our Agency's reaction to these reports will depend upon the circumstances. Perhaps the drug should be contraindicated for certain conditions. Perhaps there should be a new warning or precaution added to the labeling. Or the reported reactions may be so serious as to outweigh the benefits that can be expected from the drug.

In making any of these judgments, it is absolutely essential that the original data are accurate and reliable. There must be uniformity in the reports, including form and language, if similar reactions are to be recognized and clustered. It is true that drugs entering the marketplace today are more thoroughly tested than ever before. But even after extensive clinical testing, previously unknown reactions may occur once the drug is used in a broader patient population under widely varying conditions.

Therefore, we can never safely dispense without a constant post-marketing surveillance program. And the pharmacist, whether he practices in or out of the hospital, can contribute to the strength of this surveillance program. A professional commitment to record and report drug reactions should be carried out with the same fidelity that is given to the accurate filling of a prescription. These reports should be made not only to the prescribing physician, but to the manufacturer, and to the government as well.

Earlier this year, the World Health Organization initiated a pilot adverse reaction reporting system on an international scale. The FDA's program and facilities are used as the core of this system.

Only a few countries are participating at the outset, but the network will most assuredly expand as time goes on. This makes even more important, the improvement and refinement of our own nation's reporting system, if we are to achieve a reliable worldwide index of drug experience.

Some of you here, and some of your colleagues elsewhere, may feel that Congress and the FDA have demanded quite enough of the profession already without marking out any new areas of responsibility. The implementation of the Drug Abuse Control Amendments of 1965, for example, has added to the work of the pharmacist. There's the job of keeping up with the list of controlled stimulant and sedative and depressant drug preparations. There are additional record-keeping requirements once the controlled drugs are in the pharmacy. There are restrictions on refilling prescriptions for drugs covered by the law.

Drug recalls, which are steadily growing in number, can be a headache to the pharmacist. Lot numbers of recalled drugs must be checked against existing stocks and, if any are found, the faulty product must be sent back to the wholesaler or manufacturer. In some cases, it may be necessary to check through customer records and trace the drug to the user so that he can be warned that the medication he received may not do what it was supposed to do. And the customer, if he reacts in a normal way, will probably blame the pharmacist, since he's the one who filled the prescription.

These may appear to be onerous obligations at times. They do serve, however, to emphasize the pharmacist's stake in the quality of our drug supply and the soundness of its channels of distribution. A drug recall is a correction of a fault; it is certainly not a solution to quality control. All of us, government administrators, manufacturers, physicians, pharmacists, and, most important of all, patients, have a strong incentive to eliminate these faults everywhere along the line of research, production sales, and use.

The pharmacist has this incentive as well—his professional commitment is to protect the health needs of his community. I am confident that pharmacists will fully explore the potential the future holds in carrying out this commitment to the public welfare.

**[The End]**

# Food Additives in Japan

By BERNARD L. OSER

**The Following Is Concerned With Japanese Regulation of Food Additives. It Was Written by Bernard L. Oser, Ph.D., Who Is This Magazine's Scientific Editor.**

THE MODERN REGULATIONS for the control of food and the food industries in Japan commenced in 1947 with the enactment of several ordinances setting up specifications. standards, and regulations concerning foods, food additives, containers. and sanitation practices.

A massive poisoning episode occurred in 1955 in which some 12,000 children were made seriously ill following the ingestion of a powdered whole milk product containing disodium phosphate, which was contaminated with arsenious oxide. On the heels of this unfortunate episode, new legislation governing food additives was adopted, based largely on the principles and procedures recommended by the Joint Expert Committee on Food Additives of the World Health Organization-Food and Agriculture Organization of the United Nations.

## Food Additives Presently Permitted

Following appraisal of the relevant data by a Food Sanitation Investigation Council, there are presently permitted as food additives by the Minister of Health and Welfare, some 350 synthetic compounds, most of which appear on the U. S. Food and Drug Administration's "White List" (Section 121.101). For each substance, the specific use for which it is permitted is stated in the Japanese regulations. There are some interesting differences, however. For example, in the preservative category, any of six alkyl p-hydroxy-benzoates are permitted, instead of two, as in the FDA regulations. Both isoamyl and propyl gallates are permitted rather than the latter alone. The Japanese list includes fourteen synthetic (coal tar) colors and their lakes, including the

eight now permitted in the United States. In addition to thiamine hydrochloride and thiamine mononitrate, which are allowed in the United States, the Japanese permit dibenzoyl thiamine and its disulfide, thiamine naphthalene-disulfates and thiamine diacetyl sulfates, dilauryl sulfates, and thiamine phenophthalate. Among the preservatives permitted in fish, meat, and soy products is 2-(2-furyl)-3-(5-nitro-2-furyl) acrylamide, at levels ranging from 2.5 to 20 parts per million.

The historical background of the Japanese regulations for food additives is soon to be published by the Food and Agriculture Organization of the United Nations as a continuation of its series on national food additive laws. **[The End]**

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STATEMENT OF OWNERSHIP, MANAGEMENT AND CIRCULATION (Act of October 23, 1962; Section 4369, Title 39, United States Code)

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I certify that the statements made by me above are correct and complete:

(Signed) Allen E. Schechter

# Rule-making as Viewed by the Commissioner, the Congress, and the Court

By WILLIAM W. GOODRICH

The Following Is from a Paper Delivered Before the Food, Drug, and Cosmetic Division of the American Bar Association at the Annual Meeting in Honolulu. The Article Is Reprinted from *The Business Lawyer* (November 1967) with the Permission of the Publisher and of the Author. Mr. Goodrich Is Assistant General Counsel of the Food and Drug Division, HEW.

THE COMMISSIONER, THE CONGRESS, AND THE COURTS have all had something important to say about administrative rule-making within the recent past. All have influenced the course of the future by words and deeds. And all of us should take heed. As a new Commissioner of Food and Drugs, Dr. Goddard, as soon as he took office, set in motion a sweeping review of policies and practices of the past, and changes in a great many of them have already been introduced. These changes have been accomplished largely by rule-making actions, and more of this can be expected. Dr. Goddard, I think, has qualified himself as an administrator concerned with the big issues—the urgent problems that demand resolution to make the objectives of the law come alive. And the most effective solutions were generally to be found through the imaginative exercise of rule-making power.

Agency performance itself can be judged by what it produces in its regulations. This is what sets the stage for both voluntary compliance and enforcement. If volume alone counts, FDA stands high on the list. But we agree that the substance of the actions is a better measure of quality performance. Congress too has been impressed that rule-making can be more effective than the slow process of case-by-case adjudication in implementing its policy decisions. Take the Fair Packaging and Labeling Act for example. This law was a

response to consumer demands for better buying information on packages which act as their own salesmen. There were interpretive rules applicable here. But they were inadequate. Significantly, Congress directed the agencies to proceed by promulgating new rules—this time with fully binding effect—and it identified the concerns that should be dealt with mandatorily and those that could be left to agency discretion. This statute represents a new approach to assist the purchaser in making better value comparisons and buying choices in the self-service economy in which we live. The Court's concern had to do with when—how soon after agency rules have been promulgated—the judiciary should take a hand to see whether the agency's solutions are acceptable ones.

Administrators, legislators, and judges necessarily look at administrative rule-making from quite different vantage points. Yet they share responsibility for making public laws work. From the administrator's point of view, rule-making is an exercise in problem solving. From the legislator's view, it is a necessary alternative, required by the pressures of time, to detailed enactments. And from the Court's view, it is a resolution of rights and responsibilities of the citizen which may be set aside if arbitrary or beyond the legislative authority given the agency. May we then examine some recent examples of administrative, legislative and judicial response to agency rules.

## Problems That Required Solutions

When Dr. Goddard arrived at FDA, he faced a series of problems that required solutions.

1. DMSO, LSD, and new oral contraceptives presented challenges in administering the investigational new drug controls.

2. There was a growing backlog of new drug applications and supplements, and a charge by industry that there were needless delays in clearing it.

3. The effectiveness of all new drugs approved between 1938 and 1962—when safety rather than safety and effectiveness was the basis for new drug approval—had not been reviewed.

4. He had a problem of serious proportions with the kind of scientific data that were being presented to the agency in IND, new drug, food additive, and other submissions.

5. There was a rising list of drug recalls, and failure on the part of too many companies to meet the standards of current good manufacturing practice.

6. The long delayed vitamin-mineral regulations needed to be pushed ahead.

7. Salmonella infections from food borne organisms were increasing.

8. And there were exaggerations and unreliable presentations in prescription drug advertising, which raised the related issue of how to reach prescribers of Rx drugs with prompt, informative, accurate and complete prescribing information.

Perhaps of most importance, the Commissioner had a directive from the Secretary to move the Agency ahead with the best possible scientific decisions. How these problems have been met and handled tells much about FDA; about its ability to perform and about the route it will take to the future. Recently, Dr. Goddard called it "creative administration" in which many new techniques, not all spelled out in the law, are called upon to reach the statutory goals.

## Examples of Accomplishment

Here are examples of what was done, and why.

Administrative review of the IND problem in preparation for a hearing before the Fountain Subcommittee highlighted the point that the Agency needed to require stricter adherence to the rules it had promulgated in 1963. The distribution of DMSO got completely out of hand because of both the Agency's failure to insist on compliance and widespread industry deviations from required practices. Investigations showed that some of the data being presented in these and other IND's was wholly fictitious. Patient consent, as required by the law, was not being obtained in too many instances. Steps were required to tighten both administration of the regulatory scheme, and the rules applicable to patient consent.

The backlog of new drug applications and supplements was analyzed and tackled by a new team review approach. But the principal cause of the delays was identified as poor quality submissions awaiting action.

While we saw industry publicity about the requirement of volumes of data to support new drug approval (a five foot shelf of data was pictured by one firm and a whole room full by another), what was not publicized nearly so well was that many of the submissions were poorly conceived, poorly organized, and poorly documented, requiring multiple reviews, multiple requests for clarification or additional data, and multiple resubmissions.

What was needed was a more cohesive and understandable new drug application or supplement. Rules to require this have been announced. And they deal with such elementary things as required indexes, summaries, and page numbering, to facilitate the applicant's understanding of what is being submitted — and why — and the

Agency's review of the rationale for the use of the drug and the data to support it.

We believe that compliance with the new rules will greatly facilitate action in approving acceptable submissions and rejecting those which do not satisfy the law's demands.

Advertising problems demanded a large segment of the Agency's time. According to the advertisers, the agencies, their lawyers, medical advisors, and executives, the existing regulations did not tell them exactly what was expected. They claimed this was the cause of our dissatisfaction with their performance.

From the Agency's standpoint, much of the trouble arose out of advertising copy which exceeded the approved claims or simply left out some of the required information about side effects (including warnings and precautions) and contraindications. But deeper problems arose from misleading headlines and graphic presentations, conflicts between the selling parts of the ads and the information parts, and the use of publications drawn from the medical literature to sell products for conditions for which they had not been approved, to extend the range of their claimed usefulness, or to minimize the limitations on their usefulness or the hazards that may attend drug use.

## Further Steps Required

Confrontations, seminars, speeches and other efforts failed to achieve full industry-government understanding of how to comply, so further steps became necessary. New and comprehensive regulations were drawn to meet the criticism of lack of specificity and to provide the advertisers with the specifics of advertising failures, as we saw them. These were based on about three years of surveillance experience under the existing regulations. We are soliciting a constructive response from the pharmaceutical industry and its advertising agencies. We hope we can avoid criticism for its own sake, in the interest of promptly improving this most important means of communication between drug producers and the physicians who prescribe these products.

That there is much room for improvement is evident from the 8 "Dear Doctor" letters, covering 14 heavily promoted drugs, that have been mailed to the profession over the past 7 months to correct misinformation in this sort of advertising. It is relevant to observe that some of the advertisements covered by these letters were for newly approved products, and the initial presentations of them to the profession through advertising campaigns were not in conformance with the conditions attached to their approvals.

Along these same lines, the Agency has reviewed its regulations on current good manufacturing practices for drug establishments, with the idea of making them more specific—and thus improving quality control in the industry. And it is considering as well the establishment of regulations on current good manufacturing practices in food establishments, to improve sanitation and to prevent avoidable contamination. The salmonella problem lends urgency to this.

The efficacy review for the approximately 3,000 drugs on the market prior to 1962, when advance proof of effectiveness was first required for all new drugs, presented a challenge beyond the Agency's resources. Not only was there a need for a special kind of medical manpower; more importantly, evidence derived from adequately controlled studies simply did not exist to support the medical claims being made for some of these drugs, even where it might be a recognized fact growing out of extensive clinical experience that many or most of them are regarded as useful in medical practice. The NASNRC undertook the job, assembled the best of the nation's experts to serve on consulting panels, and will soon begin to feed back to the Agency opinions on which efficacy judgments may be based. We will have to create new techniques for imposing these judgments on the promotional material for the drugs. The substance of the panel opinions will have to be communicated to the Companies—probably through statements of policy—and then labeling revisions will have to be volunteered or required through new drug procedures involving classes of drugs.

In a related move, the Agency is preparing to go ahead, this fall, with its special dietary food regulations to simplify vitamin-mineral preparations—to make them more rational and understandable and thus improve the public's ability to make choices between competitive products and to buy on the basis of fully informative labeling.

## Fair Packaging and Labeling Act

While the Agency was busily engaged with the problems I have described, Congress brought to enactment by a virtually unanimous vote the Fair Packaging and Labeling Act. The need here arose out of the inadequacy of the existing labeling and packaging rules and the desire of consumers generally to have better buying information on the packages of consumer commodities, particularly foods, drugs, and cosmetics. Congress could not deal with the details of regulation, but it could and did say what policy it wanted the Agencies to pursue. First, it identified the specifics of mandatory and discretionary labeling and packaging reforms it considered justified; second, it iden-

tified the agencies to carry out the reforms; third, it called for this to be accomplished through administrative rule-making rather than through protracted case-by-case adjudicatory proceedings; and finally, it provided the public procedures and judicial reviews that would attend the rule-making activities.

The initial regulations to carry out the new law were signed week before last, but they are subject to objection and public proceedings on any objection that may be filed. Their effective dates may be thus delayed, but from initial reactions this is not likely.

In the weeks ahead, we can expect the mandatory regulations for drugs and cosmetics, as well as the beginning programs on the discretionary regulations—regulations making exemptions, regulations for cents-off and other bargain promotions, regulations to prevent non-functional slack filling of containers, regulations for "large," "small" and "king" size containers, and regulations requiring additional ingredient information in the labeling of drugs and cosmetics.

How, you may ask, is all this flurry of rule-making affected by the Supreme Court's decisions last May, making pre-enforcement judicial review possible? The decisions laid to rest any question of judicial power to entertain such suits, but a decision to review or not to review regulations at this early stage was left largely discretionary. Where Section 701 (e), the statutory review procedure, applies, we believe that will continue as the required route for the challenger. The opinion of the Court of Appeals in the District of Columbia in the vitamin case indicates as much. But otherwise it appears that the Courts will entertain a pre-enforcement challenge only when there is a great hardship on private parties in withholding court consideration and when the cases present essentially legal issues that are ripe for judicial resolution without an evidentiary trial or administrative hearing.

## Fitness of Issue for Judicial Decision

What makes an issue fit for judicial decision? *First*, the interpretive regulations must be issued after notice and an opportunity for comment, as provided in the Administrative Procedure Act, and must carry no hint of informality. This is "final agency action" within the meaning of the Administrative Procedure Act. Such regulations, if authorized by the Federal Food, Drug, and Cosmetic Act, the Court said, have the status of law and violations carry criminal and civil sanctions. Their immediate legal impact makes them reviewable. *Second*, they must present a purely legal question of statutory construction in terms of Congressional intent or statutory language, and

must not involve factual matters that require Agency resolution. The Supreme Court said that if, at an evidentiary hearing, the District Court is persuaded that technical questions are raised that require a more concrete setting for proper adjudication, such as would arise in an actual enforcement proceeding, a pre-enforcement order should not issue.

Once the issue is found to be fit, the District Court is then to decide the question of hardship which will arise if early judicial relief is denied. Here, the most important consideration is the impact of the regulation. Does the regulation have an immediate, direct and legally binding impact upon the day-to-day business affairs of the affected industry? Primary conduct must be affected. The regulation must cause the industry, for example, to test or substitute ingredients now—not perhaps—not in the future—now.

And the Supreme Court found it particularly relevant that the plaintiffs challenging the interpretative regulations represented nearly all—90 percent—of the affected industries. If there is a substantial governmental interest against judicial inquiry in a pre-enforcement setting, that interest is to be protected. Relief can be denied on the ground that there is a multiplicity of suits for harassment purposes. And those regulated cannot sit idly by with the intent to institute a suit to review the regulation sometime in the future "in case things get hot." The Court specifically pointed out that the defense of laches is available to the Government.

Finally, even if a suit is instituted and the Court decides to hear the case, that is not an automatic stay of the application of the regulation. The burden is on the applicant to allege and establish the necessity for the stay along the traditional lines. These decisions do not provide automatic access to the Courts, but they do grant the District Courts power to review some interpretive regulations issued as the final action of the Food and Drug Administration. Informal advisory opinions, even by the Commissioner, rulings of subordinate officials and tentative regulations remain nonreviewable.

## Summary

To sum all this up, the FDA is committed to new administrative approaches, with a determination to develop and use procedures that best serve the high purposes of its charge. Congress has endorsed the idea that rule-making offers possibilities for more effective administration. The Courts have announced a readiness to review rule-making in advance of enforcement, when industry hardship and the nature of the issues permit. **[The End]**

# Purchasing and Subcontracting

By WILLIAM F. WEIGEL

The Following Is from a Presentation at the Proprietary Association's Third Manufacturing Controls Seminar in a Panel Session on "Purchasing and Subcontracting" on Thursday, October 26, 1967, at Saddle Brook, New Jersey. Mr. Weigel Is the Associate General Counsel of the Proprietary Association.

I AM SURE YOU ARE ALL AWARE of the increased activity in the past five years of the Food and Drug Administration (FDA) brought about by the requirements of the 1962 Amendments, of the increasing number of new and more detailed regulations for our industry, of the proposed further legislation, and of the practical problems that have made drug manufacturing a legal nightmare. Legal considerations are becoming an ever increasingly important factor in decision-making and in the day-to-day operation of your business. This is just as true with respect to your purchasing arrangements and subcontracting agreements, which are the two areas we are exploring today.

Although one's initial reaction might be to rely upon a supplier's guaranty or to enter into a subcontracting arrangement as a means of avoiding many of these ever-present legal pitfalls, I am afraid that the solution is not that easy. One might be able to shift the burden of legal compliance on a supplier or a contract manufacturer in a few areas, but these advantages would probably be more than counterbalanced by the addition of new problems inherent in the nature of such a relationship.

I can't possibly call to your attention all of the legal problems that are involved in such arrangements, let alone solve them. We can, however, explore some of the more important areas in which problems are most likely to arise. Their solution should best be left to your own attorney who alone will be in a position to consider them against the particular factual background of your business.

If you do plan to have a portion of the manufacturing, processing, packaging or other aspect of your operation done on a contractual

basis, you may be faced with special legal problems with respect to such things as labeling, registration, factory inspection, quality control and product liability. I shall try to touch briefly on some of these special problems.

## Labeling Requirements

The Food and Drug law is to a large extent a labeling law. Unless the product is inherently defective, the labeling is the principal criterion on which compliance with the law is judged. Accordingly, every manufacturer must pay careful attention to the labeling requirements of the Act and should, under no circumstances, delegate this responsibility to a subcontractor or other third party. In most instances the labeling will be prepared and supplied by the manufacturer or product owner. If it is not, he should check thoroughly all labeling to be used and make certain that it does comply with the law, since the person who holds the drug out as his will be every bit as liable for misbranding as the person to whom he has delegated the labeling operation. Good intentions or lack of knowledge will be no excuse in this area. One preparing your labeling at your request would be considered your agent but you, as principal, will be liable for his failure to do it properly.

There is only one unique problem in the labeling of a drug product where a subcontractor has performed one or more of the manufacturing operations. Section 502(b) of the Food and Drug Act provides that a drug shall be deemed to be misbranded unless it bears a label containing "the name and place of business of the manufacturer, packer or distributor." The regulations under this Section provide that, if the drug is not manufactured by the person whose name appears on the label, the name shall be qualified by an explanatory phrase such as "Manufactured for and packed by XYZ Co.," "Distributed by XYZ Co.," or other similar phrase which expresses the facts. Accordingly, you must be certain that there is an informative non-deceptive statement on the label. This, of course, does not mean that you must spell out in detail your arrangements with your subcontractor or, in most instances, even indicate that you have one.

Usually it is not too difficult to determine who is the manufacturer for labeling purposes. The person who performs the principal physical operations that result in the finished product's being in a form suitable for consumption would appear to be the manufacturer for the purposes of this Section. Conceivably, this could be a joint operation, so that it would be difficult to make a precise determi-

nation. As a general rule, however, it would be the person performing the final operation, short of packaging and the affixing of labels.

## The Trademark

Often a trademark owner who has subcontracted the entire manufacturing operation wishes to hold himself out as the manufacturer on the theory that the drug is manufactured according to his formula and under his direction and control. This is not an uncommon practice in the proprietary field, where one owns a valuable trademark, but does not wish to concern himself with the problems of present day drug manufacturing. Such a representation, however, is likely to be considered deceptive, unless the label indicates that it has been manufactured "for" the trademark owner. On the other hand, one should make certain that there is some indication as to who owns the trademark, since in such situations, the trademark is usually the most valuable remaining asset and its integrity will be preserved only if the owner controls the nature and quality of the goods.

## Registration

There are very few situations involving the use of a subcontractor where either party will be relieved of the requirement of registering as a manufacturer under the Drug Amendments of 1962 and the concomitant subjection to factory inspection. Under the statute, manufacturing includes repackaging or otherwise changing the container, wrapper or labeling of the package in furtherance of the distribution from the original place of manufacture to the person who makes the final delivery or sale. And, the regulations provide that "Sampling, testing or control procedures applied to the final product or to any part of the process" will be considered as part of the manufacturing process for registration purposes. This would seem to include your consulting laboratories and others conducting tests on your product or its ingredients, but probably not those performing animal or clinical tests on the finished products. Thus, your subcontractor may perform only the most incidental operations, if he is to avoid registration.

A drug which has been manufactured in an establishment not duly registered will be deemed to be misbranded and subject to seizure. Accordingly, you should make certain that your subcontractor is a registered manufacturer and that his registration is current, since it will be your product which will be seized, if there is a violation of this provision of the law. A word of caution — registration is not a license or stamp of approval from FDA. It

merely indicates they have the registrant's name and address and may, or may not, have gotten around to inspecting his plant.

## Adulteration Determination

The Drug Amendments of 1962 have created a new problem area for subcontracting arrangements which are of particular concern. This relates to the requirements for use of good manufacturing practices and the respective responsibilities of the principal and his subcontracting agent. As you all know, Section 501 of the Act now provides that a drug shall be deemed to be adulterated "if the methods used in, or the facilities or controls used for its manufacture, processing, packing or holding do not conform to or are not operated or administered in conformity with current good manufacturing practices to assure that the drug meets the requirements of the Act as to safety and has the identity and strength and meets the quality and purity characteristics which it purports or is represented to possess." This provision sets up an entirely new basis for finding a drug adulterated. Adulteration had always been thought to consist of an inherent defect in the end product and not the failure of one to take some affirmative act or step in its production. Even if the end product is satisfactory and complies with the law in every respect, it still may be deemed adulterated, if the manufacturer does not operate in accordance with good manufacturing practices—that is to say, methods, facilities and controls. For example, failure to take the recommended steps to guard against cross-contamination could result in an adulterated drug, even though no cross-contamination occurred. A similar result might occur where one did not have an adequate recall system, even though a recall never became necessary.

This poses a real problem for the product owner who has part of his manufacturing or processing done by a third party. The third party must comply with the provisions or the end product becomes adulterated, even though there is often no method of determining by examination or testing of the end product whether your subcontractor did operate in accordance with good manufacturing practices.

Adulteration, of course, is a very serious violation of the statute and can result in multiple seizures of the adulterated product. Accordingly, if you are using or considering a contract manufacturing arrangement, it would seem to be prudent to take some affirmative steps to assure yourself that your subcontractor can and will comply with the provisions. In any event, your arrangement should always be made with a manufacturer or processor in whom you have the

utmost confidence and whose plant, facilities and methods of operation have been personally observed.

## Good Manufacturing Practices: Responsibility and Liability

As we have seen, what constitutes "Current Good Manufacturing Practices" has been given a very broad interpretation. It involves such things as buildings, equipment, personnel, raw materials, records, control procedures and the like. FDA is using this provision of the law to interject itself into every phase of the manufacturing and control operation, and, in effect, has developed a quasi-licensing system for drug manufacturers. As a result, many smaller companies have found it easier to have their manufacturing, or a substantial part of it, done on the outside than to attempt to comply with the detailed regulations and the accompanying record-keeping. One who chooses that route or employs a subcontractor for any purpose must remember the great responsibility that is being delegated to the subcontractor and must exercise constant vigilance over his operation. If the subcontracting operation is sufficiently substantial to justify the expense, it may even be well to place at least one of your own technical personnel in the subcontractor's factory to observe and supervise the work being done. In any event, one should reserve the right to inspect the operation from time to time. This becomes particularly important when a problem occurs, and it is necessary to resolve it quickly and determine the relative liability of the contracting parties.

As long as one is the motivating instrumentality which causes a drug to enter commerce, he will be held responsible for a violation of the Act, if the end product is not in compliance. This is true regardless of intent or motive or even knowledge of the wrongdoing. This was the result in a very important case decided by the Seventh Circuit a few years ago with respect to a cosmetic manufacturer (*United States v. Parfait Powder Puff Co.*, 163 F. 2d 1008). In that case the defendant entered into a contractual arrangement with a private manufacturer whereby the latter agreed to manufacture, place in packages and distribute to the defendant's customers hair lacquer pads. The defendant supplied the subcontractor with flannel pads, labeling material and shipping containers. The subcontractor agreed to impregnate the pads with a shellac lacquer, place them in labeled jars bearing defendant's name, and ship the finished goods in accordance with the defendant's instructions. The subcontractor, without the knowledge of the defendant, substituted for shellac a gum which proved to be deleterious in use. As soon as the defendant learned

of the substitution, it forbade further use of the gum. Nevertheless, the government brought a criminal action against the defendant for shipping adulterated cosmetics in interstate commerce. The defendant was convicted and fined and the conviction was upheld by the Appellate Court.

This decision spells out clearly the far-reaching extent of liability of the product owner in a subcontract arrangement. The Court's reasoning is interesting and should serve to put all of you on notice of the risks you may be undertaking. The Court was of the opinion that the defendant could not shift its liability to the instrumentality which it had created for the purpose of taking over the manufacture, distribution and sale. Rather, the defendant was bound to see that its product, when introduced into commerce, was not violative of the law. In other words, one who owes a certain duty to the public and entrusts its performance to another, whether it be an independent contractor or agent, becomes responsible criminally for the failure of the person to whom he has delegated the obligation to comply with the law.

As the Court said, "One may not put into operation forces effectuating a placement in commerce of a prohibited commodity in its behalf and then claim immunity because the instrumentality it has voluntarily selected has failed to live up to the standards of the law." Although this may seem like a harsh decision, it need not necessarily discourage anyone from entering into a subcontracting arrangement. There should be emphasized, however, the need for picking a reputable manufacturer and being constantly aware of his activities. A system of actual tests and quality control of the end product should also be part of every such arrangement.

## Guaranty Protection

Drug manufacturers have attempted to limit their potential liability by insisting that their suppliers deliver goods under a guaranty. I believe that too much reliance has been placed upon these guaranties, and question their applicability to the usual manufacturer-supplier relationship. Although I see no harm in asking for the usual food and drug guaranty, I doubt that it will effect any substantial diminution of liability. The sophisticated manufacturer, by tests and controls, will have to assure himself that he has a non-violative product and not rely upon the representation of his supplier.

Although the term "guaranty" is used rather loosely, there are really two specific defenses or exemptions set up in the Act to

protect the unintentional violator. These are available only in a criminal prosecution and are not pertinent in a seizure or injunction action. The first protects one who has *received* an article in interstate commerce and delivered or proffered delivery of it *in good faith,* provided that he furnishes, on the request of FDA, certain information about his vendor. This would be the usual manufacturer-supplier situation and technically would not involve a guaranty.

The other statutory exemption does involve a guaranty and protects one who *introduces* in interstate commerce a violative product, provided he has obtained a guaranty from his vendor as to the article's fitness and has received the article in good faith. Where the first or "good faith" defense is applicable, the goods would have moved in interstate commerce so that FDA could always bring a criminal action against the party's supplier who violated the Act by introducing the goods into interstate commerce. If, however, the original shipment was intrastate, FDA would have no recourse against the supplier or anyone else, if a plea of good faith alone were permitted. Accordingly, the Act denies the person *receiving* goods this defense and forces him to protect himself by obtaining a guaranty. FDA can then proceed against the original seller for the giving of a false guaranty, since the Act does not require that this violation take place in interstate commerce.

When these defenses have been raised, the courts have interpreted "good faith" to require not only ignorance of the violation but also in many situations affirmative action to discover, where practicable, whether the articles do in fact violate the Act. Thus, in all instances, notwithstanding the existence of a guaranty or the basis of a "good faith" plea, you should make every reasonable effort to confirm your supplier's representation of compliance with the Act. This, of course, means full and complete testing of all raw materials or finished goods received from your supplier. Although the courts have placed a very narrow construction upon the effect of guaranties, many manufacturers continue to procure them from their suppliers. They certainly do not hurt, unless one is thereby lulled into a false sense of security. A guaranty may be either limited to a specific shipment or may be a general and continuing guaranty covering any shipment between the same parties. Suggested forms of guaranty are set forth in the regulations, and we believe that these forms should be used in order to preclude FDA's contention that there has not been strict compliance.

In order for a guaranty to operate as an exemption from the statute there are four necessary elements:

(1) The charged criminal violation must be the *introduction* in interstate commerce of a misbranded or adulterated article.

(2) There must be prior existence of a guaranty or undertaking. One may not procure the guaranty after the shipment has been made.

(3) The guarantor must be a person residing in the United States.

(4) The goods and the guaranty must have been received in "good faith."

The difficult concept is that of "receipt in good faith." The courts have held that "good faith" does not exist where one repackages, relabels and reships violative articles bearing his own trade name. Indeed, at least one court has held that the guaranty provision applies only in the case where the party who introduces the product into interstate commerce acts "merely as a conduit through which the merchandise reaches the consumers." By analogy the good faith defense would probably not be available to one receiving a violative article, if he had ordered a private manufacturer or subcontractor to further prepare, package and distribute the article to his customers.

The "good faith" defense has recently been given an even narrower interpretation, if not eliminated, by the Federal court in Connecticut. In *U. S. v. H. L. Moore Drug Exchange Inc.*,[1] the defendant wholesaler moved to dismiss a criminal action on the basis that it was exempt from prosecution, having received the drugs and proffered them in good faith and having disclosed the identity of its supplier. The motion to dismiss was denied, the Court interpreting the intent of the Act to protect only innocent *dealers*. It concluded that wholesalers, jobbers and manufacturers were not the type of innocent "dealers" Congress had in mind. In effect, it restricted the defense to retailers, stating:

> . . . in the interest of the larger good, it is not only important that the first violator shall be punished, but also all those in whose case it can be said that punishment would induce them to keep their suppliers and themselves up to the mark. 239 F.Supp. at 259.

Since there was no actual guaranty present, the defendants could not raise that defense. Equally obvious, however, is that the presence

[1] Food Drug Cosmetic Law Reports ¶ 40,191, 239 F. Supp. 256 (DC Conn. 1965).

of a guaranty would not have influenced the Court. The *Moore* case, thus, vitiates much of the certainty of the statutory defenses for innocent violators. The holding is as I said, narrow and conflicts with prior decisions. It indicates the Courts' attitude, however, to hold drug distributors to the highest possible standards of strict liability.

## Interstate Manufacturing Operations

A final and related problem of increasing significance involves articles moving interstate between two factories of the same operator or between a manufacturer and his subcontractor who is to perform certain of the processing operations. It has long been clear that the shipment of an adulterated article under these circumstances is violative of the Act, even though the shipment is for the express purpose of curing the adulteration. With respect to misbranding, however, the situation is not so clear, since the Act does authorize FDA to establish exemptions where "in accordance with the practice of the trade" such goods are to be processed, labeled or repacked in substantial quantities at other establishments. At this time FDA allows such exemptions only where the shipper also operates the plant to which the goods are consigned or where there is a signed agreement between the parties setting forth the specific work to be done. Since it is often difficult, if not impossible, to establish exactly what constitutes "in accordance with the practice of the trade" or "substantial quantities," the written agreement is helpful and should be employed even where both plants are operated by the same person. In all instances there should be a very precise written direction of the nature of the work to be done, labeling to be used, tests and controls to be employed and the like.

## Summary

Any person who wishes to enter or remain in the drug business must realize that he owes a certain duty to deliver to the consumer safe and effective medication. He must also realize that he is engaging in one of the most highly regulated of all businesses. Although some of the headaches of the business may be avoided by having some third person do some of the manufacturing or processing of your product, your legal responsibilities are not likely to be lessened. Indeed, as we have seen, they may well be enhanced. Accordingly, the laws and regulations relating to the manufacture and distribution of drugs will continue to be of concern to you, whether or not you choose the subcontracting route. **[The End]**

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