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Food Drug Cosmetic Law JOURNAL

Concluding Papers Presented at the Twelfth Annual Educational Conference of The Food and Drug Law Institute, Inc., and The Food and Drug Administration

Has the Pendulum Swung Too Far?

. . . . . VINCENT A. KLEINFELD

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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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Changing Concepts in Sanitation

By LAWRENCE ATKIN

The Following Report Was Presented at the Food and Drug Law Institute, Inc.—Food and Drug Administration's Twelfth Annual Educational Conference at Washington, D. C. on December 3, 1968. Dr. Atkin Is the Director of Research, Standard Brands Inc. Succeeding Articles in This Issue Were Presented at the Same Conference.

ALL AVAILABLE PUBLIC HEALTH REPORTS indicate that food-borne salmonellae may constitute a potential health hazard to the consumer. The dramatic reports of large numbers of intestinal disturbances following public picnics, banquets, and similar functions, and equally dramatic accounts of disturbances experienced by occupants of hospitals and other institutions testify to the public health significance of salmonella.

There is reason to believe that salmonellosis is also a problem in the home and in small food-handling operations with sufficient frequency to justify the concern of all. The processed food industry has therefore a responsibility to operate so as to avoid contributing to this health hazard.

The manufacturer of processed foods deals with an additional hazard that we may call the regulatory hazard. Due to changing concepts and associated factors, the regulatory hazard has at times grown so large as to be totally out of proportion to the health hazard. It is these changing concepts that will be explored by considering the origin, significance, and interrelationship of the following:

(1) National recalls of processed foods.

(2) Self-certification contracts between government and industry.

(3) Proposed good manufacturing practice regulations (GMPs).

(4) The plant evaluation system (PEV).

(5) Field Legal Action Guides (FLAGs).

Each of these has appeared on the national scene during a very short space of time, and it seems worthwhile to ask why so much prominence has been achieved so quickly. In one way or another, each of them involves sanitation and salmonella, whether or not these are the only or principal factors involved. The question thus becomes how did salmonella in processed foods become so important so suddenly?

This is not an easy question to answer. Like the various accounts of the recent election, the answers are likely to differ widely; they may even be somewhat controversial. For instance, some cynics have suggested that not many years ago a federal agency was established to chart and study the incidence and distribution of certain communicable diseases with heavy emphasis on polio. When it was fully staffed and functioning, Salk and Sabin appeared on the scene. With the virtual elimination of polio, a variation of Parkinson's Law took over: Effort on salmonella was expanded to take up the time available. This version of history is probably inaccurate, but it may be hard to prove that it doesn't have some small grain of truth.

A more reasonable explanation is to suppose that there came a point in time when logic and the scientific method suggested emphasis on one special aspect of sanitation.

Inspection as a Measure of Effectiveness

Sanitation is defined in one dictionary as (1) the act or process of making sanitary, or (2) the promotion of hygiene and the prevention of disease by maintenance of sanitary conditions. Considering potentially harmful food-borne microbes, the objective of sanitation would be to keep them out, or eliminate them, and the most direct way to measure the effectiveness of sanitation would be to examine the finished product for microbes. The availability of sophisticated and sensitive procedures for identifying and enumerating microbes, especially salmonella, made this approach attractive as well as practicable.

There is, of course, nothing new about inspecting completed processed foods as a check on the sanitation program under which they were prepared. There was a time when sanitarians and their cohorts spent a great deal of time peering through microscopes learn-

ing to identify and count insect fragments, rat hairs, and other extraneous matter. They were always counting something, but then they were faced with the problem of deciding how many rat hairs were acceptable, and how many are too many. We still have inspections and specifications for extraneous matter, but no hue and cry, and few national recalls. It may be that we have come to share the sophistication of the waiter in the old limerick:

"There once was a young man from Kew
Who discovered a mouse in his stew.
Said the waiter, "Don't shout
And wave it about,
Or the rest'll be wanting one too."

To return to microbes, we must agree that the matter of viable microorganisms in our food, and especially potential pathogens, is not a question of aesthetics or sophistication. We must conclude that testing for live microbes is sensible.

Strangely enough, this reasoning was not officially advanced in 1966 or 1967. On the contrary, we have been told repeatedly in public and in private that the main reason for conducting food inspections in a bacteriology laboratory was the lack of sufficient manpower to conduct in-person inspections of the ever-growing number of food processing plants.

Whether or not the history and motivation can be accurately explained, one thing is clear. We, the scientific and technical community at large, were unprepared to interpret the salmonella test results that came forth on any but the most provisional basis. The improved methodology that was applied is so sensitive that it can detect a single microorganism in several hundred grams of a food, and what is more, this sometimes occurs in processed foods produced under sanitary conditions *previously* regarded as the best in the world.

The levels of salmonella encountered were extremely low if judged by common experience in food microbiology, and under ordinary circumstances the levels found would have been regarded as insignificant, except for the fact that just about then, salmonellosis was being advertised as the number one public health hazard. The dramatic incidents of salmonellosis in mass or group feeding mentioned earlier were receiving wide publicity, and a climate had de-

veloped that suggested that the country was faced by a new and spreading menace. We shall never know how much salmonellosis existed before the improved reporting system of the Communicable Disease Center was created.

In only a few of these instances were processed foods implicated as possible vectors, but as it turned out, it was mainly consumer-type processed food items that were subjected to the painful and frustrating national recalls that caused so much concern to the food industry. There were some incidents, exactly how many we do not know, wherein certain lots of food or food ingredients were condemned that, to the best of our knowledge, contained one or less than one microorganism per hundred grams.

Looking backward with 20/20 hindsight, it seems reasonable to conclude that if we knew then what we think we know now, many of the episodes that led to recalls and condemnations might have been handled differently.

Salmonellae are far more common than had been thought prior to 1966. There is a growing belief that any assessment of our total environment will show that there is a level of salmonella encountered in our daily lives that is tolerable, and if not always perfectly safe and harmless, is at least something we manage to endure. This could be called the background or existential level of encounter. The exact concentration and composition of this background is clearly difficult to ascertain, but all available evidence indicates that it exists, and furthermore it is highly probable that it is likely to remain with us for an indefinite period.

To get back to the climate in *1966*, we should remember that salmonella was being touted as the number one public health problem. We were told that it was spreading and must be halted. The sources must be located and eliminated and the cycle or pathway between farm products and consumers must be broken.

In the face of this situation, it is difficult to fault anyone for adopting the official position that one viable salmonella per carload was sufficient to condemn the lot as "poisonous and deleterious."

It is doubtful that anyone really believed this, and certainly no one believed that it should be applied without discrimination to any and all kinds of foods. However, without recognized criteria relating low levels of salmonella in specific foods to concrete potential

health hazards, there seemed to be no recourse except to operate on the basis of zero tolerance. Experience and further thought soon made it apparent that the concept of zero tolerance is untenable as applied to foods not retorted or otherwise subjected to sterilizing conditions.

Many persons in both the Food and Drug Administration (FDA) and the United States Department of Agriculture (USDA) were undoubtedly well aware of this situation, and a number of surveys and research projects were undertaken. Most importantly, both agencies early in 1967 requested the National Academy of Sciences—National Research Council (NAS/NRC) to undertake a broad study of the salmonella problem and its impact on human health and food technology in the United States. The NAS/NRC appointed a committee under the chairmanship of Dr. E. M. Foster, of the Food Research Institute, which has become known as the NAS/NRC Salmonella Committee. We understand that this committee made a very thorough study of virtually every aspect of salmonella, including the matters of criteria and discrimination that we have been discussing. In November of this year it was reported that the FDA and USDA are studying the report of this committee, which according to news reports, contains many recommendations concerning control of salmonella. Publication of this report, and official reaction to it, are eagerly awaited by us all. We hope that it will point the way toward workable criteria and thereby tend to make the *regulatory hazard* more consistent with the *health hazard*.

At about the time that the assistance of the NAS/NRC was being sought, or shortly thereafter, industry self-certification, GMP proposed regulations for food processors, and the PEV system appeared on the scene, followed slightly later by FLAGs. Each of these has much to do with sanitation, and we should therefore examine the concepts involved.

Self-Certification

We have just received an up-to-the-minute status report on the self-certification program. In this program, a unit of the food industry enters into a contract with the FDA in accordance with which they jointly devise a program of sanitation and/or bacteriological quality control covering a specific process and a specific product.

From the point of view of salmonella, it seems fair to describe the first of these contracts as an experiment to test the feasibility of the zero tolerance approach.

A very good selection of a processed food was made because it is one that contains both dried milk and dried eggs, both animal products, and both potential vectors of salmonella. The final outcome of this experiment will be received with great interest, because top-level research workers and top-level statisticians tell us that the only way to establish the complete absence of salmonella (zero tolerance) in a non-retorted food like the one in question is to submit the total lot to bacteriological test; an obvious impossibility or absurdity. We are told further that any level of testing short of complete destruction can provide nothing more than limited confidence regarding the untested portion.

If, for example, 60 separate units of packaged food taken from a carload are individually tested, and each is negative for salmonella, the sanitarian will have a 95% chance of being correct if he assumes that there will be no more than 5 positive packages per 100 units drawn from the same carload if the entire lot were to be subjected to test. There may be no positives at all in the next 100 units tested, or indeed in the whole carload, but the testing of 60 units, all of which are negative, gives him the aforementioned confidence limit and *nothing more.*

We have every reason to believe that these statistical considerations are now known to the participants of the prototype self-certification program. Of necessity, they must have developed working criteria that provide less than 100% confidence that the product being produced has zero salmonella. In other words, they must have established a schedule of testing for salmonella that may fit the description of a practical equivalent of zero.

The Practical Equivalent of Zero

This may be a good place to explore the concept of microbiological criteria.

Everyone is familiar with the numerous problems related to residues of pesticides and other unintentional chemical additives, and the fantastic problems created by the incredible sensitivity of analytical methodology. Without going into the harrowing details, the situation can be summed up by saying that by one means or another, the

concept of an insignificant residue is being developed, even though the substances can be detected and in some cases measured quantitatively at lower levels. It is agreed that at certain dilution levels, the chemicals involved represent no hazard. An acceptable level so designated deserves to be called "the practical equivalent of zero."

Clearly this is what we need for salmonella, and eventually for many other microorganisms that occur in processed foods (not retorted or otherwise sterilized and hermetically sealed). However, unlike chemical compounds, microorganisms cannot be diluted or reduced to the vanishing point. If there is only one organism in 100 grams of a food, there might be none at all in 99 single gram portions, but then there must be one in the hundredth. If the sample drawn by an inspector includes the one hundredth gram, the test result will be positive; otherwise the test result will be negative. In other words, testing for viable microorganisms is basically a go-no go procedure; a result is either positive or negative, and there is nothing in between.

As mentioned earlier, it is the hope of many that after reviewing the NAS/NRC Salmonella Committee's report, something akin to the practical equivalent of zero will be promulgated.

We should not leave this topic without making reference to the problem of discrimination. Assuming that a means is found to develop a working definition of zero, the next question is, "Should the identical definition be applied without discrimination to every processed food or food ingredient?" Both experience and reason suggest that the answer to this question should be in the negative. If the food is such that low initial levels of salmonella can become much higher by the time the food is eaten by the consumer, such a food justifies the most rigorous criteria. This description does not fit a large proportion of processed foods, that is, those for which there is practically no chance that a single organism in a unit of the food will be any more than a single organism when the unit of food is eaten. It seems logical therefore to apply different criteria to different types of foods.

GMP

No one will argue that GMPs are not basic to sanitation. The current GMP proposal published in the *Federal Register*, December 15, 1967, was, however, cast in the form of a regulation. In comments on this proposal prior to its publication, it was suggested that if and

when the GMP regulations are adopted, a food might be condemned if it was not produced in accordance with the regulation, irrespective of the sanitary condition of the finished food product.

Being put forth as it was in the midst of the confusion created by the zero tolerance situation, the GMP proposal was probably intended to be part of the general war against salmonella. As such it will be helpful. The proposal does not however contribute much in terms of the concepts in sanitation that we have been discussing. The published proposal contains no provision for, nor recognition of, the value of objective tests, controls, or corrective measures used during or after the processing operations. Emphasis is placed instead on routines and procedures in a way that strongly suggests a ritual. Atavistic is an adjective that almost seems appropriate.

A ritualistic approach to sanitation is not without some merit, but to place major reliance on it must be considered a rather primitive approach in comparison to objective quality control testing.

From one point of view, the issuance of the GMP proposal and the time and effort devoted to studying and arguing about the details could be considered an unfortunate diversion. It would be unfair, however, not to recognize the educational value of the discussions.

Plant Evaluation Systems

More or less coincident with the appearance of the GMP proposals, a growing series of check lists has been developed for internal use by the FDA. These, called PEVs, have been distributed to industry. Each one covers a single type of food or food ingredient. They are designed to be completed by Food and Drug inspectors. The check list is a series of coded questions, each of which can be answered yes or no. The questions deal with plant equipment and procedures, and they seem to be clearly related to the provisions of the GMP. Some people have viewed PEVs as scorecards of GMP "compliance." The system is clearly computer-oriented.

On at least one occasion, it was reported that an Health, Education and Welfare (HEW) official said that PEV reports would not be used as a kind of quality scorecard of an individual food processor. An appropriate response to this statement is, "Maybe *you* won't, [use the report as a scorecard] but the computer will."

So be it. Computers are here to stay. If the programmers handling the PEV reports do not improvise sanitation concepts all their own, there may come a day when all our sanitation problems can be handled by arranging to have their computers talk to our computers.

FLAGs

A more recent development, and one of considerable interest and possible portent for the future, is the development by FDA of certain microbiological criteria called Field Legal Action Guides, or FLAGs. The acronym itself seems portentous.

Covering frozen cream pies and frozen breaded shrimp, the two FLAGs so far developed are specific as to the microbes to be tested for, the number of samples to be tested, and how the results are to be interpreted. Most interestingly, the criteria did not amount to a zero tolerance for the organisms involved; not salmonella, to be sure, but not "zero" either.

Although intended for internal use by FDA, we understand that the FLAGs were not viewed by industry with much enthusiasm, mainly because, as it was claimed, they did not relate a potential health hazard to practical operational procedures in a reasonable way. This is a believable and an almost predictable result. Unless a way can be found to handle the development of such criteria, in a reasonably objective manner, via industry and academic or scientific participation, we may as well look forward to endless controversy.

Nothing said so far should be taken to mean that we have any criticism of what might be called conventional sanitary practices. Far from it. These practices are just as important as ever. You could even say that, in the face of the many innovations in food handling and food processing that occur every day, they are more important than ever.

Inevitably, however, the end result of sanitation in food processing must be judged by the microflora of the finished food. Salmonella are not, unfortunately, the only members of this microflora, and consequently it can be argued that the paramount need of the food industry, to paraphrase a slogan about fifty years old, is to develop a series of "open criteria openly arrived at."

If the food industry would like to chart a course towards these criteria, somewhere between the Scylla of Zero Tolerance and the

Charybdis of FLAGs, it should consider the development, industry by industry, of voluntary codes or criteria based solidly on considerations of safety and public health.

The public and official acceptance of these criteria will naturally depend on their demonstrable soundness technically and practicably, and it is recommended that industrial groups or associations work openly at developing their criteria under the auspices of organizations like the Food Research Institute of the University of Wisconsin. Organizations like ASTM (The American Society for Testing & Materials) and USASI (United States of America Standards Institute) are also available to assist industry groups in tasks of this sort.

Summary

The experience of the last two years can he summarized as follows:

1. Microbiological criteria for foods are seriously lacking in large segments of the food industry.

2. If the scientific community, which includes Government and Industry, does not develop reasonable and workable criteria, we can look forward to further confusion and frustration from either zero tolerance on the one hand, or arbitrary FLAGs on the other.

Mr. Franklin Depew, in the June 1968 issue of *FDA Papers*, may have summarized another changing concept when he wrote:

> The amendments (to the Federal Food, Drug and Cosmetic Act) indicate a basic trend away from a merely regulatory statute (1) separating judicial and legislative power and (2) establishing an objective standard of conduct which may be tested in the courts. *In contrast, the amendments have added and developed a philosophy of regulation by license or administrative expertise.* The factors of consumer protection were found to be of such overriding importance as to warrant the impositions of these restrictions on the freedom of action of the industries involved, even though they might operate to hamper research. (emphasis supplied)

The trend toward regulation by license or administrative expertise described by Mr. Depew need not engulf the processed food industry if we accept the concept that microbiological criteria, that are reasonable and practicable, are worthwhile and can be developed by cooperative effort. **[The End]**

Intensified Drug Inspection As Industry Sees It

By ALLAN S. KUSHEN

Mr. Kushen Is a Divisional Counsel for the Schering Corporation.

IT WOULD BE PRESUMPTUOUS of me to attempt to speak for industry or any substantial portion of it—and indeed I do not. I speak merely as a sometime inspectee and observer of inspections for close to fifteen years, and what follows are my personal observations purely.

A brief review of the underlying statutory authority for drug inspections is in order first. Section 704(a) of the Federal Food, Drug and Cosmetic Act[1] authorizes designated Food and Drug Administration (FDA) employees "to enter, at reasonable times, any factory, warehouse, or establishment in which . . . drugs . . . are manufactured, processed, packed, or held, for introduction into interstate commerce or after such introduction . . ." Inspection "at reasonable times and within reasonable limits and in a reasonable manner" must be "commenced and completed with reasonable promptness." It extends to "all pertinent equipment, finished and unfinished materials, containers, and labeling therein." The Drug Amendments of 1962 expanded the scope of the inspectional authority for prescription drugs. In the case of locations where such drugs "are manufactured, processed, packed, or held," the inspection may extend to "all things therein (including records, files, papers, processes, controls and facilities)" which bear on whether they "are adulterated or misbranded . . . or may not be manufactured, introduced into interstate commerce, or sold, or offered for sale . . . or otherwise bearing on violation" of the Act. Specifically exempted from the expanded prescription drug inspection authority are financial and pricing data, sales data (other than shipment data), personnel data (other than data

[1] 21 U. S. C. § 374(a).

concerning qualification of technical and professional personnel performing functions subject to the Act), and research data other than those subject to the record-keeping and reporting requirements for new drugs and antibiotics.

The Drug Amendments of 1962

Let us examine for a moment the extent to which the Drug Amendments of 1962 have, in fact, enlarged the scope of FDA's inspection authority over places making or handling prescription drugs. The only *documents* relating to non-prescription drugs subject to inspection are those which constitute labeling as defined by the Act. As to prescription drugs, however, such documents as batch records, assay reports, complaint files, shipment records, and certain kinds of research and personnel data, are all amenable to inspection—*but only if these records bear on some violation of the Act.* Thus, they are subject to inspection only upon some showing by FDA that a violation may have occurred—such as a physician complaint alleging such a violation; an FDA laboratory report showing a misbranding or adulteration; or evidence indicating shipment of a new drug not covered by a New Drug Application (NDA) or Investgational New Drug (IND) exemption. A fishing expedition into a manufacturer's records to determine whether some violation might have occurred is simply not permitted by Section 704(a). Section 510(h) of the Act,[2] also added by the Drug Amendments of 1962, contains further language with respect to drug inspections. Section 510(b)[3] requires registration of all drug manufacturers, whether or not engaged in interstate commerce. Section 510(h) makes all registered establishments (and I understand that there are approximately 10,000) subject to Section 704 inspection at least once every two years. The original concept here was that every drug-producing establishment in the nation, regardless of size, have a thorough general factory inspection at least biennially. It has been my observation, however, that that aim has not always been fulfilled, due to FDA personnel shortages and self-imposed priorities which allocate enforcement and inspectional efforts primarily to companies having the most widespread distribution. I believe that this is a deficiency in the system which may allow too many marginal operations to introduce drugs of questionable integrity into regional marketplaces. In particular, the smaller drug manufacturer should be subject to Intensified Drug Inspection Program (IDIP) to the same extent as the major producer.

[2] 21 U. S. C. § 360(h).

[3] 21 U. S. C. § 360(b).

My earlier remarks indicated that FDA inspectional authority, while extensive, is not unlimited and, even as to prescription drugs, does not offer *carte blanche* to the inspector. You heard Mr. Goodrich yesterday describe the two 1967 Supreme Court cases which mandate the use of warrants upon a refusal to permit inspection.[4] Thus, a further limitation has, at least in theory, been imposed upon FDA's inspectional authority.

Yet we are given to understand that the inspection warrant has had to be used most infrequently by FDA since these decisions. Moreover, those of us who have been closely connected with drug inspections, both before and since the passage of the Drug Amendments of 1962, can cite innumerable instances of the FDA inspector asking to inspect, and being allowed to inspect, documents or other things, to which, strictly speaking, he is not entitled under the Act. This seemingly complaisant attitude does not stem from laziness or ignorance of the law on the part of industry, nor even from a subconscious desire to "do in" our employers or clients. Rather it is a recognition of the fact a knowledgeable inspector on a meaningful mission may have need for access to certain things to which he is not, under a literal interpretation of Section 704, entitled. It is a further recognition that it is, in the long run, in the best interests of our companies to give full cooperation to FDA when it is within reason to do so.

Inefficiencies in the FDA System

It is, however, most frustrating to the would-be cooperative inspectee to be told, for example, at the conclusion of a relatively unimportant inspection by a rather inexperienced inspector, that he wishes to report his findings to the president of the company, and only to the president. It is not productive of anyone's time for a company to be sought to be inspected for current production on drugs long-since discontinued from its line or manufactured in fact by its competitors. The inspector of the packaging line who dips his hand into it to procure a container or two violates many companies' own internal Good Manufacturing Practices (GMPs) and runs the risk of severe tongue-lashing (or worse) by the zealous line supervisor who has been taught that such a practice is a mortal sin. The dispatching of one or two inspectors on a fifty-mile round trip simply to pick up routine assay samples is certainly an inefficient method

[4] See also Edelman, Sidney, "Search Warrants and Sanitary Inspections—The New Look in Enforcement," 23 FOOD DRUG COSMETIC LAW JOURNAL 52 (February 1968)

of accomplishing a necessary objective. Telephone or mail requests would be promptly honored by most companies, at much less cost to all concerned. A request for production of a costly IBM distribution printout for other than recall purposes is unreasonable and should not be honored. Finally, there is something wrong with a system that makes it easier for an FDA inspector to procure from a company, than from his own Washington headquarters, copies of communications to or from FDA.

IDIP and Voluntary Compliance

As we heard yesterday, a recently added ingredient to this industry's regulatory alphabet soup is IDIP—Intensified Drug Inspection Program. This is an innovative undertaking whereby an FDA team—usually inspectors and chemists—conduct a painstaking and meticulous inspection of a drug plant. As you heard Commissioner Ley report yesterday, it was FDA's aim that 500 drug plants receive an intensified inspection during a two-year period. He also stated that FDA will apparently fall far short of that goal. We assume that FDA's drug inspectional staff will not become so deeply involved in IDIP that specific problem areas go undetected. Some way should be found, moreover, to extend the program to all establishment registrants within a reasonable time. These two equally important but divergent goals lead one to the inevitable conclusion that FDA is overextending itself with this project.

The intensified inspections conducted thus far have varied in length between four weeks and six to nine months. Intensified inspection differs only in degree, not in kind, from the general factory inspection. It should be viewed by both FDA and industry essentially as an educational and voluntary compliance tool—not as a regulatory one. I noted Mr. Barnard's comment yesterday that the ultimate goal of IDIP is production of legal products or cessation of manufacture of illegal products. One might erroneously infer from this that companies subject to IDIP are not now in compliance. This is misleading, and I am sure that Mr. Barnard did not intend to mislead. IDIP depends for its success upon complete and wholehearted cooperation of the inspected company—particularly as certain of the areas and means of inquiry are not within the purview of Section 704. It therefore behooves FDA to treat this program primarily as one to foster the four C's (Communication, Collaboration, Cooperation, Compliance) which are the theme of this meeting, through its educational and voluntary compliance values. On the other hand, any manufacturer foolish

enough to ignore important and sound adverse findings significantly affecting the integrity of its output should not be surprised at finding itself at the receiving end of the injunctive process.

How does IDIP work? The program is too new for any significant quantity of information to have been collated as yet. Moreover, some of the details undoubtedly differ from District to District. What follows is based on observation of a small cross-section of intensified inspections.

Preparation Prior to Inspection

When your company is selected for an intensified inspection it will be notified in advance and invited first to confer with appropriate District FDA officials and the inspectional team. This in itself is a significant improvement over the practice heretofore with regard to general factory inspections—the sudden appearance at the door of an inspector conducting such an inspection regardless of a company's vacation schedules, seasonal production schedule fluctuations, etc. This first meeting, usually held at the FDA District office, is most important to the success of the intensified inspection. It is at this meeting that the ground rules will be set and that rapport will hopefully be established between inspectors and the key company personnel involved in the inspection. Bring to it your management personnel in the relevant areas—your production manager, your quality control manager, and those whom they might choose to serve as liaison or contact with the inspectional team. I cannot stress too strongly the importance for a company to train one or more quality control and/or production-oriented individuals to serve as contact for all FDA inspections. Such people can be invaluable assets in conserving the time of key company personnel, in reporting daily to management the details of an inspection and the inspector's findings, and in guiding the inspector so that his time is not wasted. Finally, many companies send house counsel to the initial meeting with the intensified inspection personnel.

Before you go to this meeting, have in mind those ground rules which you wish to advance. When you arrive, learn something of the background of the inspectional team. If they are not thoroughly experienced and seasoned drug inspectors, the inspection will be a failure. If your immediately upcoming production schedules are not representative of your total yearly output, so advise the FDA. Find out whether the inspectors intend to remain at your plant steadily throughout the inspection period, or whether they will alternate one or two weeks at the plant and the next one or two weeks at their

office to prepare reports. Make certain that if two or more inspectors are involved they understand that they cannot split up and visit two or more areas separately and simultaneously unless you have sufficient liaison personnel to accompany all inspectors. Be prepared to suggest whether it would be more efficient for the inspectors to follow given products one by one through their entire production cycles or whether it makes more sense for the inspection to be conducted on a department-by-department basis. If you plan transfers of manufacturing or quality control activities in the near future to other locations, so advise the FDA. Find out whether the inspection contemplates review of records not involved directly in manufacturing or quality control functions—such as medical or complaint files. Know in advance what your attitude will be to a request to inspect such files in a wholesale fashion. Learn whether the inspectors will wish to take photographs; if you decide to permit this activity, make certain that you arrange to receive duplicates of all photos taken. Obtain a commitment that questions to line personnel will be channelled through their supervisors or your inspection liaison man. Thorough understanding and agreement on these matters at the outset will help to assure a smooth and useful inspection.

Meanwhile, what should you be doing "back at the ranch?" If your plant is an infested pesthole, believe me, it's too late to get it into shape for the intensified inspection. I'm assuming, however, that none in this audience operate such enterprises. You do your company and your people a disservice, however, if you do not assemble your supervisory personnel in advance of the inspectors' arrival and advise them in a clear and straightforward fashion what is about to occur. Indeed, you will all be very well off if you go back to your companies tomorrow and undertake a "dry run" for an intensified inspection. It should include, among other things, scrupulous review of all manufacturing and quality control practices to determine that they comport exactly with your written procedures and instructions. This kind of exercise should not, of course, be an isolated or one-shot deal, but should be part of every company's continuing program of self-regulation. Normally the inspectors will render daily oral and weekly written reports of their findings, and a final written report. You should be prepared to respond promptly and forthrightly to all findings and recommendations. Your response will be oral initially but under some circumstances might ultimately be reduced to writing. If you decline to accept any recommendations, make sure that you have good reasons and that these reasons are communicated

in detail to the inspectional team and to its supervisors, and even to the District Director if they involve items of major magnitude.

What Does Industry Require of the FDA?

In September the New Jersey Pharmaceutical Quality Control Association and the FDA jointly sponsored a Seminar on GMPs for the Drug Industry. The words of one industry speaker are particularly relevant to an understanding of the proper objectives of the intensified drug inspection:[5]

> We look to the new FDA program of intensified drug inspections as an importantly useful means to alleviate . . . problems [of understanding and communications]. I believe that if each inspection in the program is carried out in an atmosphere of real cooperation much will be accomplished. Superficial findings based on less than all the facts will be eliminated. The manufacturer will have the benefit of carefully studied recommendations which can but improve his control. But to be beneficial, the recommendations must be based on a thorough, exacting exploration of all the facts by the inspector; the same kind of exacting performance FDA expects of the industry. Those manufacturers who are not willing to benefit from such study will, through enforcement, be required to improve or to go out of business. And a channel of communication will have developed leading to greater FDA understanding of the industry problems . . .

Another speaker at this same Seminar[6] addressed himself at one point in his presentation to "What Industry Wants from the FDA on the District Level."

> Industry wants above all, fairness—an even-handed application of the Law. Industry wants really good inspections. They want to deal with inspectors and officers whose knowledge and competence inspires respect. Industry wants the FDA to take decisive action to rid the Industry of those few firms whose continued disregard of the law of the land brings dishonor and lack of confidence to an industry which, when all is said and done, is and should remain a monument to man's conquest of disease, pain and often, death itself.
>
> Industry wants in actions, not words, a clear indication that there is a basic willingness on the part of the FDA to be cooperative.
>
> Industry wants positive assurance that the FDA speaks with a single tongue. There must be some real reliance by a company, that if it cooperates wholeheartedly with the FDA on a voluntary compliance basis it does not wake up some morning to find that it is faced with a regulatory compliance situation leading to the courts.

I think you will agree that we are well on the way toward achieving these goals when I tell you that those words were spoken not by an industry representative, but by the Executive Officer of the New York FDA District. **[The End]**

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[5] Williams, Richard, "GMP—An Industry View," presented at the Seminar on Good Manufacturing Practices for the Drug Industry, Nutley, New Jersey, September 25, 1968.

[6] Silver, Kenneth A., "Requiem for the Adversary Relationship?" presented at the Seminar on Good Manufacturing Practices for the Drug Industry, Nutley, New Jersey, September 25, 1968.

Teamwork for Consumer Protection: A Panel Discussion

FDA's Programs

By JOHN W. SANDERS, JR.

Mr. Sanders Is Technical Advisor to the Office of the Commissioner of the Food and Drug Administration. An Article by Theodore R. Gamble, the First of Four Based on the Theme of Consumer Protection, Appeared in the January Issue of the Journal. The Three Remaining Articles are Presented as a Group in This Issue.

UPTON SINCLAIR'S LEGENDARY PACKINGHOUSE WORKER, Jurgis Rudkis, would be astounded today at this conference or hearing this panel discussion on "Teamwork for Consumer Protection." He would be convinced that the old, overworked maxim *caveat emptor* is becoming obsolete in today's consumer vocabulary.

However, teamwork for consumer protection is neither new nor novel. Within a year after the advent of Jurgis Rudkis, the Pure Food and Drug Act was passed and the first annual report of 1907 stressed teamwork—teamwork by industry, by state officials, by federal officials, and by the consumer. "One of the most gratifying features . . . has been the almost unanimous support accorded by the trade to the principles of the act. . . . Supported by public opinion, and the active collaboration of producer and consumer . . . The rigorous enforcement of the Federal food law will be greatly facilitated by the cooperation of the several states, and to this end inspectors have been instructed to establish cordial relations with the State food officials."

During the intervening years the consumer, the producer and the official—local, state, and federal—have progressively improved programs that assure every consumer the best food and drugs in the entire world.

This is continuing. On October 18, 1968, the White House released a list of twenty major consumer bills passed during the Johnson Administration. As impressive as it is, even this list does not include all the legislation favorable to the American Consumer. In addition, every state has also enacted consumer protection legislation. The affected industries have supported these bills.

The Health Planning and Public Health Service Amendment

The White House list did not include the Comprehensive Health Planning and Public Health Service Amendment (PL 89-749) of 1966, which could develop into a landmark in teamwork for consumer protection. As my contribution to this panel, allow me to briefly discuss some facets and impressions of this Amendment.

The Amendment authorizes the Surgeon General to make grants to states for Comprehensive Health Planning, and also authorizes the Secretary of (Health, Education and Welfare) HEW to arrange for assignment of officers and employees of states to the Department, and assignment of officers and employees of the Department to states. The Secretary must determine that such assignments will aid the Department in the more effective discharge of its responsibilities in the field of health. This interchange of personnel with states may be for any period of time, up to two years.

The interchange may be carried out through (1) a detail to the Department or the State, or (2) appointment by the Department or state while on leave without pay.

There are a number of provisions of the Amendment which are advantageous to the Department of HEW, the state agency, and the federal or state employees. Department employees on assignment to a state may retain all their rights and privileges under civil service. In case of assignment while on leave without pay, the state compensation may be supplemented to the extent of the federal salary. Operation expenses necessary to the assignment may come from Department or state funds or both.

State employees may be assigned to the Department without regard to civil service laws, but if compensated from Department funds they receive certain federal fringe benefits. Regardless of the type of assignment, such persons are governed by certain conflict-of-interest provisions and the Federal Employees Compensation Act. Operation expenses necessary to such an assignment may come from the Department.

Such grants, or other forms of assistance to the states are neither new or novel. The first of these, the Merrill Act of 1862, established our land grant colleges. Many similar measures have established other programs subsequently. All further a true partnership between the federal government and the various state and local governments. Even before the Comprehensive Health Bill, HEW, through the Public Health Service, administered grants and exchanged personnel with the States.

The Illinois Program

The Food and Drug Administration (FDA) had not participated in these programs prior to my assignment to the Illinois Department of Public Health in November 1967. My work of over 30 years for or with state officials helped me acquire a first hand knowledge of the organization and implementation of food and drug laws. The Illinois assignment afforded me the opportunity to work more closely with state officials and assist in the implementation of some new programs for better consumer protection.

At the time of my assignment the Illinois General Assembly had just enacted a Food, Drug and Cosmetic Act which actually extended the Association of Food and Drug Officials of the United States (AFDOUS) Bill, encompassing most provisions of the Federal Act and automatically adopting federal food standards and most federal regulations. For the first time, all responsibility in this field was given to the Illinois Department of Public Health.

At that time, Dr. Franklin Yoder, Director of Public Health of Illinois, aptly described the scope of consumer protection: "All elements of the health team must work together to eliminate consumer risks. When we speak of this health team, we are thinking not only of federal, state, and city government officials, but all those in private industry, the academic world and all professionals with interests in this area." Your attendance and participation at this joint Educational Conference confirms this.

Much has been written and said about the Illinois program. *FDA Papers* for March 1968 carried an excellent, informative article on "Illinois' New Food and Drug Act" by Douglas C. Hansen. This article discussed the legislation in detail and stressed federal-state partnership. Last June at the AFDOUS meeting in Hartford, Connecticut, Dr. Yoder outlined his short and long range plans for implementing this Act.

The Division of Food and Drugs of the Illinois Department of Public Health, though less than a year old, now has the nucleus of an organization which can grow and eventually carry on a cooperative, coordinated, harmonious program of maximum consumer protection in the food, drug and cosmetic field.

We have negotiated written cooperative food protection programs with a number of county and city health departments, giving the county or city officials total responsibility in certain areas, that is, food-service establishments, retail food stores, etc., and giving the state total responsibility in certain other designated fields, that is, food warehouses, food processors, etc. In order to ensure uniform protection and the equivalent levels of compliance the State Health Department, under this program, makes periodic evaluation surveys, giving a full oral and written report to the local officials.

In addition, we have worked closely with the Chicago District of FDA maintaining almost daily contact in joint planning conferences, joint work plans, joint inspections and co-sponsorship of industry and consumer workshops.

We have planned a program of consumer education, which should be operative next year. It will be integrated with the FDA program. We have developed narrative completion-form inspection reports that are brief, factual and informative. At the present time only two types are used—one for foods and one for drugs—and a copy is always left with the firm. We hope to develop more specialized reports which will be accepted by the industry and other cooperating enforcement agencies.

Wisconsin Participation

Last July I was given a similar three-month assignment with the Wisconsin Department of Agriculture, working directly with the Secretary of Agriculture and his staff. We studied the Wisconsin food and drug acts (basically patterned after the 1906 Federal Act), compared them with the proposed AFDOUS Uniform Bill, and prepared plans for the organization and implementation of a program similar to that in Illinois.

The Wisconsin Department of Agriculture has negotiated written cooperative food protection programs with the Minneapolis District of FDA and a number of city and county agencies. These programs are similar to those in Illinois.

During the past several months, the Agriculture Committee of the Wisconsin Legislative Council has held a number of regional hearings on a food law patterned after the AFDOUS Bill. Numerous industry and consumer groups have testified in favor of this bill.

Last August, John Mahre, who had extensive experience in the FDA Office of Federal-State Relations and with the State of Washington, was given a similar three-month assignment with the Minnesota Department of Agriculture. His progress is very encouraging.

During the past year, I have received numerous inquiries from state officials about assignments under this Amendment. The consensus appears to be that such assignments will further cement federal-state relations and foster uniform legislation, uniform interpretation, and uniform compliance.

I have discussed only one phase of this "Partnership for Health" Act. If we are to attain the basic objective of this legislation, there must be a substantial exchange or dual assignment of experienced personnel. Mr. Ralph Bernstein, formerly Assistant Director, New York State Department of Agriculture and Markets, was similarly assigned as one of nine Regional Assistant Commissioners of Food and Drugs. I'm sure many of you heard Mr. Bernstein's report at the last AFDOUS meeting in Hartford. That report stands as a testimonial to the soundness of the program.

I believe that much good would come from a substantial extension of this program. I am also firmly convinced that a substantial interchange of personnel under this act will do much to unite and combine the total available resources toward maximum consumer protection.

At the present time, I am completing my two assignments, working with Illinois and Wisconsin. While attached to the Office of Commissioner of Food and Drugs, I am actually working directly for the Secretary of Agriculture of Wisconsin and the Director of Public Health of Illinois. I prefer to think of these assignments as working for the American consumer.

As indicated by the attendance at this Conference, we are all interested in consumer protection, not only as consumers, but also as industry representatives, attorneys, association representatives, officials, educators, etc.

In fact, I am convinced that all of us attending this Conference are actually working for the American consumer. Let's strive for every American consumer to participate more actively in teamwork for consumer protection.

New Ideas in Cooperation

By EATON E. SMITH

Mr. Smith Is the President of the Association of Food and Drug Officials of the United States.

THE SUBJECT MATTER OF THIS PANEL, "Teamwork for Consumer Protection," was never more timely or of more importance than it is today, from the standpoint of all regulatory officials—whether they be federal, state or local—and of members of one of the regulated industries.

Although I appear on the program under the designation of President of the Association of Food and Drug Officials of the United States (AFDOUS), I am going to speak primarily from my personal viewpoint and experience as a regulatory official in the Department of Consumer Protection, State of Connecticut. However, at the outset, I would like to place in the record three of the objectives of AFDOUS that spell "TEAMWORK"—namely:

(1) To encourage and support programs that will contribute to consumer protection, consistent with the broad purpose of the laws.

(2) To disseminate information concerning food and drug law enforcement and to assist in the official publication of the AFDOUS Quarterly Bulletin.

(3) To encourage and promote cooperative enforcement programs with federal agencies and between related enforcement agencies within each state.

These objectives certainly fall in line with the theme of this Joint Educational Conference—"The Four C's of Consumer Protection: Communication, Collaboration, Cooperation and Compliance."

We are truly living in an era of teamwork; never in my long experience have there been so many examples of teamwork between federal and state governmental agencies and industry for consumer protection. This is fine; this is good. But we must not stop where we are or stand still if we are to reach our goal of the utmost in consumer protection with the least possible duplication and unnecessary expenditures of our tax dollars.

I have taken the liberty of communicating with Webster to find out what he thinks the "Four C's" and "Teamwork" really mean. This is what I found:

Communication—"The act or action of transmitting facts or information."

Collaboration—"The act of working jointly with others willingly."

Cooperation—"The act of working together in a common effort."

Compliance—"The act or action of yielding to pressure or demand."
(We like to believe these days that in large measure compliance is being achieved without a great deal of pressure or demand.)

Teamwork—"Work accomplished by a number of associates with usually each doing a clearly defined portion, but all subordinating personal prominence to the efficiency of the whole."

Now, there are several requirements for effective teamwork, and the first is that the members of the team have confidence in each other and know each other's special capabilities and limitations—and all must work together "on the same side of the street." We all have a critically important job to do, a job that cannot be done by any single agency—federal or state, public or private—but which can be done by all of us working together. No single agency can do the job alone.

And in order to really make this team work, all of us who are involved in this important job must coordinate plans and programs, not alone, but together, to get rid of a great deal of the duplication of effort that now prevails and to eliminate the expenditure of duplicating resources.

As I said earlier, we have seen increasing use of the federal-state partnership—working as a team to get the job done.

I would like to emphasize certain areas that are sound and some of the things that the state can do to make the team a winning one.

T W X Alert

One of the major barriers to improved relationships between state and federal officials is a lack of quick and effective communication. The New York District of the Food and Drug Administration (FDA) has been experimenting with a *teletype network* connecting the various consumer protection agencies in the area around New York

City. This is an effective, *two-way* communication system that is of relatively low cost, known as the *Teletype Alert Network*. This has been reported to be a definite success in the close-knit New York area.

The Boston District of the FDA has requested (and it is my understanding they have been granted) permission to set up a pilot operation to determine if a more widespread group of agencies can achieve similar benefits from such a system which makes possible the exchange of a much larger volume of information at a rate much lower than telephone rates, and furnishes a written record of the messages.

I can say from first-hand knowledge that this teletype system can be an area for better teamwork and cooperation in our consumer protection activities. We have installed this equipment in my state and it is now in operation. We are now receiving messages directly from Washington and the New York District, which makes it possible for us to have information immediately upon its release. A fine example is a recent nationwide recall of an article that was announced late on a Friday, and Connecticut was the only state in the New England area to have such information prior to its reaching the news media. I know you all realize how important this is.

I believe this type of network communication is necessary among officials if we are to increase our ability to work together and to reduce the duplication of effort which has gone before. The teletype facility is a good example of teamwork for consumer protection

Food Standards Committee

I would like to turn to another approach to teamwork with which I am very familiar, and that is the Food Standards Committee. This Committee was established by the Commissioner of Food and Drugs, more years ago than I remember, to represent the views of state food control officials in the area of food standards, and to function as a source of advice and consultation to the FDA Commissioner in the discharge of his statutory responsibility for food standards development. The committee consists of nine regular members, seven of whom are state regulatory officials (one from each of seven geographical regions of AFDOUS), and two members of the FDA, one of whom is the Director of the Office of Legislative and Governmental Services—Paul Pumpian, who is now Chairman of the Committee.

I've had the pleasure of serving on the Food Standards Committee and I would like to say it has been upgraded in its importance in advising the Director of Legislative and Governmental Services and, through him, the Commissioner of Food and Drugs, regarding those areas in which the development of food standards would, in the committee's opinion, aid state and federal regulatory officials in administering their consumer protection programs. The committee serves as a liaison between the Commissioner of Food and Drugs and the state regulatory officials in the various geographical AFDOUS regions in all matters pertaining to food standards. This committee is a fine example of "teamwork for consumer protection."

Delegation of Authority to State and Local Officials

The next avenue of teamwork that I would like to elaborate on is the commissioning of state officials. Dr. James L. Goddard, then Commissioner of Food and Drugs, made the following comments in his address before AFDOUS in Kansas City, Missouri, on June 22, 1966:

> We still believe that state and local agencies play as prominent a role in protecting the health of this nation as any Federal agency does, and that state and local food and drug officials are indispensable partners in the enforcement of consumer protection laws.

I'm sure you'll agree that these are remarks that express teamwork.

Section 702(A) of the Federal Food, Drug and Cosmetic Act provides for delegation of certain specific authority to state and local food and drug or health officials. This delegation of authority permits state or local officials to carry out certain provisions of the Federal Act with the same authority as an FDA official. When acting under such commissioning authority, he *is*, in fact, an official of the FDA. FDA has issued such commissions to state officials who are qualified for and capable of carrying out delegated authority. I hope this will continue as it is an area of teamwork and partnership that cannot be over-emphasized.

In the New York FDA District, there is work in progress to provide a level of teamwork with the New Jersey Department of Health that should be superior to anything previously seen. To make this possible, a program of "reciprocal commissioning" has been established. Already sixteen officials of the FDA have been commissioned by the state as special agents. This took place after the FDA inspectors passed a training course given by the state. A similar

training course by the New York District for State Inspectors is under way, and I understand that commissions to its graduates will be issued in the future.

Memoranda of Agreement and Understanding

Now let us move to another field of cooperation, partnership and teamwork. I speak of the signing of memoranda of agreement and understanding by FDA and the states to the effect that the state agency will be responsible for making all inspections of certain types of firms in the state. The Food Regulatory Section of the Virginia State Department of Agriculture and Commerce and FDA's Baltimore District have in effect such an agreement for the state to assume the responsibility for inspections in certain food plants. The State of Indiana and the FDA's Cincinnati and Detroit Districts have signed a memorandum of understanding for fiscal 1969 whereby the State of Indiana will be responsible for making all inspections of canneries and bottling plants within the state; and, in addition, activities involving pesticides will be shared. My own State, Connecticut, has signed an agreement with the Boston FDA District to assume the inspections of all bakeries and food warehouses, whether they are engaged in interstate commerce or not. Other areas are being explored in which cooperative planning would avoid duplication of effort.

These are just a few examples of this type of real cooperation and teamwork that is going on at the present time. This type of understanding and agreement is a real challenge to the states and augurs well for future activities in this area if the states live up to their responsibilities and do the really good job they are capable of doing. If states take over some of the work mentioned, it will relieve FDA for other work under its jurisdiction and will do away with a lot of the costly, needless duplication of inspections that serve no useful purpose to the agencies involved, and that particularly must be a thorn to industry.

In broadening this theme of cooperation and teamwork, the Minnesota State Department of Agriculture has become the first state agency to take part in FDA's pilot plans for industry self-regulation, in a cooperative effort between the State and federal agencies in an arrangement entered into with the Green Giant Company. This new project is an example of teamwork among a state and federal government and industry, providing for a full exchange of information be-

tween the firm and the regulatory agencies, to attain the goal of better consumer protection through increased industry initiative. This could very well be a forerunner of additional similar tripartite agreements.

While we're talking about federal/state teamwork, let us not forget the many agreements between the United States Department of Agriculture, Consumer and Marketing Services and nineteen or more states who have signed agreements under the United States Wholesome Meat Act. And there is the teamwork project that is in progress by the Alaska Department of Health and Welfare for its inspectional personnel to accompany District FDA inspectors during fishery inspections in Alaska.

I may also mention the agreements that were in effect between the FDA Bureau of Drug Abuse Control and many states, that have been since passed on to the Department of Justice, Bureau of Narcotics and Dangerous Drugs. These involve participation by the states in the Drug Abuse Control program whereby state agencies have assumed enforcement responsibilities at the retail drug store level, thus allowing the federal agency to concentrate special activity toward the diversion of stimulants and depressant drugs at levels other than retail.

Cooperation with AFDOUS

In some of the past years one of the complaints voiced by state people was that FDA often did not make contact and communicate with them on matters of mutual concern. It seemed to the states that FDA would often formulate actions and complete them without giving the states a chance to voice their opinions and thus to take a part in formulating policy currently under consideration by the FDA. I can now see a change in this attitude, for which FDA deserves a compliment for the "good of the team." For example, FDA has established a policy of consulting with the AFDOUS Executive Board in many matters. For instance—the proposed regulations under the Fair Packaging and Labeling Act (FPLA) were presented by FDA to the AFDOUS Executive Board with a request for their comments. And when implementations of the Drug Abuse Amendment were being considered, a joint meeting of the AFDOUS Executive Board and representatives of FDA was held here in Washington to discuss them.

The Federal Trade Commission (FTC) and the Commerce Department, presently reflect the same policy of cooperation and team-

work with the state agencies in the implementation of the FPLA. This is all to the good, and I am sure it will continue on an enlarged basis. I read somewhere that one official of the FTC stated in a talk, and I quote:—

> The "Travel your own path" and "Look after your own garden" relationship presents the greatest possible danger in bringing about effectuation of common policy by Federal and State administrators of consumer legislation. It can lead to petty differences, confusion over enforcement, inadequate enforcement, and the absence of enforcement, to the detriment of consumer protection and the subversion of public policy.

Today's conference certainly affords us an opportunity for making an examination of the status of federal-state cooperation on consumer matters, and the outlook for the future. One good example is the FPLA and the fine attitude of cooperation and teamwork by the three agencies involved in this legislation.

Exchange of Personnel and Comprehensive Health Planning

Just a few words about Public Law 89-749 which has been in effect since November 3, 1966. This law gives an opportunity to state and local governments to upgrade their programs, and by so doing, better assure consumers of safe food and drugs. I'm just going to talk briefly about one provision of this important piece of legislation —and that is for the exchange, or interchange, if you will, of personnel between the states and the federal government. John Sanders, who preceded me on this panel, and who is Technical Advisor to the Office of the Commissioner of the FDA, can give you first-hand information on what the value of this law has meant to the State of Illinois; for it was he who was loaned to that state to assist in implementing its new Food and Drug law. This interchange of personnel appears to be a real opportunity for teamwork in making stronger state organizations. I am sure there will be a great deal more of this interchange in the future.

The opportunity for state officials to cooperate more fully with their counterparts in the federal government in scheduling industry workshops at the local level should not be overlooked when we are discussing ways and means to make for better teamwork. What better way can we all work together in exemplifying the "Four C's". I could elaborate on many other examples of teamwork among those who are vitally interested in consumer protection.

Of concern to all of us in government, and to those outside, is the duplication of services provided by government. We must work

hard to eliminate overlapping and duplication. We should all cooperate with our brother agencies for teamwork that must include joint planning—federal agencies planning with the states and the states planning with local governing agencies.

What can we, as state officials, really do to assist the team and make teamwork really work? We can cooperate, communicate and collaborate in the fullest measure possible, by really making it a "two-way street", to the end that we shall achieve the highest degree of consumer protection under the laws that we administer, with a minimum of duplication and no unnecessary expenditure of our tax dollars.

I would like to quote Alfred Barnard, of the FDA, who stated in a talk he gave on June 17, 1968, at Jackson, Wyoming:

> We are moving away from the old concept that the responsibilities for consumer protection should be split strictly on interstate, intrastate lines. We are seeking to move with the states more and more toward coordinated programs designed to ultimately yield the maximum consumer protection for the total consumer tax dollar, whether at the state or at the Federal level.
>
> As part of this process, we are developing and manning training programs to help strengthen capabilities at the state level, both inspectional and laboratory; we are seeking to develop a statutory basis for financial support for state programs. We are beginning to engage in the exchange of personnel between state and Federal offices, and we are urging our District Directors to engage in continuing planning conferences with our state level counterparts.

I think that Mr. Barnard hit the nail right on the head, in setting forth our mutual objectives toward teamwork in consumer protection. I sincerely hope that the part concerning financial support for state programs will become a reality in the near future. Many states need help in this direction.

At the dedication of the new FDA building in Washington, D. C., Secretary Gardner said that "The protection of the public calls for a vast collaborative effort. We intend to play our part in that collaboration, and we are going to expect others to play their role. The stakes are high."

The states must live up to this expectation, for only by a true federal-state partnership can the job be accomplished.

Let us continue on the road ahead, and by teamwork all along the line, end up with a winning team. By so doing, we may bring about such protection of the consumer in this great country of ours as we all, as consumers, deserve.

PMA's Role in Consumer Education

By SUE BOE

Mrs. Boe Is Consumer Information Specialist for the Pharmaceutical Manufacturers Association.

ANYONE CONNECTED WITH THE PHARMACEUTICAL MANUFACTURING INDUSTRY, and many connected with the government, know full well the great extent of teamwork between the two for the protection of the consumer.

As a matter of fact, there have been many comments about the obvious lifelong partnership between the Pharmaceutical Manufacturers Association (PMA) and the Food and Drug Administration (FDA)—the marriage, if you will—and they have been couched (if you'll pardon the expression) in the various gradations of appraisal to which any marriage is subject.

It is obvious that PMA and FDA share the same objectives—the preservation and strengthening of a system which produces the best, the safest and the most effective drugs in the world. It is also obvious that neither can do the job of serving the interests of the public alone, for the practical reason that the job is too enormous.

It is the responsibility of government to oversee the operations and facilities of manufacturers of drugs so that they adhere to official standards and label their products truthfully, and, in general, to prevent dishonesty and wrongdoing. But this mission cannot be fulfilled without the cooperation of industry, for the responsibility to manufacture commodities and to see that they are of as high quality as possible remains in the hands of private citizens in this country. A commodity, made by a reliable manufacturer who has identified himself with his product, still possesses the most reliable guarantee of quality no matter how many regulatory rules are enacted.

Reliable manufacturers have a long history of voluntarily initiating programs which demonstrate their awareness of their responsibility for quality production.

What is now our PMA Biological Section was founded in 1917 to work with the Public Health Service on the safety and potency of biologics, and the Quality Control Section was established in 1924.

Actually, a large proportion of the efforts of most of the PMA sections and the scientifically-trained members of the staff is devoted to matters concerned with the high quality of pharmaceutical products. Their activities are deeply involved with aspects of total quality control which begin with the earliest steps in design of the drug, then proceed through all the stages of formulation, preclinical screening and evaluation, clinical testing and evaluation, preparation and processing of the new drug application, pilot plant production, purchasing of raw materials, preparation of promotional material, and finally production and marketing of the finished drug.

PMA-sponsored sections have over the years worked with FDA, the United States Pharmacopeia and the National Formulary to establish methods of analysis, tests for purity, and drug standards. In recent years, standards for plastics used in various ways with drugs were drawn up under PMA sponsorship. In another area, PMA cosponsorship of the tissue registry of the Armed Forces Institute of Pathology, together with the National Institutes of Health, the American Medical Association and the FDA, is evidence of our interest in developing reliable pathological information on alleged drug reactions. To build better understanding of problems and needs with respect to drug safety generally, PMA sponsored the Drug Safety Commission.

Current Programs and Projects

Current examples of this type of industry initiative are the workshops proposed to FDA by PMA and currently being planned, to smooth out the operation of Investigational New Drug and New Drug Application (NDA) submissions. Additional workshops are being planned to discuss the submission of NDA supplements and adverse reaction reports.

Also, there have been collaborative projects in which both PMA and FDA have participated. One good example are the seminars on production controls held both in Wisconsin and Pennsylvania, planned by PMA and FDA and held under the auspices of the University of Wisconsin School of Pharmacy. Another example are the PMA-FDA Conferences that were aimed at increasing government and industry actions to curb drug abuse when that concern was still under FDA jurisdiction.

PMA member companies cooperate in helping FDA train its inspectors, too. As a write-up in the October issue of *FDA Papers* mentions, part of the University of Rhode Island's basic course for FDA inspectors is a visit to a large drug plant. A major manufacturer opens its entire plant for this facet of the course so that the students can gain the experience of practical application of their academic studies.

In other ways, too, PMA has provided assistance to FDA. To help FDA formulate its rules for Good Manufacturing Practices PMA supplies the industry's own established Principles for Total Control of Quality. When the then-Commissioner, Goddard, made an informal request for industry's views on the factors involved in preclinical drug safety testing, PMA's Medical and Research and Development Sections undertook the project of establishing guidelines on the conceptual relation of studies in animals to studies in man, and after months of careful work produced a scientific paper on the subject. In like manner, PMA worked carefully with representatives of the National Academy of Science and FDA in formulating the procedural guidelines for the Drug Efficacy Review Study required by the 1962 Food and Drug Law Amendments. PMA also supplied the outline of the expanded Summary and Evaluation page to be optionally submitted with drug applications under the New Drug Regulations.

Such evidences of industry initiative and cooperation for the betterment of the public's interest abound. Unfortunately, fulfilling responsibility isn't enough today. The public must *know* you are doing so and until last January the manufacturers of ethical drug products had made little coordinated effort to provide information about their activities and their products to the ultimate consumers.

This was based on a very sound reason. It had been considered necessary to inform only physicians and pharmacists of such matters, because it was recognized that:

> Prescription drugs are, in fact, *medical treatment in product form*, made available for *physicians* to use in the health care of patients. Such drugs are every bit as much a medical tool as is a scalpel—indeed in some cases they replace the scalpel because of their effective action.
>
> The medical treatment that prescription drugs provide is only available to the *patient* when ordered by the physician

on the prescription that he writes. Only if the patient is well enough, and the drug treatment can be self-administered, is the patient allowed to purchase and administer the medicine himself; if the patient is hospitalized, or the drug must be injected, someone other than the patient procures and administers the drug treatment even as other forms of treatment such as x-ray, surgery, or physicial therapy are administered.

When these concepts are understood—that prescription drugs are medical treatment and that the physician has not only the responsibility but also an obligation to the patient to determine and order, as precisely as possible, the exact drug treatment he wishes the patient to have—it is obvious that the *physician*, not the consumer, rightfully makes the decisions about the choice of prescription drug products.

The Consumer's Right to Know

Consumer information to patients has only been considered advisable as it has become obvious that persons not educated in the practice of medicine have *not* understood this role of prescription drugs in the overall medical management of their health, and have sought to make decisions which should rightfully remain the responsibility of physicians.

Because we believe this lack of understanding could in itself produce health problems, and because it *is* the consumer's money which ultimately pays for the medicine, whether directly at the retail pharmacy or indirectly through taxation when drugs are provided by governmental programs, the pharmaceutical industry has taken the stand that consumers are entitled to whatever information will assure them that they are getting the best possible products at the lowest possible prices.

Part of their assurance, of course, must result from the consumer's confidence in the judgment of his physician and the integrity of his pharmacist. But assurance will also result, we believe, from the consumer's added knowledge about how pharmaceutical products are discovered, developed, tested, produced and distributed.

It was to this end that a program of Consumer Information was inaugurated last January by the PMA. It's primary goals are to provide these facts about the industry, as well as facts about the

proper role of the consumer, as a patient, in his relationship to his physician and his pharmacist, and facts about the proper handling and use of prescription drugs.

Two pieces of printed material directed to the consumer have been produced so far. One is a folder, on which is printed a letter that explains the purpose of consumer information about drugs. This folder is used to hold whatever assortment of industry publications are sent to a consumer.

The second is a pamphlet, just off the press, called "The Medicines Your Doctor Prescribes—Facts For Consumers." Included are such suggested safeguards and guidelines as:

"If you go to more than one physician, be sure each one knows about all drugs you are taking."

"Be sure to tell your physician if you don't have a prescription filled, or if you don't use the medicine after you buy it."

"Do not ask a pharmacist to refill a prescription against your physician's orders."

"Do not share your medicine with someone else, and do not take medicine prescribed for another person."

"When you travel, take a copy of your prescription with you."

(In the pamphlet, these guidelines are amplified with justifying explanations).

At least one additional pamphlet, containing questions and answers about various aspects of the research, manufacturing and distribution of pharmaceutical drugs, is still to be produced. Other materials now available include two slide presentations, one about the industry and one about the problems related to drug abuse. Also, several speeches have been prepared for presentation to consumer audiences.

All of these consumer materials have been designed to supplement, not duplicate, the information already available about prescription drugs from other sources. For instance, the Council on Family Health, established by many of our member firms, provides information to promote safety in the home, so we limit our activity in that field. Similarly, the FDA provides information about federal regulations established to insure consumer protection, so our efforts in that area also are limited.

Teamwork for Consumer Protection

But the teamwork that exists between these representatives of both government and industry in this effort of consumer protection is abundantly evident. One example is the new kit of materials issued by the Council on Family Health entitled, "Safety Measures are Living Treasures." This was developed with the cooperation of what was then called the Injury Control Program of the United States Public Health Service.

Another example is the cooperation between FDA's consumer specialists, both at the national and the regional level, and PMA's consumer information specialists. I was invited to participate in a national meeting of these FDA district specialists, and since that time have been called upon, by them, to be a program participant in various regional FDA Consumer Conferences. The most recent of these was a Conference on the Use and Misuse of Drugs in Kansas City, where I was asked to deliver the keynote address. Also, at their invitation, PMA-printed materials were provided free of charge for distribution to attendees at each of these conferences.

In turn, we have informed other audiences to which we have spoken of various materials available from FDA; FDA representatives are frequent speakers at PMA meetings, and PMA member companies have made good use of the FDA film, "No Margin For Error."

This type of teamwork is not only logical and necessary from a functional standpoint, but serves another important purpose as well. It demonstrates to the public that each such participant recognizes the credibility and importance of the factual contribution that is made by the other participant, and that teamwork between industry and government does indeed exist. In such a framework, the other evidences of government and industry teamwork for consumer protection that I mentioned earlier can be called to attention.

After all, in this age of consumer paranoia, consumer confidence needs all the reinforcement that can be provided—particularly in something as vital as the drugs which may mean life or death.

As we said earlier, doing a good job is only half of the answer. Insuring public awareness of it is the other half—and our Consumer Information program hopes to help provide that awareness. We hope FDA will be part of the team in this effort, too. **[The End]**

Has the Pendulum Swung Too Far?

By VINCENT A. KLEINFELD

The Following Article Was Presented at the Research and Scientific Development Conference, the Proprietary Association, in New York City on December 5, 1968. Mr. Kleinfeld Is a Member of the District of Columbia Bar.

IT TOOK FIVE YEARS to effect passage of the Federal Food, Drug and Cosmetic Act in 1938. As is always the case when social and economic legislation is sought, there was bitter opposition both from those who wanted no further controls and those who really wanted licensing and sought to put industry in a straitjacket. In between, there were many in industry as well as in the Food and Drug Administration (FDA) who realized that there were serious defects in the 1906 Act which had to be remedied, and that a stronger law would inure not only to the benefit of the consuming public but also to the reputable manufacturers in the food and drug industries who wished to market safe and effective products but felt that a complete shackling of industry was not required.

Those in industry who had this real vision realized that, just as in Gresham's Law bad money drives out good, unscrupulous competition by those who marketed debased products with deceptive representations would tend to force others into the same category. Again, as in the case of other social and economic legislation, a series of compromises had to be made, and some of the groups which had sought unnecessarily restrictive legislation threw up their hands in horror and declared that the 1938 Act was worse than none at all. This was most unrealistic.

New Provisions of the 1938 Act

The Federal Food, Drug and Cosmetic Act of 1938 was far stronger than the 1906 law and was a long step forward in conveying greater protection to the public. Most of the loopholes in the earlier

statute were plugged. There were provisions for factory inspection and for control of therapeutic devices and cosmetics. The definition of "drug" was expanded to include a great variety of products, including obesity remedies. Drugs were declared to be misbranded if their labeling was false or misleading in any particular. The labeling of drugs was required to contain adequate warnings and directions for use. A drug would be misbranded, even if its labeling contained true and accurate representations, if material facts were not disclosed or a misleading impression was conveyed.

The "distinctive name" weakness was removed, and the FDA was authorized to issue regulations, having the force and effect of law, defining and standardizing food products. Due largely to the sale of a drug product with an untested solvent which had killed over 100 persons, a provision was inserted in the Act (a most unusual one because it was a real step forward toward licensing) requiring that new drugs could not be marketed in interstate commerce unless their safety had first been established to the satisfaction of the FDA. (As a pacifying gesture towards those who would have flinched at the use of the ugly word "approve," the new drug section provided for the government's permitting a New Drug Application (NDA) to "become effective.") Penalties for violations were increased, and the government could now obtain injunctions as well as make multiple seizures under specified conditions.

The Act was not designed, however, to create unnecessary restrictions on legitimate industry. Proponents of the statute stated that "it should operate in the interest of all honest manufacturers" and that "it must impose on honest industrial enterprise no hardship which is unnecessary or unjustified in the public interest."

There is apparently a basic law of nature that no federal agency is satisfied with the statute it is administering and inevitably finds a compelling need for additional legislation granting further authority to it. No rational person can dispute that the Federal Food, Drug and Cosmetic Act of 1938 was far-reaching and powerful. Nevertheless, not long after its passage, many amendments were sought and some were passed. Finally, the thalidomide tragedy gave the government what it had long desired—the opportunity to overhaul the 1938 Act in many particulars.

It is to be noted that a good deal of what was made a part of the Drug Amendments of 1962 had already been, or could have been, accomplished. Thus, prior to 1962, an NDA for an ineffective drug offered for a serious condition was not permitted to become effective

by the FDA and Congress had been informed of this position. Further, with respect to an ineffective new drug offered for a minor condition, an admonition by the government that the application was being permitted to become effective but that the claims on behalf of the product were, in the opinion of the government, false or misleading, would have taken care of most of these situations. In addition, regulatory action predicated on Section 502(a) of the Act was always available to the government. People have forgotten, also, that the Investigational New Drug (IND) regulations were issued pursuant to the authority possessed by the FDA under the 1938 Act.

Nevertheless, the Drug Amendments of 1962 were a real leap forward in granting additional authority to the FDA and constituted one more stride towards licensing. The drug adulteration section of the law was amended so as to provide that a drug would be deemed to be adulterated unless its manufacture was "in conformity with current good manufacturing practice." The manufacturer of a new drug was now specifically required to prove that his product was effective as well as safe. The holders of approved NDAs were directed to maintain records and make reports of pertinent data to the Secretary. Batches of every antibiotic were required to obtain certification, release or exemption, and their manufacturers were also required to keep records and make reports. At long last, jurisdiction over prescription drug advertising was vested in the FDA, and a requirement was made that these advertisements contain a "brief summary relating to side effects, contraindications, and effectiveness." The government was given vastly increased factory inspection authority with regard to prescription drugs. Consulting laboratories were made subject to inspection. All producers of drugs, including those engaged only in intrastate commerce, were directed to register with the FDA and were made subject to inspection at least once every two years.

Aggrandizement of the Law

To those uninitiated in the food and drug area and who had never been compelled to try to find their way through the labyrinth of administrative and judicial construction of the Federal Food, Drug and Cosmetic Act, it appeared that the FDA would be satisfied with the vast additional authority granted to it by the 1962 amendments. These neophytes might well have thought that since, due to thalidomide, the FDA had been put in the position where practically anything it wished from Congress would have been granted, and perhaps because the extensive authority granted by Congress would need

digesting before more authority was sought, at least some period of time would elapse before attempts were made to employ the familiar process of administrative and judicial aggrandizement of the law. As would have been predicted by those forlorn persons who are the initiated, this was not to come to pass.

Nothing is clearer, for example, than that Congress has never sought to do away with, or create unnecessary restrictions upon, the right of a person to treat himself for minor ailments. It was specifically pointed out in the legislative history of the 1938 Act, for example, that Congress did not wish "to restrict in any way the availability of drugs for self-medication. On the contrary, it is intended to make self-medication safer and more effective." The then Chief of the FDA referred to "the intelligent and safe use of drugs for self-medication." Despite these specific statements, revealing the congressional intent not to hamper the right of an individual to obtain medication for himself, and the refusal by Congress in 1951, in the Durham-Humphrey Amendment to the Act,[1] to accept unnecessary restrictions on the right of self-medication, the government consistently made the exercise of this right difficult.

The passage of the Drug Amendments of 1962 appeared to spur, rather than halt, the continuing desire of some in the government to restrict self-medication. It is now impossible for one to tell, with any degree of certainty, when some official will suddenly resume the ploy that, since the average person cannot tell with certainty whether his "minor" pain is caused by arthritis, or his stomachache by acid indigestion, or his headache by some digestive upset or over-indulgence in liquor or something equally delightful, or his nasal congestion by sinus difficulty, any product referring to these conditions should be marketed only on a prescription basis since it "is not safe for use except under the supervision" of a physician because of its "potentiality for harmful effect, or the method of its use, or the collateral measures necessary to its use."

I do not see how we can leave these determinations solely to the personal predilections of some doctor in the FDA or to a change in the medical thinking of some administrative or enforcement official of the Agency. Of course, the average person cannot know with positive assurance that his minor ache is caused by arthritis or bursitis or some sprain or strain, or his digestive upset by excess acid,

[1] See Brennan, "The Right to Self-Medication—A Continuing Conflict Between Congressional and Agency Policy," 23 FOOD DRUG COSMETIC LAW JOURNAL 487 (October 1968).

or that he is harboring pinworms or roundworms. But would this be sufficient reason for declaring that aspirin, one of the most remarkable as well as the most widely used of all drugs, may not be sold over-the-counter for minor arthritic pains, or that bicarbonate of soda may not be marketed for gastric hyperacidity, or that an effective product for pinworms and roundworms may not be promoted for those conditions?

Nevertheless, every once in a while an ambitious or doctrinaire official will suddenly decide that some pain or ache may possibly be caused by a grievous disease, that the person affected may be kept away from his physician by an over-the-counter (OTC) medication "until it is too late," and that the drug may therefore "indirectly cause his death." Yet, as pointed out by one of our leading pharmacologists a few years ago, "Most common symptoms of complaint are not associated with serious disease and the availability of a number of effective home remedies affords patients a means of easily and cheaply attaining relief." But if the continuing and underlying philosophy of some in the government is ultimately accepted, practically every OTC product on the market would have to be switched to sale on a prescription basis, regardless of the tremendous expense to the public and the almost desperate shortage of physicians in many areas of the country.

The "Grandfather Clause"

In the 1962 amendments, one appetizing bone was thrown, or apparently thrown, to those engaged in the drug industry. Provision was made in the amendments to the effect that with regard to a drug which, on October 9, 1962, was commercially used or sold in the United States (litigation may be necessary before we know the full meaning of "commercially used"), was not a new drug, and was not covered by an effective NDA, the new criterion of effectiveness would not apply to such drug "when intended solely for use under conditions prescribed, recommended, or suggested in labeling with respect to such drug" on that day.

Let us consider this "grandfather clause." A reasonable interpretation of the provision would have been that it gave protection to a pre-1962 drug which had never been a new drug or had once been a new drug but became an old one because it had become generally recognized as safe. The position was promptly taken by the government, however, that the grandfather umbrella did not cover any drug which had been a new drug at one time in the past. Certainly it would seem peculiar that Congress intended that a drug which a

least had been determined to be generally recognized as safe (in many instances by the FDA itself) should be given less protection than a product which had never been scrutinized in any connection by the government.

But since this problem has not been definitively resolved by the courts, let us consider a drug which was generally recognized as safe and had been marketed without the submission of an NDA. The FDA has taken an extremely limited viewpoint with respect to such a drug. Apparently even the use of an additional warning or caution statement may cause the grandfather protection to be lost. It would not surprise me if the government were to take the position (an erroneous one in my opinion) that a drug which had been marketed on an OTC basis for many years, but which the FDA now demanded be sold on a prescription basis, would be transformed into a new drug since the "labeling with respect to such drug" had been changed.

An example of the restrictive construction of the grandfather clause taken by the government is the *Allan* case,[2] decided by a high court in 1966. In that case, a drug was condemned as misbranded on the ground that false and misleading therapeutic claims had been made for it. Pursuant to the 1938 Act, the condemned product was returned to the claimant to be brought into compliance under the supervision of the FDA. The government urged, however, that because the product had to be re-labeled in order to reduce the representations for the purpose of bringing it into conformity with the law, it now became a "new drug" requiring the submission of an NDA. The court upheld the government's contention, declaring that the relabeling did cause the drug to lose the protection of the "grandfather clause," notwithstanding that the claims made on behalf of the drug were lessened in the revised labeling, since the revision did not contain the exact representations concerning the drug's use as did its labeling on October 9, 1962.

All of us are probably familiar with the policy statements with regard to new drugs and new drug status opinions which appeared in the *Federal Register*[3] on May 28 of this year. The fundamental change made in these statements was that all opinions previously given by the FDA that an article is "not a new drug" or is "no

[2] *United States v. Allan Drug Corporation*, CCH FOOD DRUG COSMETIC LAW REPORTS ¶ 80,123, 357 F. 2d 713 (CA-10 1966, rev'g DC Colo); cert. denied, 385 U. S. 899 (1966).

[3] CCH FOOD DRUG COSMETIC LAW REPORTS ¶ 40,294, 33 Fed. Reg. 7758.

longer a new drug" are revoked. The statements further provide that any drug "introduced through the new-drug procedures or marketed without new-drug clearance" may be "listed" as not now requiring an approved NDA "when it is determined by the Commissioner that such drug, adequately identified and meeting appropriate standards, is generally recognized by qualified experts as safe and effective for use under the conditions prescribed, recommended or suggested in its labeling and that it has been used to a material extent and for a material time under such conditions."

In my opinion, the small manufacturer should move more warily before accepting this "gift" than did the Trojans when they accepted the wooden horse left before their gates by the Greeks. Cassandra warned the Trojans that the horse would result in their doom and, as we know, it did, for inside were Greek warriors. Accepting this beneficence would be almost as fantastic a step as writing to the government and asking whether a product is a new drug. Certainly the writer of such an unfortunate letter, if he is experienced, should be required to undergo psychiatric examination unless he personally was convinced that the product was a new drug. As a practical matter, it may well be true that any drug, old as it may be and although it never was considered to be a new drug, is in a parlous position if new data disclose that it is not effective. Sections 502(a) and 201(n) are always potent weapons in the armamentarium of the FDA. Still, a drug which has grandfather protection should be guarded zealously. The fundamental cautions to be taken in this connection are: (1) not to make any changes, beneficial though they may be to the manufacturer or to the public, in the drug's formulation or labeling; (2) not to ask silly questions of the government about the drug or its status; and (3) to assemble as much data as possible as to its effectiveness. Further investigational work may be performed without filing an IND, since the product is being legally shipped in interstate commerce. In addition, a manufacturer of an OTC which the FDA now seeks to place in a prescription category should contemplate the possible loss of grandfather protection.

The Instability of Definition

It is to be borne in mind, also, in connection with the administrative pronouncements on past new drug status opinions, that even the FDA should not be able to amend the definition of a new drug. If a manufacturer is convinced that his product, which has been on the market for a considerable period of time and without hindrance

from the FDA, is in fact safe and effective and generally recognized as safe and effective by qualified experts, the drug is to be treasured and placed in a bank vault, perhaps in a numbered account in Switzerland, with explosives surrounding it, in order to protect it from government marauders.

It is probably unsophisticated, however, to say that the FDA can not, with the eager assistance of the courts, revise the statutory definitions. In a recent case[4] a high court held that products which clearly appeared to be therapeutic devices, and thus outside of the definition of a "drug," were drugs and could therefore be new drugs. The manufacturer or distributor of many products which he formerly believed to be devices, therefore, might well study the grandfather clause and what he might do to gain and retain such protection as it conveys.

What are the reasons for these new policy statements dealing with "new-drug status opinions" and providing for the "listing" of "any drug introduced through the new-drug procedures or marketed without new-drug clearance"? Basically, of course, the FDA seeks to retain control, which virtually amounts to licensing, of a host of drugs and to add a multitude of drugs, past, present, and future, which were not, are not, and should not be, subject to new-drug controls.

Further, the FDA took the position, shortly after the passage of the 1962 amendments, that "me-too" drugs, which were virtually identical with products which had once been but were no longer new drugs, might be marketed without the submission of NDAs although their fate was bound to the fate of the drugs they imitated. The hawks in the Agency may now regret this reasonable point of view.

In addition, it has probably occurred to these same predators that, from their viewpoint, they may have inadvertently created a problem by the use of the National Research Council (NRC) committees to pass on the efficacy of pre-1962 new drugs. Let us consider a product, for example, which obtained new drug clearance as to safety from the FDA in 1954. In 1969, a committee of learned experts created by the prestigious NRC determines that the product is effective for the conditions for which it is marketed. If the new drug section in the Act is still on the books, as it is, the product is no longer a new drug when marketed under substantially the same labeling since it is generally recognized, by qualified experts, as safe and

[4] *AMP, Inc. v. Gardner*, CCH FOOD DRUG COSMETIC LAW REPORTS ¶ 80,192, CA-2 1968, aff'g DC NY; cert. denied, U. S. Sup. Ct. 1968. See also Kleinfeld, "Surgical Implants—Drugs or Devices and New Device Legislation," 23 FOOD DRUG COSMETIC LAW JOURNAL 510 (October 1968).

effective for use under the conditions set forth in its labeling and has been used to a material extent and for a material time under such conditions. This would mean, of course, that any manufacturer may now commence marketing the product without any necessity for submitting an NDA or seeking any so-called "listing." Of course, as with any drug, good manufacturing practices would have to be adhered to.

An intriguing and unresolved problem is presented by a report of effectiveness by an NRC committee predicated on a labeling change. The FDA may take the position that any labeling change causes the product to become a new drug even though it is abundantly clear that the drug is safe and effective and generally so recognized. I criticize the government for this construction of the law, based in part on an unfortunate and poorly-reasoned decision of a court of appeals. For on the basis of such a position, no manufacturer of any drug, old or new, OTC or prescription, covered or not covered by an NDA, may safely make any change in labeling, even to reduce the scope of the representations made for the product or to add a warning or caution statement. I cannot fault the manufacturer who, under these circumstances, is hesitant to make the change. In my opinion such a position by the government is extreme, uncalled for by the Act and is bottomed on the desire to prevent any product from removing itself from new drug controls.

I will advert, briefly to the situation created by a report by one of the NRC Committees that a pre-1962 new drug is "ineffective." It will be very difficult to defend a move by the FDA to force the product off the market. Nevertheless, the company involved has a legal right to a hearing and its day in court—the right to cross-examine the members of the committee; constitutional due process is not satisfied, in my opinion, by the mere use of the word "ineffective."

Further Legislation Unnecessary

In my opinion, the pendulum has swung too far toward administrative aggrandizement, with judicial acquiescence, of the authority granted by Congress. If consumer protection is our sole objective, we will ultimately have licensing, censorship of all promotional material, testing of all drugs by the government, and perhaps nationalization of the drug industry. Current strong and potent law offers comprehensive protection to the public. Further legislation is unnecessary and will only result in delays, frustrations and an inordinate increase in the price of drugs, generic or trade-marked. **[The End]**

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