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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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H. Thomas Austern inquires into the enforcement of the Federal Food, Drug and Cosmetic Act, in a paper appearing at page 617. Mr. Austern is an adjunct professor of law at the New York University School of Law.

The suspension procedures involving new drug applications are explored by a well-known Washington D. C. attorney, *Vincent A. Kleinfeld.* In an article at page 632, he suggests that a special scientific committee be formed to determine the safety and effectiveness of new drugs and points out a number of reasons supporting his idea. "I suggest that this further addition to our traditional system of checks and balances, at least in the vital drug area, would be beneficial not only to industry, but also to the government and the public itself," he concludes.

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Food·Drug·Cosmetic Law
Journal

Food Additives— Facts, Fads and Fallacies

By DR. JOHN GILBERT DAVIS

This Interesting Article Appeared Originally in *Progress*, the Unilever Quarterly, London. Dr. Davis Is Principal of a London Consultant Practice in Food Science and Technology, and Microbiology.

ONE OF THE TRENDS IN RECENT YEARS has been an increasing interest in the quality of food and its purity in both a hygienic and a "pure food" sense. There has been much publicity recently on this question, and societies have been formed to further the consumption of "pure food," "natural foods" and "whole foods." These societies and some individuals have actively campaigned against the processing of foods and the use of food additives, to which they generally refer as "chemicals in foods." Food is important to all of us and it is natural to take a healthy interest in it. Moreover, we spend about a third of our income on food and devote an appreciable part of our free time to eating and drinking. Appreciation of good food and drink is a pleasure which we can enjoy throughout our lives and socially it is one of our most important activities. Food and drink should be as good as possible for all of us.

Unfortunately, most people take as gospel the letters and articles in the popular press. Some of these are quite sound, but too many are inaccurate, grossly exaggerated or wrong by implication, and are sometimes simply nonsense. We accept axiomatically that we are all entitled to our own opinion on food purity, as on all other controversial matters, and a minority of enthusiasts is certainly entitled to proclaim its views, to endeavour to convert the unbelievers, and to campaign for legislation for food reform. Nevertheless, there are

two unforgiveable sins in all such activities. One is to falsify the facts, and the other is to present only one side of the story or suppress those facts which are inconvenient to the belief.

Before discussing the pros and cons of this most important subject it is well to understand clearly what we mean by *processing* and *food additives*. Both have the same objective—to make food keep and/or make it more attractive. Both processing and additives alter foods in certain ways; obviously they could not achieve their objectives unless they did. The two methods often merge; for example, such processes as heating, smoking, souring and fermenting produce certain chemical substances and it is these substances which contribute at least in part to the value of these processes.

The Processing of Foods

In the food industry processing may be defined as "any alteration in properties intentionally induced by physical, chemical or biological means." Thus it may vary from a very mild heat treatment which has only slight effect on the nature of the food, as in the pasteurization of milk, to such major types as the conversion of wheat into bread, milk into Stilton cheese, butter or milk powder, fruits into fermented beverages and vegetable extracts into spirits. Because many foods normally go sour, putrid, oxidize or otherwise decompose, any process which prevents or retards this natural change may be regarded as processing. The main types of operation involved in current food processing are summarized in the table below.

Modern processing not only permits the sale of all foods all the year round, but also enables an adequate supply of these foods to be made available in densely populated regions at an economic price.

Some food-conscious people distinguish natural from artificial processing, but this distinction is illusory. They are fundamentally identical, and such differences as exist are minor and of little significance. Thus in processing physical factors are more accurately controlled than in nature, and chemical materials are purer than those responsible for natural processes, for example, acetic acid and vinegar. For every type of processing so far devised there is usually a parallel natural physical treatment or chemical action. Even for such apparently artificial things as preservatives and antioxidants there are corresponding naturally occurring chemical substances, such as essential oils, acids, salts, ascorbic acid and vitamin E. When we digest our food we are processing it.

Main Types of Current Food Processing

Physical	*Method*	*Typical products*
Heat	Pasteurization	Pasteurized milk
	Boiling	Cooked ham
	Sterilizing	Sterilized milk, most canned meats, fruits, vegetables and made-up foods
	Smoking	Some fish and some meats
Evaporation	Concentration	Sweetened condensed milk Evaporated milk
	Drying	Milk powder, soups, vegetables, ready prepared meals
	Freeze-drying	Many foods
	Quick freezing	Fish, meat and vegetables
Crushing and dividing	Milling	Cereals
Extraction		Vegetable oils
Chemical		
Acidification	Pickling (vinegar)	Many pickled vegetables
Salting		Vegetables Cheese
Bleaching	Sulphur dioxide	Fruits
	Chlorine dioxide	Flour
Preservation	Benzoic acid, sulphur dioxide, etc.	Fruit juices, sugar syrups, sausages, etc.
Biological		
Souring	Lactic acid fermentation	Cheese Cultured milks and cream
	Acetic acid fermentation	Vinegar
Alcoholic fermenting		Beers Wines Spirits
Flavour producing		Ripened cream butter

The idea that "natural treatments" such as cooking, smoking, souring, heat-drying and pickling do no damage to foods, but that "scientific processing" or addition of chemicals is harmful, is also a fallacy. Heating foods as a process has many advantages. It kills harmful micro-organisms, both those causing disease and those decomposing the food, and it may make it more appetizing and digestible. However, it may destroy a proportion of the heat-labile vitamins (for example, C, B_1, B_{12}) and may slightly reduce the biological value of the proteins.

Scientific processing such as canning, like cooking, may cause slight losses in nutritive value but confers a very long keeping quality.

Freeze-drying does less damage to the food than any other process except quick-freezing which retains more flavour, and promises to be the method of the future. Weight may be reduced by over 80 per cent and refrigeration is not required for storage.

Food Additives

There are three main types of food additives:

(1) Complex substances such as proteins extracted from other foods, for example, caseinates as used for sausages and other prepared meats;

(2) Naturally occurring well-defined simple substances such as salt, acetic acid, ascorbic acid (vitamin C) and phosphates;

(3) Synthesized substances not found in nature such as certain dyes ("coal tar-colours"), anti-oxidants, emulsifiers, preservatives and substances conferring special physical properties on foods, for example, keeping them moist, prevention of staling, anti-caking.

We may define an additive as any substance added to a food to give it a desired property. Thus fundamentally there is no difference between processing and the use of additives.

The use of additives may not only improve appearance, flavour and keeping quality, but may preserve or even increase nutritive value, as when ascorbic acid, carotene or vitamin E is used as an anti-oxidant.

Some people believe it is wrong to do anything to food which is "unnatural," but it is difficult to find any unanimity as to what is a natural food or a natural process. Man exists on a very mixed diet and no one food can be considered "natural" apart from human milk for babies.

It is important to realize that all foods are constantly changing in some way. Food is a dynamic, not a static commodity. Some change very rapidly in warm weather, like milk and meat, and others like vegetables and fruit change only slowly, but they all change in some way. In other words, different foods have different keeping qualities. All foods become unfit for consumption in a shorter or longer time. The changes are usually due to the growth of micro-organisms which contaminate the food, but some changes are brought about by the natural enzymes in the foods. If the organisms are dangerous we get food poisoning, and there are still several thousand cases of food poisoning every year even in the United Kingdom.

It may be emphasized that the processing of foods (this term includes the use of additives) is not merely a device of the manu-

facturers to use cheap foods or make higher profits. In practice only the best quality foods are used for processing, for the simple reason that the use of poor quality food often leads to faulty canned and other types of processed foods. Processing and the use of additives allow the manufacturer to supply everyone with all types of food at all times of the year. Moreover, these foods are attractive in appearance, of high nutritive value and good shelf life.

Some Popular Fallacies

The critics of modern food processing and the use of additives often assume that these are modern inventions and are "slowly poisoning the population." The first idea is quite wrong and there is no evidence for the second contention. Although such glib phrases are used by the enthusiasts for pure food it is doubtful if there is a single responsible qualified food scientist or medico-legal or health specialist who would consider that such a statement has ever been proved. Some persons who feel deeply on the subject can let themselves be carried away by their emotions and make statements or suggest implications unsubstantiated by any facts. The chain of reasoning is often grotesquely loose. For example, the following sequence may be developed in various ways:

(1) Coal tar dyes are being increasingly used in foods;

(2) More and more people are dying of cancer every year;

(3) Therefore coal tar dyes are causing cancer and killing more people every year.

Those trained in scientific method may smile at this crude line of reasoning, but it is surprising what conviction can be induced by a casual remark by a speaker or writer, especially if he has a medical or scientific qualification.

To discuss only one part of this fallacy, the second statement is not intrinsically true for cancers other than lung cancers. The widespread use of antibiotics has greatly reduced deaths from infections. More people survive childhood and early manhood so that the average age of the population has been steadily rising. For example one person in about ten is now over 65. Cancer is essentially a disease of old age so that *relatively* more people are dying of cancer. The expectation of life at birth has increased considerably in the last 100 years, but the expectation at 50 has increased only slightly. So far as the writer knows no evidence has ever been produced for an association between the use of the "coal tar colours" now used in foods and

cancer generally. These colours are tested very thoroughly and if there is the slightest suspicion of any harmful effect (at very much higher concentrations than those used in foods) that colouring matter is prohibited. There are only about 30 permitted synthetic colours in the United Kingdom, of which only some six or seven are in regular use, and one was recently prohibited on suspicion.

There are well-recognized examples where a primitive people living on a simple restricted diet have succumbed to certain dietary diseases when modern foods and modern ways of living have been introduced. However, these have been caused by changes in the amount and types of food, and so far as we know no evidence for suspecting food additives as such has ever been produced.

Historical Aspects

The preservation of foods by heating, dehydration, salting, souring, smoking and addition of preservatives has been practised for over 2,000 years and it is often mentioned in classical literature. By Graeco-Roman times a considerable skill had been obtained, for Epicurus (about 300 B. C.) writes, "Send me some preserved cheese, that when I like I may have a feast." Such cheese might have been preserved by spices and salt or even by heating and sealing away from the air, so that fundamentally it would have corresponded to modern processed cheese. Horace (about 20 B. C.), writing of his desires for perfect happiness, expresses a wish for books and food that would last for at least a year.

It is evident that foods have been systematically preserved for a very long time, and that in early days such preserved foods were a luxury. Today, thanks to the food technologist, nearly all foods can be preserved for months, and often for years, in a palatable form and at a price which can be afforded by all in the more developed countries. However, in spite of modern scientific knowledge it has been estimated that about 25 per cent of the entire world food supply is still wasted or spoilt by pests of one sort or another. Much still remains to be done in this direction therefore.

It is wrong to think of food technology (that is the application of scientific knowledge to the food industry) as a modern skill. There are many examples to prove the contrary. Thus, even for such apparently modern ideas as "tenderizing" meat there is evidence that the natives of tropical countries achieved this 400 years ago by wrapping pieces of meat in paw-paw leaves. We may think of microbiology

as a modern science but many principles of hygiene were known to ancient peoples, as witness the Mosaic laws in Leviticus, and even 2,000 years ago there was some form of culture control for bread-making (1 Corinthians 5, 7).

Natural and Artificial Substances

The concept held by some enthusiasts that anything produced naturally is right or safe to eat, while changes produced or chemicals used by man are harmful, is false. There is no fundamental scientific difference between meat, potatoes, bread, milk, fish, emulsifiers, anti-oxidants, antibiotics, vitamins, hormones and drugs—they are all chemicals. Food additives are chemically much simpler than foods and usually have a known molecular structure. Foods vary greatly in their chemical structure. Some like salt, vitamin C and sugar are simple; others like proteins and some vitamins are complex. We have all been eating and drinking processed foods (including beverages) for thousands of years, and there is no reason to believe that these are harmful in normal intakes. Obviously some chemical types of processing and some additives may be injurious, and these must not be used, but chemicals as a whole cannot be condemned without evidence. On the other hand, some of the deadliest substances known to man are produced by natural processes, for example the toxin of *Clostridium botulinum* (the most dangerous food poisoning bacterium), the plant alkaloidal poisons and the toxic principles of some fungi. Even parts of well-known vegetables, such as the potato, may contain poisonous substances under certain conditions, and cases of poisoning from such sources have been known.

There is no difference between substances produced by nature and those synthesized by the chemist. Provided that the substances are chemically identical they have the same beneficial or harmful effect independently of their origin. Due consideration must be given to subtle differences.

What Is a Poison?

The terms "poisonous," "harmful," and "dangerous" are meaningless in respect of food constituents and food additives unless considered in relation to concentration. Thus salt (sodium chloride) is essential to life, and yet one pound of salt would probably kill a man if taken over a short time. Even oxygen can be toxic if present in tissue in too high a concentration. Many metals such as copper, manganese, zinc and cobalt may also be essential in trace amounts,

but would be poisonous in considerably larger quantities, although the concentrations would even then still be quite small by comparison with other substances. Arsenic is a recognized poison and yet is present in appreciable trace amounts in many natural foods. Many people who object strongly to addition of chemicals to food do not realize that these same substances or closely related substances are always present in the natural foods they eat.

In discussion of the possible poisonous effects of both natural foods and of substances added to foods, due consideration must always be given not only to the nature of the substance in question and the concentration in the food (natural or added), but also to the amount normally consumed every day in the diet. Many natural foods can be poisonous or harmful if consumed in excessive amounts, for example, tea, coffee, cocoa, some herbs and spices, and shellfish. Thus pigs have been killed by being fed a mixture rich in cocoa. Foods like these are normally eaten in only small amounts, and there is no evidence that the quantities consumed in a normal diet do any harm. The same reasoning applies to food additives, and government regulations take this aspect into consideration. Permitted preservatives and other additives are much more restricted for those foods which are consumed in any quantity, and higher concentrations are permitted for those foods which are consumed in very small quantity, for example, condiments, flavourings, constituents of beverages, cheese-making rennet.

Loss of Nutritive Value

Modern processing and the use of additives are sometimes accused of seriously lowering the nutritive value of foods, or "taking all the goodness out of them." This is complete nonsense. It is true that sometimes there may be a slight reduction in some vitamins, but the advantages far outweigh the disadvantages.

In the 1920's there was a great outcry in some quarters against the pasteurization of milk, and even some well-known medical men and scientists campaigned against it. Some even stated that the nutritive value was virtually destroyed, and claimed that rats fed on pasteurized milk died. It seemed to be completely forgotten that the heating done by the housewife in her cooking was much more drastic than the dairyman's pasteurizing! However, in due course careful scientific experiments showed that the loss in nutritive value was negligible, and today pasteurization of milk is taken for granted. The same course of events will probably take place for

the current outcry against "chemicals in food." The slight losses in nutritive value are of no consequence if we take a well mixed diet.

Control of Additives in Britain

Britain has been a pioneer in food control and the protection of the consumer against adulteration of foods, and especially against the use of harmful chemicals in foods. In the first half of the nineteenth century sophistication of foods, often by poisonous substances, was rife everywhere, and in spite of all the propaganda in some quarters today our food is much purer now than it was then. Following agitation by some medical men and public analysts the Pure Food Act was passed in 1960. Our legal control today is based on the Food and Drugs Act 1955 and its various regulations. Some countries, for example, the United States and Canada, have far more detailed food regulations than we have, but our system based on control by local authorities with the public analysts as "watch dogs," is reasonable and in general very effective.

Preservatives, colouring matters, anti-oxidants and emulsifying and stabilizing agents are all controlled very rigidly in British law. Only permitted substances may be used, and even then often only in specified foods.[1]

The 360 odd local authorities (authorized authorities under the Food and Drugs Act) in England and Wales, and also those in Scotland and Northern Ireland are constantly taking samples of all types of food, especially those likely to be a matter of interest, through their inspectors and all these samples are examined by a public analyst. In consequence the chances of any food manufacturer or retailer breaking the law, or selling unsatisfactory food to the public, are remote.

World Food and Preservation

Certain parts of the world produce more food than the populations require (for example, North America and Australia) and other parts cannot produce enough for their peoples (for example, India and China). Even in one country the bulk of the food produced may be grown in only one part of it, and production of most foods is seasonal. It is not sufficient to produce foods somewhere at some

[1] For details see O'Keefe, *Bell's Sale of Food and Drugs*, London; Pearson, *The Chemical Analysis of Foods*, London; Hinton, in *Food Directory*, London. All food regulations for the United Kingdom may be obtained from Her Majesty's Stationery Office, Kingsway, London, W. C. 2.

time. It is highly desirable for all people throughout the world to have a safe, nutritious and attractive diet at all times of the year. It follows that some form of preservation is necessary to permit food to be stored from the times of production for the rest of the year, and also to permit transport from areas of high production to areas of low production. Even in developed countries like the United Kingdom, which produces large quantities of food (although this is not always realized), it is necessary to preserve much of it by some form of processing or by the use of additives.

The ideal food is obviously that which is freshly taken from the ground, or from a tree, or if an animal one that is freshly killed. However, more than half the United Kingdom population is urban and over one-third of it lives in towns of over 100,000 inhabitants. It is quite impossible to feed such a population with entirely fresh food; in fact about 60 per cent of our food has to be imported from countries often many thousands of miles away. Some form of preservation of all imported food and much of our home grown food is essential.

The fast increasing population of the world (it is expected to be doubled by the year 2,000) will necessitate not only the production of more food, and especially good quality protein, but increased transport of food. Demands for increasing efficiency and distribution will continually be made on the food technologist, and every advance in packaging and storage of foods must be utilized to the full. These trends must inevitably increase the need for the use of those additives —preservatives, anti-oxidants—which have been shown beyond doubt to be harmless to humans.

No one will claim that a sophisticated or processed food is quite as attractive as the natural product but modern methods in food technology bring the two very close. An attractive appearance is a very important part of palatability and palatability is a big feature in appetite and digestibility which in turn can influence efficiency of absorption. Stored and preserved foods often lose their attractive colour and flavour, and restoration of these properties by harmless substances is fully justified. It is better to have supplies of fruit and other perishable foods in good condition all the year round, than to do without them for six or nine months of the year. If the colour and flavour of fruit and vegetables are retained by processing or the use of additives, then the labile vitamins such as C, A and β-carotene are usually also retained with but little loss.

It is not the purpose of this article to suggest that processed foods and foods containing additives are better than fresh foods. But unfortunately it is not only impossible in practice for the whole of a dense population, such as that in the United Kingdom, to live on fresh foods, but economically it would be out of the question. Any attempt at such a scheme for the population as a whole would considerably increase the cost of food. A small proportion of the population, by the circumstances of their way of life, for example, farmers, can obtain much of their food fresh, and some people are prepared to pay a higher price for such food. This aspect is entirely a matter of individual choice.

Food and Health

All health authorities agree that an adequate amount of a well mixed diet is essential to health and mental well-being. Additives can help in this problem not only by preserving foods in an attractive form, but sometimes by actually increasing their nutritive value. There are many fortified foods on the market containing added proteins, vitamins, minerals and trace elements. It is interesting to note in passing that some of these, although described as "natural health foods" (or implied to be such) may contain nutrients synthesized by the chemist or produced by laboratory controlled fermentations. Government regulations may require vitamins and/or minerals to be added to some foods. It is not generally realized that a considerable part of our vitamin and mineral requirements are supplied by legally compulsory additions to certain foods as follows: calcium, flour; iron, flour; aneurin (thiamine), flour; nicotinic acid, flour; vitamins A and D, margarine; vitamin D, national dried milk.

Startling improvements can be effected in undernourished populations by the provision of a "made-up food" designed on sound scientific principles. A good example is "Incaparina," made in Guatemala by adding vitamin A, calcium carbonate and yeast to a gruel preparation based on maize, cottonseed, sorghum and leaf meal. This has proved to be of high value for children suffering from protein deficiency.

Of all aspects of food technology, preservation of food in an attractive and safe condition with the minimum loss of nutritive value is probably the most important today. An adequate supply of a well balanced diet is necessary not only to keep people healthy and happy, but is also essential for efficiency in both physical and mental work. The long accepted laziness and mental inertia of the peoples

of tropical countries have been shown to be due not so much to climate or race, but to under-nutrition or malnutrition. The commonest deficiency is simply in calories, but many diets are deficient also in protein, vitamins and/or minerals. There are many well-recognized diseases caused by specific deficiencies in this way.

Accidental Additions of Chemicals

Protests by the public against food additives are usually directed to the food processors, but it must not be forgotten that so far as abuses are concerned food producers are at least equally guilty. The uncontrolled or excessive use of penicillin and other antibiotics by farmers for mastitis in dairy cattle leads to an appreciable level of antibiotic in the milk, and some people suffer from discomfort or skin trouble from this cause. Uncontrolled use of aureomycin and other antibiotics for animal growth purposes can also be harmful to the consumer. Indiscriminate use of sprays for crops, and the use of the wrong chemicals, or of sprays at the wrong time can lead to undesirable amounts of the chemicals in the food as sold to the public.

In cases of proven harm to human beings, it can usually be shown that the fault lies in the improper use, particularly in excessive concentrations, use at the wrong time or unwise choice of the substance concerned. The real solution to the problem is to insist on the control of all these substances, and in particular, to restrict their choice and the concentration at which they can be used. To ban them completely would be economically difficult, if not impossible, and nutritionally unwise.

Economic Aspects

In the United Kingdom we spend about £5,000,000,000 annually on food—nearly £100 a head, and there is little doubt that we are one of the best fed countries in the world. This is largely due to the food technologist. Without modern hygiene, transport, refrigeration, processing, additives, and packaging, it would be quite impossible to feed the United Kingdom population efficiently at this price.

Another important factor in the necessity for the best possible food technology is the increasing demand by the housewife for "convenience foods" or foods partly or wholly prepared ready for consumption. The demand for canned meats and vegetables has trebled since 1939. "Instant" coffee and tea are the forerunners of another type of "convenience" food. About one-fifth of our expenditure on foods is devoted to prepared foods, and the proportion is increasing.

Policy for the Future

The present rigid control of all food additives in the United Kingdom by government regulations has already been emphasized. What should be our policy for the future?

The first point to emphasize is that we still have a lot to learn about food from all angles—nutritional, processing, additives, packaging and distribution. Research on all these aspects should proceed on parallel lines and with proper cooperation and coordination.

Secondly, legislation should be constantly revised to keep it in line with the latest knowledge on the subject. Legal control should extend to all foods and all additives so that there are no loopholes for ignorant or unscrupulous food manufacturers and retailers. Food additives should be kept to the minimum necessary. If there is the slightest evidence for toxicity or any reasonable grounds for suspicion, then that additive should be forbidden. On the other hand officialdom should not be permitted to prevent a reasonable use of additives when adequate evidence has been presented for the safety of any substance.

No attempt should be made to suppress criticism of food additives; we live in a free country and freedom of thought and expression is our birthright. The higher circles of science, medicine and government usually ignore uninformed criticism, but there is a good case for education of the public on *facts* as distinct from opinion. This could be done by lectures, and articles in the press and popular magazines, and possibly also food might be a subject worthy of attention in schools and colleges. Even in the medical curriculum teaching on food is confined to a limited amount of education in the fundamentals of nutrition.

Finally, we must emphasize the need for the unification of international regulations for food, especially in respect of labelling, additives and packaging. The present position can only be described as chaotic. **[The End]**

CONGRESS ON MEDICAL QUACKERY HELD

The Second National Congress on Medical Quackery, held October 25-26 in Washington, D. C., was attended by more than 700 delegates representing professional medical and educational groups and the news media. It was sponsored by the American Medical Association and the Food and Drug Administration as part of a continuing joint educational effort to combat medical quackery. HEW Secretary Anthony J. Celebrezze, who opened the meeting, commented that the gullible buyer of useless and sometimes dangerous products for which extravagant claims are made "is not only fleeced of the price . . . but is also deprived of considerable benefits of modern medicine."

Sanctions in Silhouette: An Inquiry into the Enforcement of the Federal Food, Drug and Cosmetic Act

By H. THOMAS AUSTERN

This Article Is Based Upon an Address Delivered to the Round Table Meeting on Legislation, 1962 Annual Meeting of the Association of American Law Schools in Chicago, Illinois on December 28, 1962, and Is Reprinted from the *California Law Review*, March 1963 Issue. The Author Is a Member of the District of Columbia Bar, and an Adjunct Professor of Law at the New York University Schoo of Law.

AS VOLTAIRE ONCE SAID of the divinity, if federal administrative agencies had not developed explosively during the past three decades, it surely would have become necessary to invent some substitute for them.

When I began practicing in Washington in 1931, there appeared to be no well-defined area known as administrative law. There was, of course, Patent Office practice with its own esoteric vocabulary and rules, but it was largely confined to a group of specialists. A few lawyers had dealings with the Shipping Board; other largely confined specialists practiced before the Interstate Commerce Commission; and there were a great many tax lawyers who shared that lucrative pasture with accountants.

Some hardy attorneys wore out their lives in the interminable hearings that followed Trade Commission complaints. But only a handful of active practitioners had anything to do with the Bureau of Fisheries or Steamboat Inspection in the Department of Commerce, or with the Food and Drug Administration then in the Department of Agriculture, or with the then relatively new and developing Federal Radio Commission.

Area of Administrative Law in 1931

In 1931, the work of any lawyer before any one of these agencies was regarded as a unique specialty, isolated in substantive content and procedure, and in most respects unrelated to any other field of law. There was no *Federal Register*. One seldom sought to discern any common patterns in how each of the separate agencies operated, in whether they gave adequate notice of what they planned to do, in the type of formal findings they made, or in the mode and scope of possible judicial review of their action. There was indeed no administrative law, but only a limited group of unrelated and fragmented specialties.

Moreover, at least half of those who dealt with administrative agencies were not lawyers. They either were other specialists—chemists, engineers or accountants—or were simply experienced and often talented men who had through previous employment in the agencies acquired what Mr. Justice Frankfurter termed *expertise*. Others were lame duck politicians whose chief competence lay in opening doors.

Most of those with a legal diploma who ventured to deal with federal agencies had never been exposed to a law school course bearing that title or with the content of those now offered. They had never had the advantage of that acrid analysis that students make of their professors' classroom observations, or the insights that professors and students contribute to the monumental writings in administrative law.

Literature on Administrative Law

Relatively, the legal literature on administrative law was fairly slim. There were a few discussions here and there on public utility commissions, some volumes on the Interstate Commerce Commission, Gerard Henderson's brilliant book on the early Federal Trade Commission,[1] but nothing like the current Niagara of horn books, articles, and notes and comments for citation in case books and dissection by students. A few legal Tories were disquieted in 1931 about the loose procedures that the then active agencies followed, but the bulk of the Bar appeared to be content to leave administrative practice at the federal level to the Washington specialists, who presumably were familiar with its procedural quirks and with the corridors of the World War I temporary buildings in which the agencies were housed.

[1] Henderson, *The Federal Trade Commission* (1924).

It was the broad exertion of administrative authority over wide segments of the American economy in the first hectic days of the New Deal—particularly by the NRA Blue Eagle, the Agricultural Adjustment Administration, the SEC, and a host of other new agencies—that first brought to most American lawyers a consciousness of the federal administrative process as a mode of government.

By 1939, when the first Attorney General's Committee on Administrative Procedure began its labors, it could point to 17 federal administrative agencies that had come into being since 1930, and, in its report in 1941, to a total of 111 federal departments, bureaus, divisions, and independent agencies which were by then in full bloom.[2]

There was, and is still, room for debate as to how many federal regulatory agencies importantly affect private interests through rule making or adjudication. But what cannot be denied is that since World War II most of these agencies have vastly expanded their activities, have sharpened their formal and informal proceedings, have fared better or worse at the hands of the reviewing courts, and have successfully complied with or evaded the Administrative Procedure Act of 1946.[3]

As a passing paradox, the proliferation of administrative agencies has rested in large part upon their asserted efficiency and expedition in dealing with complex regulatory problems. Yet with each passing year the administrative process has become increasingly sluggish, criticism of inordinate delay in decision has intensified, and expedition becomes less and less a characteristic of almost every federal agency.

Doubts in Applying Concept of Strict Criminal Liability

Against that background, I should like to focus on the relation between the sanctions imposed for administrative regulations and the scope and content of the authority delegated to an agency. In particular, I hope to suggest some doubts as to the propriety of imposing criminal penalties and, perhaps, major doubts as to ever applying the concept of strict criminal liability for violation of complex administrative regulations.

As an illustrative case, I offer the Federal Food, Drug and Cosmetic Act[4] and the agency known in Washington alphabetic jargon as the FDA.

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[2] United States Department of Justice, *Final Report of the Attorney General's Committee on Administrative Procedure* 10 (1941).

[3] 60 Stat. 237 (1946), 5 U. S. C. Secs. 1001-11 (1958).

[4] 52 Stat. 1040 (1938), as amended, 21 U. S. C. Secs. 301-92 (1958), as amended, 21 U. S. C. Secs. 301-92 (Supp. III, 1962), as amended, 21 U. S. C. A. Secs. 321-81 (Supp. 1962).

The FDA has long fascinated administrative law scholars. To begin with, the public needs to which it is directed—protection of the public health and the consumer's pocketbook—command universal approval. This was recently and dramatically demonstrated in the Drug Amendments of 1962.[5] In final form, that measure passed the Senate by a vote of 78 to 0,[6] and the House by unanimous voice vote.[7] Few enactments—not even a declaration of war against an aggressor—have commanded like unanimity on both sides of Capitol Hill.

Since organized government was first created, everyone has wanted the sovereign to protect the population against impure food, deleterious drugs, and any debasement or adulteration of what a man puts down his gullet. As Mr. Justice Frankfurter observed three years ago in the *Smith* case,[8] in contrasting the constitutional protection of free speech with absolute criminal standards in the food and drug area: "There is an important difference in the scope of the power of a State to regulate what feeds the belly and what feeds the brain."

That universal approbation of purpose has resulted in a fascinating administrative edifice—with probably the broadest powers of rule making found in the federal government. It has its own peculiar vocabulary, structure, and procedures. The applicable standards for administrative action are as elusive as they are semantically colorful. Enforcement is achieved through the triple sanction of seizure, injunction and criminal prosecution. Most significant for the immediate inquiry is that the most rigid concepts of strict criminal liability are applicable.

A full description of what the FDA can regulate by its rule making—and of its unique procedures—would, and in many law schools does, warrant a full seminar. A few significant highlights must suffice here as background for our principal inquiry.

As originally conceived in 1906, and amplified in 1938, the statute was an intricate complex of prohibitions. The FDA was essentially a policing agency. Food, drug and cosmetic manufacturers had responsibility for compliance. Seldom was court action needed. Instead, the bulk of enforcement action was informal.

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[5] 76 Stat. 781 (1962), 21 U. S. C. A. Secs. 321-81 (Supp. 1962).

[6] 108 *Congressional Record* 16360 (daily ed. Aug. 23, 1962).

[7] 108 *Congressional Record* 21135 (daily ed. Oct. 4, 1962).

[8] *Smith v. California*, 361 U. S. 147, 162 (1959) (concurring opinion). The Justice indicated his awareness of the relationship between the sanction employed and what is being regulated by referring to "the balance that is struck between this vital principle [scienter] and the overriding public menace inherent in the trafficking in noxious food and drugs."

System of "Jaw-Bone Enforcement"

A developed cooperation between the regulated industries and the enforcement agency, the drastic sanctions, the desire on the part of most to comply, the fear of adverse publicity on branded foods and proprietary drugs, and the black shadow of strict criminal liability, combined to create what I have elsewhere called a system of "jaw-bone enforcement."

Professor Davis has termed this type of administrative reliance on informal methods of enforcement the use of the agency's "supervising power."[9] Administrative enforcement often does not require formal adjudication but merely "the lifted eyebrow," the suggestion, or the implied threat of action or publicity. It is, of course, not unique to the FDA.

The informal exertion of authority in questionable areas is often employed in many other agencies. The Federal Communications Commission notably uses correspondence rather than formal proceedings—backed by the threat of the sanction of nonrenewal of a license or refusal to accord additional facilities. Indeed, its enforcement of the original "equal time" section of its act through informal procedures ultimately led to Congressional amendment.

The Securities and Exchange Commission uses the "deficiency letter," which leads almost invariably to acquiescence by the proposed issuer—over whose head hangs the possibility of a stop-order proceeding. The Civil Aeronautics Board has firmly entrenched itself in a number of areas of doubtful jurisdiction merely through correspondence and negotiation, where the shadow of a suspension order leads to the adoption of the Board's suggestions.

These informal methods of administrative enforcement are subject neither to the procedural safeguards of the Administrative Procedure Act nor to any effective judicial review. Whether one likes it or not, this mode of administrative enforcement constitutes the bulk of regulatory action. The court cases bear about the same relation to total agency conduct as the visible portion of an iceberg does to what lies beneath the surface of the sea.

By and large, however, the use of informal procedures is found in those administrative agencies having policing functions. Their employment in the enforcement of complicated agency rule making is more questionable, and turns, I suggest, entirely upon the severity of

[9] 1 Davis, *Administrative Law Treatise*, Sec. 4.01, at 233 (1958).

the available sanctions. Where these are economically severe—such as the loss of a television franchise—there are many who believe that periodic Congressional scrutiny is warranted and salutary. But where the available sanction is the threat of a criminal prosecution for failure to obey, and where the penal proceeding is based on strict criminal liability, I believe more pointed inquiry is warranted.

Added Policing Powers of FDA

The FDA is a striking example. Over the past decade, through a series of vast and intricate amendments, the FDA has had added to its policing powers under the original enactments a sweeping licensing structure. This system covers the prior approval of agricultural pesticides in very broad, detailed, and effective fashion despite whatever doubts Rachel Carson may have recently suggested.[10]

All new food ingredients for man and animals are now subject to prior approval. Most antibiotics must be batch-certified. As the public learned in the recent Thalidomide episode, the *safety* of all new drugs is subject to prior clearance. By the recent amendment, the efficacy of all new forms of drugs must likewise surmount prior detailed administrative scrutiny and approval. Beginning next year, the use of all colors for foods, drugs and cosmetics will be brought under full licensing control.

Just a year ago, in the Federal Hazardous Substances Labelling Act,[11] the FDA was also given regulatory control over every household article that is not a food or drug or cosmetic, to determine which should be denominated "hazardous" and require cautionary labelling. This new authority covers products ranging from cleaning compounds to shoe polish.

The resulting FDA statutes are over 100 pages long. The almost daily flow of complicated regulations, exceptions, extensions, certifications, and the like, fills and refills hundreds of pages of fine print. Their bulk is formidable, and their technical vocabulary is as difficult to fathom as the mathematical formulae of nuclear physics.

In practical terms, the *Code of Federal Regulations* is as current and reliable as the old English Pipe Rolls. Indeed, in this area even the looseleaf services are usually far behind the times. It takes familiarity with chemistry, pharmacology, and processing nomenclature to

[10] See Carson, *The Silent Spring* (1962); 68 Stat. 511 (1954), 21 U. S. C. Sec. 346a (1958).

[11] 74 Stat. 372 (1960), 15 U. S. C. Secs. 1261-73 (Supp. III, 1962).

parse the continual supplements, deletions, revisions, and modifications. However necessary all of this may be in the public interest, it is not only delegation running riot—but it is plainly rule making not expressed in ordinary English or even familiar legal jargon.

Both basic coverage and standards for administrative action in the controlling statutes are fundamentally vague. The safety of foods and drugs and the efficacy of drugs turn on what is *not* "generally recognized among experts qualified by scientific training and experience." How many experts are required for general recognition—how their qualifications are to be established—and on what facts these experts are to base their judgments—is left wholly at large.

At first glance, the necessity for the FDA establishing its basic jurisdiction by proving a negative—that the facts controlling coverage are "*not* generally recognized . . ."—might appear to be an odd form of statutory drafting. But as we shall see, in this field what the agency concludes, the court approves; and most of those regulated do not often dare to challenge an informal assertion of power.

Test of "Fitness of Consumption"

The test of "fitness for consumption" is that a food may not be "filthy, decomposed, or otherwise unfit for consumption." This test is applied not in terms of what the housewife might accept, but on aesthetic criteria determinable only through a binocular microscope.

The statutory guide for promulgating standards regulating the composition of foods—in some respects the diet of the American consumer—is phrased "to promote honesty and fair dealing in the interest of the consumers." In operation, that standard pragmatically could be equated to the more familiar guide of "effectuating the purposes of the Act."

Each of these rule-making authorities carries with it further indirect controls. For example, determining that a new food ingredient is safe for the intended use does not suffice for its authorized use. The detailed labelling of every food product in which the ingredient may be used is subject to prior administrative scrutiny lest its use, though completely safe, might in the a priori judgment of the FDA lead to collateral misbranding.

Like authority exists with respect to the use of admittedly safe food and cosmetic coloring. It extends also to so-called "New Drugs" which, though admittedly both safe and effective, now must also

have their labelling and much of their advertising initially approved by the FDA.

The statutory criteria for determining what is proper food labelling are phrased in terms of the likelihood of potential violation of the misbranding prohibitions of the rest of the act. Since these basic prohibitions are inherently vague to begin with—such as, that labelling must be "reasonably conspicuous"—what is essentially authorized is a desk-top determination of an apprehension of potential illegality.

These new controls do not merely authorize prosecution for violation; they are also conditions of granting the necessary license. Interstate shipment without prior license is made criminal wholly apart from whether the food is in fact wholesome or the drug is in fact safe and effective.

Discretion on Issues of Economic Policy

What is sometimes lost sight of is that in all these agency determinations and the detailed rule making, there are not merely questions of protecting the public health; there is also a wide ambit of administrative discretion on issues of economic policy, and for the embodiment in the regulatory structure of arguable ideas about dietary preferences. These involve no hazard to health and no threat to the public, and do not remotely involve any menace "inherent in the trafficking in noxious food and drugs."

How much butterfat should be required in cottage cheese as contrasted to cream cheese—or whether pineapple chunks may be colored green—or honey added to peanut butter—or whether vitamins may be added to chocolate bars—or, to use a more familiar example, now settled by statute, whether colored margarine should be permitted to be sold—do not involve any scientific determinations or questions of public health, but instead are issues of economic policy.

Whether the per cent of polyunsaturated fats, or the ratio between saturated and polyunsaturated fats, may be disclosed to the public embodies both highly arguable nutritional theories and fundamental political questions as to how far a paternalistic or relaxed FDA should go in permitting a supposedly literate population to make its own dietary judgments.

Never forget that where the FDA disagrees, the product is outlawed. The need for or desirability of each of the elements in this FDA regulatory structure may for some be a matter of debate. It suffices for present purposes to suggest that the pattern thus far appears to

be that whatever additional delegated authority may be sought in this area, Congress will usually grant it.

Our inquiry is directed toward the type of sanction that should be applied in the event of violation.

In many FDA situations, it may be wholly beyond the power of an individual to know or to control whether or not he is in compliance. A manufacturer may purchase an essential ingredient from another who may inadvertently and without negligence deliver materials which do not comply with these detailed requirements. The status of literally hundreds of ingredients remained uncertain for several years under the Food Additives Amendment of 1958.[12] Many of them fell through the interstices of the vast network of exemptions, extensions and exceptions embodied in the regulations.

There is, of course, in these statutes detailed provision for court review. The ordinary pattern is by petition to a United States Court of Appeals on a paper record. But every experienced food and drug lawyer will tell you that in 999 out of 1,000 cases, even the most sanguine counsel knows that he hasn't a prayer of persuading an appellate court to second-guess the FDA.

Resort to Negative Findings

Every finding is dressed up as a scientific determination. Where there is no evidence, the FDA often resorts to *negative* findings—reciting that there is an absence of evidence showing that to permit the continued sale of a particular product or the use of an ingredient will benefit the consumer. Colorful phrases of remote bearing—such as "poisoning the public," "prevention of cancer," "deleterious foods injuring the public"—are regularly trotted out.

It is indeed a sturdy appellate judge who is not tempted to clutch his stomach, to recall every episode of family illness, and to react in favor of those who march under the banner of protecting the aged, lactating mothers, and infant children.

Realistically, *Universal Camera*[13] and any other case on judicial review you care to name have little bearing in this area. The FDA rule-making process, by and large, has virtual immunity from judicial intervention or correction.

Recognition of the impracticability of judicial review probably underlies in part the recent recommendation of the Second Citizens

[12] 72 Stat. 1784 (1958), 21 U. S. C. Secs. 321-46 (1958).

[13] *Universal Camera Corp. v. NLRB*, 340 U. S. 474, 19 LC ¶66,191 (1951).

Advisory Committee on the FDA that independent, nonagency, scientific groups should be employed as review boards.[14] That idea originated and was incorporated in the Miller Amendment in 1954 for the licensing of pesticide chemicals.[15] It was there provided that after the regulation was promulgated, any objecting person could have the entire regulation referred to an independent advisory committee whose recommendations were thereafter to be taken into account in re-examination by the FDA.

Objections to Private Advisory Committee

It may well be that some system of having an extracurricular advisory committee can be developed. As the proposals now read, I remain unpersuaded and have publicly opposed them. For the FDA to abdicate its responsibilities to a private scientific advisory committee seems to me to be objectionable. These groups will be acting privately, on evidence not of record, and, I believe, exposed to every type of direct and indirect lobbying. If the only solution to some of these problems is to create an administrative flying buttress to agency rule making, I think some basic re-evaluations might be preferable.

But every detailed rule and every aberrant interpretation are enforceable by penal action under strict criminal liability. Both companies and individuals are vulnerable. Indeed, as the *Dotterweich* case[16] illustrates, the individual may be held even though the company is exonerated. Knowledge of the facts, intent, or willfulness are not required elements for conviction.

Identical Punishment for Major or Minor Violations

Criminal prosecution can follow with equal ease for violations of minor economic regulations as for major threatened injury to the public health. The same penal consequences can flow from using the wrong words or too small a size of type on a salad dressing label as would follow from the addition of a poison to that food. Punishment can be identical for slight exaggeration as to the contents of a bottle of suntan oil as for the failure to put a vital warning statement, or for including a false therapeutic claim, on a drug label. Accidental

[14] Report of the Second Citizens Advisory Committee to the Secretary of Health, Education, and Welfare on the Food and Drug Administration, 17 FOOD DRUG COSMETIC LAW JOURNAL 581, 615-16 (1962).

[15] 68 Stat. 511 (1954), 21 U. S. C. Sec. 346a (1958).

[16] *United States v. Dotterweich*, FOOD DRUG COSMETIC LAW REPORTS, ¶ 2151.25; 2151.63; 2211.77; 2217.92; 2245.55; 2501.83.

violation of the most intricate detailed requirement is made equally reprehensible with the willful bootlegging of toxic drugs. Employment in a food of flavoring material beyond specified levels, measured in parts per million, can be equated for criminal prosecution with the willful adulteration of drugs.

This indiscriminate application of the same drastic criminal sanction, irrespective of the character or magnitude of the violation involved, and under the absolute rule of strict criminal liability, is an historical accident in this field. It resulted because the format of the earlier policing statutes was carried over while the delegated rule-making authority was vastly expanded. Curiously, except on civil rights issues, Congress seems to pay little attention to the form of any sanction embodied in the statutes it enacts.

In Terrorem Technique

You may well ask whether this drastic sanction is really employed? The unhappy answer is that it occasionally is used. Nominally, the law prescribes that there must be an administrative hearing before any criminal prosecution is ordered, and that minor violations need not be prosecuted where the FDA considers that the public interest would be adequately served by suitable written notice or warning. But, unbelievably, it has been held that the precedent administrative hearing is not a jurisdictional requirement for prosecution.[17] Moreover, in practice the FDA often uses the prerequisite Notice of Hearing more as an *in terrorem* technique in many situations where actual penal action might never be instituted.

But the real thrust of this criminal sanction of strict liability is that its very existence leads to administrative conduct which some of you might be tempted to challenge. Would you dare do so?

The FDA is not unaware that it has this strict criminal sanction in back of its intricate rule-making power and its own interpretations of its own regulations. On occasion, in informal discussions of whether a regulatory proposal is authorized, or is based on any solid facts, or will have an unreasonable or discriminatory impact, one encounters the reply—offered with a smile yet with grim undertones—that these are not the real questions. The real point, it is suggested, is whether any company or company official wants "to risk being the Patsy in having the point tried out in a criminal proceeding."

[17] Cited at footnote 16.

Granted that this does not occur often. Granted that most of the FDA officials are the finest public servants—with no axe to grind, no set of developed predilections, and free of all elements of vindictiveness. Still, the question remains whether it is good government both to delegate this technically complicated and practically unreviewable rule-making authority, and to back it up with the sanction of strict criminal liability.

There are some who insist that the present FDA has a curious blind spot about these penal sanctions. Early in 1962 the FDA asked Congress for complete and unfettered power to inspect all of the files of every individual company subject to the act, in order to determine the existence of any violation, or potential violation, of the statute, or of any of the regulations issued under it. The only response to a suggestion that this would trespass constitutional limitations was an FDA insistence that the complexity of its own regulations and the difficulties of enforcement made this additional grant of authority necessary.

This FDA insistence, I might add, was coupled with an adamant position that full enforcement required the continuance of strict criminal liability—even absent knowledge or intent or any lack of reasonable care on the part of an inadvertent violator.

No Equivalent System in Federal Administrative Law

I know of no equivalent system of criminal enforcement in federal administrative law. There are some conservation statutes, such as the White Act authorizing agency determination of lawful fishing areas, where confiscation of fishing gear is authorized without inquiry into willfulness, knowledge, or intent.[18] But strict criminal liability for violation of complicated rules and regulations is, I suggest, at least a novelty.

Historically, that doctrine of strict criminal liability—which Bishop once called "too monstrous to be accepted as law"—is a development of the past 125 years. There was a parallel development in England and the United States in the statutes controlling the sale of intoxicating liquor and food. Professor Sayre suggested that the doctrine ought to be limited to regulatory areas where the penalty was slight and the social injury resulting from violation might be widespread.[19]

[18] 43 Stat. 466 (1924), 48 U. S. C. Sec. 226 (1958); see *Hynes v. Grimes Packing Company*, 337 U. S. 86 (1949).

[19] Sayre, "Public Welfare Offenses," 33 *Columbia Law Review*, 55, 78-79 (1933). Some state court decisions go further. See *Ogburn v. State*, 168 Ark. 396, 270 S. W. 945 (1925) (one-year imprisonment for the possession of a car having a mutilated motor number

Whatever may be the reasons for imposing a strict criminal liability for statutory rape, or selling liquor to minors, or, as in Massachusetts, for unintentional bigamy where there was a reasonable belief that the first spouse was dead, I join with Henry Hart [20] and Jerome Hall [21] in condemning the whole doctrine. In federal law, it is limited to control of narcotics,[22] and food and drug law violations where, as I have suggested, imprisonment can be imposed even for offenses in no way injuring public health or safety. While I cannot warrant a search of all of the substantive statutes, a run-through of Title 18 of the United States Code has brought to light no other example except possibly Section 14 of the Federal Trade Commission Act,[23] which might be, but has not as yet been, interpreted to embody strict criminal liability for the false advertising of drugs where immediate and widespread danger to the public health will result. Where the substantive rules are found not in an act of Congress but in the complex details of agency rule making, I find no other instance in which the sanction of imprisonment follows violation according to strict criminal liability. The most that one finds is the so-called civil penalty, the amount of which is usually left to the discretion of the judge.[24]

Question of Form of Sanction in Hart Bill

In September 1962 this question as to the form of sanction to be employed for violation of administrative regulations came sharply into focus in the so-called Hart bill [25] which is to be considered by the 88th Congress. The bill proposes new and comprehensive rule making to control the packaging and labeling of a broad range of "consumer

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and serial number; defendant's lack of knowledge was not a defense); *State v. Dobry,* 217 Iowa 858, 250 N. W. 702 (1933) (felony conviction for filing false statement upheld, absent any showing that defendant knew the statement to be false); *State v. Lindberg,* 125 Wash. 51, 215 P. 41 (1923) (affirming felony conviction for borrowing money from a bank of which the defendant was a director; evidence tending to show that the defendant reasonably believed that the money came from another bank was held properly excluded).

[20] See Hart, "The Aims of the Criminal Law," 23 *Law & Contemporary Problems,* 401, 422-25 (1958).

[21] See Hall, *General Principles of Criminal Law,* 325-59, 375 (2d ed. 1960).

[22] *United States v. Balint,* 258 U. S. 250 (1922). But see, *Smith v. California,* cited at footnote 8; *Lambert v. California,* 355 U. S. 225 (1957); *Morissette v. United States,* 342 U. S. 246 (1952); *Baender v. Barnett,* 255 U. S. 224 (1921).

[23] 52 Stat. 114 (1938), 15 U. S. C. Sec. 54 (1958).

[24] In a forthcoming article in the *Antitrust Bulletin,* it is noted that the Supreme Court and the courts of appeals have now insisted that where monetary civil penalties are to apply, administrative orders must be both specific in scope and explicit in what they prohibit. In addition, the bark of these civil penalties is usually far worse than their bite.

[25] S. 387, 88th Cong., 1st Sess. (1953).

commodities." It is a new form of agency economic control embracing everything from toothpaste to toilet tissue, from soup to nuts, and from paper napkins to detergents. For all products for personal or household use, it authorizes detailed regulations prescribing the sizes and shapes of packages, the unit volumes in which these products may be manufactured, the use of label illustrations, the declaration of net contents, the label type size to be employed, the use of so-called economy-size packages, "cents-off" deals, and any references to the number of servings a product may supply.

The authority to issue regulations is to be shared by the FDA and the Federal Trade Commission, depending upon whether the product is a food, drug or cosmetic now subject to FDA enforcement, or is any other household product. The latter would be under FTC jurisdiction.

But the penalties for violation would, under present law, be wholly different—on substantially the same regulations—depending on which agency issued them. Failure to comply with a regulation issued by the FDA could mean penal enforcement with strict criminal liability. Noncompliance with the same regulation issued by the Federal Trade Commission would in contrast expose the violator only to a cease and desist order, subject to a civil penalty if not obeyed.

This proposal again illustrates the strange Congressional lack of awareness or indifference to the type of sanction to be authorized for the enforcement of administrative rule making.

In discussions with FDA officials, I have found that they are extremely loath to surrender the sword of strict criminal liability. They urge that they are cognizant of the occasional unfairness of using it and that if widely employed it might not long survive. They insist, however, that it provides an understandable direct motivation for compliance with any rule or interpretation they wish to advance. Since company officials can be prosecuted even without any knowledge or intent, all subordinate employees will usually yield to FDA views rather than expose their superiors to penal prosecution. FDA also believes that no monetary consequences will be sufficiently large to act as a real deterrent.

This is all very well when the rules are simple and understandable. But when they are complicated, technical, and often neither precise in meaning nor clear in coverage, the lack of balance between the severity of the sanction, as well as its *in terrorem* potential, and the economic questions involved is not good government.

Conclusion

In my view, both revision and refinement of these sanctions would be desirable. For noncompliance that directly endangers the public health, a criminal sanction can be accepted. Strict criminal liability cannot be countenanced.

For violation of regulations that are essentially economic, the use of a cease and desist order, backed up by both injunction and civil penalties for further violation, would be adequate. This is not remotely the "trafficking in noxious food and drugs" which Mr. Justice Frankfurter took as his springboard in the *Smith* case.[26] Moreover, $5,000 per day would seem to be a sufficient economic deterrent.

In his Holmes Lectures this year, Judge Friendly pleaded for more intensive study in the law schools of the substance of administrative law. He was talking about adjudication, not rule making. I hope that some of you in the academic cloisters who have time for study in depth, penetrating thought, and the aid of talented research assistants, may be moved to make a full and objective re-examination of this question of how the sanction for violation ought to be related to the form and subject matter of administrative regulations. **[The End]**

SMOKED FISH TO BE FROZEN FOOD ONLY

Smoked fish from the Great Lakes area will henceforth be stored and distributed as a frozen food, according to an announcement by the National Fisheries Institute and the Food and Drug Administration.

The Institute, which represents 90 to 95 per cent of the United States fish smoking and curing production and dollar value, advised FDA Commissioner George P. Larrick of this and other measures which the industry will undertake to insure against further instances of botulism poisoning by smoked fish. The botulism toxin does not develop below freezing temperature.

These actions of the Institute followed FDA's recommendation on October 25, that all smoked fish products from the Great Lakes area should be destroyed. The FDA's warning applied only to smoked fish, not to fresh, frozen, pickled or canned fish. The FDA emphasized that these recent actions by the Institute does not change the situation regarding smoked fish already distributed.

"The Institute is to be commended for its prompt action in dealing with an emergency situation. The measures they have agreed to adopt are consistent with recommendations of the FDA's advisory committee on botulism. They will be adequate to prevent botulism while technological studies are being made to develop practices for long-range application," the Commissioner said.

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[26] Cited at footnote 8.

New Drug Applications and Suspension Procedures

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Mr. Kleinfeld Is a Member of the Washington, D. C. Law Firm of Bernstein, Kleinfeld & Alper. This Paper Was Presented at a Two-Day Briefing Conference Sponsored by the Federal Bar Association in Washington, D. C. on June 27-28, 1963.

IT IS APPARENTLY A FUNDAMENTAL and immutable part of the administrative process that no direct grant of authority by Congress to the executive branch of the government, even if it is co-extensive with, or greater than, that requested by the agency concerned, remains sufficient for more than a few months. I often wondered some years back, while with the Department of Justice, just how various positions taken by agencies as to the scope and breadth of the laws they were administering were arrived at. I had a mental picture of a group of zealous (perhaps over-zealous) and dedicated (perhaps over-dedicated) officials getting together in an office (this must not be confused with the smoke-filled room which we all know is invariably employed by politicians and industry) and saying gleefully, as they rubbed their hands, "Now, let's see what we can do to give the consumer greater protection." Another way of putting this is "Now, let's see how we can extend the statute to areas which we, in our expertise, believe ought to be covered, although Congress apparently did not."

Whatever the rationale or philosophy may be, it is an unalterable law, probably originally enunciated by Hammurabi or Justinian, that every agency, local, state, or federal, must stretch an ordinance or law to the breaking point, and sometimes beyond. After all, explain these Argonauts, we are merely attempting to protect the public. And if one dares remonstrate, the disingenuous answer is "Well, you can always meet us in court." Of course, in many instances the only way in which one meets an agency such as the Food and Drug Administra-

tion in court is on the receiving end of a criminal prosecution. Certainly counsel for the manufacturer, at least, cannot be lighthearted about this. It is his client who can be found guilty in a criminal prosecution without any proof of knowledge, intent, or wilfulness. He knows, also, that a corporate officer can be found guilty if, to use the all-enveloping language of Justice Frankfurter, the officer had "a responsible share in the furtherance of the transaction which the statute outlaws." It is he who must advise his client that the penalty for the first violation (each shipment constituting a separate offense) can be a fine of $1,000, or imprisonment for one year, or both, and for a second offense, or for a first offense with intent to defraud or deceive, a fine of $10,000, or imprisonment for three years, or both.

Difficulties at the Federal Level

And on the federal level at least, just try to settle the difference of opinion "in court," as blithely suggested by the government, by means of a suit for a declaratory judgment rather than awaiting a seizure action or criminal prosecution. If this is essayed, watch the bitter governmental opposition to such a suit on the ground that, as a matter of constitutional law, no "case or controversy" exists since the Attorney General of the United States has not threatened prosecution. The Attorney General, of course, when asked for his views on whether he intends to prosecute, replies by the stock and hallowed expression that "The Attorney General is authorized by law to render opinions only to the President and heads of the executive departments of the government.[1]

[1] The various administrative agencies, aided and abetted by the courts, have whittled down the Declaratory Judgment Act so that it is of little practical value. See, for example, the recent case of *Kennedy v. Rabinowitz, et al.*, U. S. App. C. C., No. 17,105, April 4, 1963, where the court dismissed a declaratory judgment suit not on the ground that the Attorney General had not threatened prosecution, but rather because of the sovereign immunity doctrine. The court stated in part:

"Appellees rely heavily on Professor Borchard in arguing that civil procedure in the area not involving moral turpitude, particularly 'where there is grave uncertainty as to what practices the general terms of a law prohibit.' Borchard, *Declaratory Judgments* (2d Ed. 1941), p. 1021. They also assert with Professor Borchard, that one of the main and most beneficial functions of declaratory judgment procedure is as a substitute for criminal prosecutions in the area of regulation of business practices.' Philosophically, we may agree. But the Congress had decreed otherwise, at least so far as agents representing foreign governments are concerned. Consequently, since appellees have failed to challenge the constitutionality of the Act, on its face or as applied, or the authority of the Attorney General to enforce it, this case should be dismissed on the pleadings as an unconsented suit against the United States."

"Incomplete Gimmick"

In the food and drug area, perhaps a classic example of administrative law-making is what is known in the drug industry, albeit not overly fondly, as the "incomplete gimmick." In 1938 B. T. (Before Thalidomide), Section 505 of the Federal Food, Drug and Cosmetic Act provided that a new drug application would be permitted to become "effective" (in reality "approved") on the 60th day after its filing, unless prior to that day the Secretary had postponed the effective date of the application to such time, up to 180 days after the filing, as the Secretary deemed necessary to enable him to study and investigate the application.

For some mysterious and inexplicable reason lost in antiquity, the government seldom, if ever, took advantage of this specific statutory grant of authority to examine a new drug application for 180, rather than 60 days. In any event, it may well be that in some instances more than 180 days were required to evaluate a drug which might have potentialities for harm as well as good. Further, and this was even more important, at the end of the 60th (180th) day after filing, the new drug application became automatically "effective" (approved) if the Secretary had not acted. Whether an automatic approval of an application in this area is good or bad is not the subject of this paper. But in any event, under the original 1938 Act, there was what appeared to be at least a practical reason for the position taken by the government with respect to the filing of new drug applications. This was because the government obviously believed that more time was needed to consider these applications than that granted by Congress. Consequently, the pertinent regulations provided that a new drug application did not have to be permitted, or not permitted, to become effective as provided by the Act, but that for any reason which the government chose to proffer, the application could be called "incomplete" and therefore not "filed."

Then came thalidomide, and whatever the government wished from Congress in the way of further authority was available for the asking. The Drug Amendments of 1962 vested tremendous power in the Food and Drug Administration. With respect to new drugs, the amendments, at the specific request of the government, give the Secretary 180 days after the filing of an application, or such additional period as may be agreed upon by the Secretary and the applicant, to approve the application or to give the applicant notice of an opportunity for a hearing. Certainly, it is a Hobson's choice with which the applicant is presented. He knows full well that should he fail to agree to

an additional period of time for evaluation of his application, the Secretary will presumably postpone the taking of any final action at the end of the 180 day period by giving the applicant notice of an opportunity for a hearing.

If the applicant, a most unusual and daring company indeed, does not agree to an additional period but instead elects to proceed with a hearing by making a written request within the 30 days after the notice, the hearing is to commence not more than 90 days after the expiration of the 30 days, and the Secretary's order at the conclusion of the hearing "shall be issued within 90 days after the date fixed by the Secretary for filing final briefs." Even more important, the failure of the Secretary to approve or disapprove the application no longer causes the application to become automatically approved.

It would appear to the uninitiated that with these changes, made at the behest of the government, the practical rationale for the incomplete stratagem no longer existed. To the surprise of some of the more unsophisticated, this disingenuous artifice is still to be employed, and the regulations which have been issued so provide.

One example that I recall is a new drug application originally submitted in December of 1961 and held incomplete (the former new drug provisions then being in effect) 59 days later. Correspondence was then had early in 1962 and another incomplete communication received in June of that year. A further submission of the application was made and, since the Drug Amendments of 1962 had now been passed, the next frustrating "can't be filed" letter was forwarded to the petitioner almost six months thereafter. In addition, the last "incomplete" missive from the government stated, and this is more customary than otherwise, that "We will reserve final comment on proposed labeling until the application is otherwise completed." (That this applicant is now comparing himself with Tantalus is not surprising.) It is clear, therefore, that the government intends to continue this artifice, although the bases which the government may have thought required it as a practical matter no longer exist. It may be stated by the officials concerned that this procedure "is the best thing for industry." I should think that industry ought to be the best judge of what is best for it.

Let us now assume that a particularly fortunate drug manufacturer has finally submitted sufficient data so that the government has determined, at long last, to accept the new drug application for filing. Now that we turn from extra-legal to legal considerations, what are the chances of the application being approved? The breadth of the

statutory language, with respect to what the applicant must submit and what will support an administration determination not to approve an application, is such that greater discretion could hardly be vested in the Food and Drug Administration.

The new drug application must contain "full" reports of investigations which have been made to demonstrate that the drug is safe and effective, a "full" list of its components and composition, a "full" description of the methods, facilities, and controls pertaining to the manufacture, processing and packing of the drug, and such samples of the drug and its components as the Secretary may require, together with specimens of the labeling. Within 180 days after the filing of the application, the Secretary is directed to approve it or to give the applicant notice of an opportunity for a hearing "on the question whether such application is approvable" (the drafters could have been a bit more literary).

At this point, considering the grounds on which the Secretary can determine that an application is not "approvable" and the ambiguity and vagueness (perhaps necessary in this area) of the statutory language, I challenge anyone, ever, at any time, in any way, to persuade any court to reverse an administrative conclusion after a hearing that the new drug application is not "approvable." The Secretary may issue an order refusing to approve the application if the reports submitted to him with the application do not include "adequate tests by all methods reasonably applicable" to show whether the drug is safe when used as directed, if the results of those tests show the drug is unsafe or do not show that it is safe, and if the methods, facilities and controls used in the manufacture, processing and packing are inadequate to preserve its identity, strength, quality and purity. In addition, and here the discretion vested in the Secretary is plenary indeed, he may refuse to approve the new drug application if, upon the basis of the information submitted to him as part of the application or upon the basis of any other information before him "he has insufficient information to determine whether such drug is safe for use under such conditions," or "there is a lack of substantial evidence that the drug will have the effect it purports or is represented to have," or "based on a fair evaluation of all material facts" the labeling is false or misleading in any particular.

"Substantial Evidence" Defined

In one of the rare instances in which Congress has chosen to explain or define one of the many rather indefinite and vague words and

phrases appearing in the Act, the New Drug Amendments of 1962 define "substantial evidence" in connection with the effectiveness of a drug for which a new drug application is filed, by providing a firm and immovable wall to hold off any daring manufacturer who may dare to quarrel with an administrative determination in this respect. The term "substantial evidence" is defined to mean evidence "consisting of adequate and well-controlled investigations, including clinical investigations, by experts qualified by scientific training and experience to evaluate the effectiveness of the drug involved, on the basis of which it could fairly and reasonably be concluded by such experts that the drug will have the effect it purports or is represented to have" under its conditions of use.

Secretary May Withdraw Approval of New Drug Application

Let us assume again that at long last a new drug application is not only filed, but is actually approved. The Secretary may choose to change his mind. If he does, after notice and an opportunity for hearing to the holder of the approved new drug application, the Secretary may withdraw his approval on the same general grounds on the basis of which he could have disapproved the application in the first place. He may withdraw his approval if data shows that the drug is unsafe for use, or if new evidence or tests, evaluated together with the available evidence when the application was approved, shows that the drug is not shown to be safe for use, or on the basis of new as well as old evidence there is a lack of substantial evidence that the drug is effective, or if the application "contains any untrue statement of a material fact."

The Secretary may also withdraw his approval of a new drug application if he finds that an applicant has failed to establish and maintain such records or make such reports as the Secretary may require, or the applicant has refused to permit the government to copy or verify his records, or the Secretary determines, on the basis of old and new evidence, that the manufacturer's methods, facilities and controls are inadequate and are not made adequate within a reasonable time after notice, or, on the basis of new and old evidence, the labeling, "based on a fair evaluation of all material facts," is false or misleading in any particular and is not corrected within a reasonable time after notice. Any order withdrawing approval of an application must state the findings on which it is based. In the event the Secretary, or the official acting as Secretary, finds that there is an imminent hazard to the public health, he may suspend the approval of the new drug appli-

cation immediately and give the manufacturer prompt notice of his action and afford him an opportunity for an expedited hearing.

Prior to the passage of the Drug Amendments of 1962, an appeal from an order refusing to permit a new drug application to become effective, or withdrawing such permission, could be had in a United States district court for a district in which the applicant resided or had his principal place of business or in the district court for the District of Columbia. That provision was included in the archaic and antediluvian days of yore, when the original Federal Food, Drug and Cosmetic Act was passed. At that time, requiring that a new drug application be submitted to the Food and Drug Administration before the drug was marketed seemed a vast grant of power to the government, which is perhaps why words considered nasty in those days, such as "licensed" or "approved," were not used. Apparently, industry felt that its chances of success in a review proceeding might be better in a district court than in a court of appeals, and the government did not seem to have quarreled with that procedure at that time. In all the years between 1938 and the passage of the Drug Amendments in 1962, only one drug company, a very small and audacious one, obtained the final judgment of a reviewing district court. This company had its petition for a review thrown out by an indignant judge who asked counsel for the petitioner how he (the judge) could possibly be requested to substitute his judgment for that of the Food and Drug Administration where a question of safety was involved. This, of course, was to be expected.

Notwithstanding this, the Drug Amendments of 1962 provided, since almost everything else was being changed anyway, that appeals from orders refusing to approve, or withdrawing approval of, a new drug application should now be taken to the United States court of appeals for the circuit where the applicant resides or has his principal place of business or to the United States Court of Appeals for the District of Columbia Circuit. This is more in line with the traditional type of administrative review and with reviews from various orders issued under the Federal Food, Drug and Cosmetic Act in connection with other facets of the statute. Whether it really makes any difference is doubtful. As in other areas of administrative law, "the finding of the Secretary as to the facts, if supported by substantial evidence, shall be conclusive." Interesting questions would arise if appeals were ever taken. Thus, as we have seen, the Secretary may refuse to approve a new drug application or may withdraw his approval if "there is a lack of substantial evidence" that the drug is effective. Apparently

the Secretary's order to that effect must be affirmed if there is substantial evidence that there is a lack of substantial evidence. This would be a juicy morsel indeed for the legal profession in other areas of administrative law where there was some point to entering into litigation.

Now why do I say in other areas than the food and drug field? The answer lies in the incident to which I have referred, in the one instance where review was had of an order refusing to permit a new drug application to become effective. We have judges, presumably in their 50's, 60's, or alas, 70's, with whom age, and the concomitant infirmities, are catching up. Certainly jurists are not pharmacologists, biochemists or medical doctors. When, to these factors, is added the presumption that the government in this area must be equated with Country and Motherhood, an attorney representing a client in the new drug field must be an incurable optimist indeed to expect a reversal of a position taken by the government involving safety. And if the problem is not of drug safety but of effectiveness, and if the vagueness of the criteria dealing with effectiveness are not sufficient to make it virtually impossible for a court to reverse the administrative decision, the government can always contend that a product which is not effective is in reality unsafe since it may keep a patient from a drug which is effective.

We all know that, in any field of administrative law, the courts give considerable weight (and properly so) to the expertise and knowledge in a particular field of an administrative body. We all realize that administrative decisions are traditionally affirmed if based on "substantial evidence," and that the courts will not reverse these decisions even though they may have reached contrary decisions if they had been the administrative bodies. Is this traditional administrative review of any utility or significance in the field of foods and drugs? It is not a harsh criticism of the government to point out that it is composed of human beings and that human beings, even in the executive agencies, sometimes make mistakes. A new drug which is improvidently permitted on the market may cause death or serious injury. A new drug which is improvidently kept off the market may result in the death or injury of those for whom no other drug was of help.

Special Scientific Committee Suggested

As I have pointed out, can we, with any degree of logic, expect any judge or court (particularly after thalidomide) to hold, under any circumstances whatever, that a decision of the government in connec-

tion with a new drug is not supported by substantial evidence? Yet, I certainly would not do away with the requirements that there be findings, an order and judicial review. It may be, however, that in this field at least, something new should be added. Might it not be advisable to provide that a decision of the Secretary to refuse approval or withdraw approval of a new drug application because of scientific considerations be submitted, at the request of the applicant, to a scientific committee? This committee would consist in each case of a representative of the Food and Drug Administration and of the Public Health Service, appointed by the Secretary, and three scientists designated for this purpose by the National Academy of Sciences. The opinion of this committee on the safety and effectiveness of the drug, together with the detailed reasons upon which the opinion was based, could go up to the court of appeals with the administrative record of the hearing which resulted in the order refusing to approve, or withdrawing the approval, of a new drug application. I do not see what harm would ensue from this procedure. Certainly it would be very helpful to a court of appeals. Perhaps more important, it would constitute a real check against the very occasional official who realizes (particularly now) that he cannot possibly get into trouble by saying "no," but may be criticized by the "after the fact" experts (particularly those in Congress) if he says "yes" and an unfortunate and unforeseeable side reaction occurs.

In no event would a new drug be permitted marketing in the first place until the court had finally ruled. Upon the basis of an administrative determination by the government that a drug being marketed under an approved new drug application presented an imminent hazard to the public health, marketing would be stopped immediately, as the law now provides. Where there was no such administrative determination of imminent hazard, however, the final determination with respect to withdrawing approval of a new drug application could at least await the concurring opinion of the committee. The ultimate decision would be made by the court of appeals.

The provisions of the Act dealing with pesticide chemicals and colors contain a provision whereby an advisory committee can be set up by the Secretary for an independent study of the data submitted by the Secretary together with other data before him. The committee can make a report and recommendations to the Secretary. It seems to me that this general pattern can well be employed, in the changed form I have suggested, in connection with the approval, or the withdrawal of approval, of new drug applications. It would appear to make

better sense to have the report of the committee, together with the underlying data, made a part of the record going directly to the court of appeals. I suggest that this further addition to our traditional system of checks and balances, at least in the vital drug area, would be beneficial not only to industry, but also to the government and the public itself. [The End]

REORGANIZATION OF FDA ANNOUNCED

Secretary Celebreeze has announced a reorganization of the Food and Drug Administration. The reorganization adopts salient features from recommendations of the Second Citizens Advisory Committee on the Food and Drug Administration, which made its report in October 1962 (17 FOOD DRUG COSMETIC LAW JOURNAL 579-720).

"An important feature of the reorganization is the upgrading of the scientific functions. I expect the reorganization to improve FDA operations all along the line, and thereby provide more effective protection of the consumer's interests," Secretary Celebrezze announced. "The reorganization will not entail the expenditure of additional funds. It adjusts existing functions and deploys the staff so that they will be able to operate more efficiently."

The appointment of a National Advisory Council to the Food and Drug Administration is an important innovation. It will be comprised of representative citizens under the chairmanship of the FDA Commissioner, and will advise the Administration on national needs and the effectiveness of program policies.

A scientist will be appointed Associate Commissioner and will give leadership from the Office of the Commissioner to the programs and functions having to do with medicine, science and research. Two new bureaus with scientific activities are established—a Bureau of Scientific Research, supporting FDA's basic mission of consumer protection, and a Bureau of Scientific Standards and Evaluation, which will handle safety clearance functions in regard to pesticides, food additives and colors, and develop scientific data to be used in setting standards and tolerances. These Bureaus replace the present Bureau of Biological and Physical Sciences.

No change is contemplated in the present Bureau of Medicine, which was recently reorganized to handle new responsibilities under the Drug Amendments of 1962.

Enforcement activities will be consolidated in a single Bureau of Regulatory Compliance replacing in part the Bureau of Field Administration and the Bureau of Enforcement, which presently have divided responsibilities.

Educational functions of the FDA are emphasized in the creation of a new Bureau of Education and Voluntary Compliance, made up of the Division of Advisory Opinions, the Industry Education Branch, the Consumer Education Branch, the Consumer Inquiries Section, and the Consumer Consultant Program.

International Food and Nutrition Programs

The Following Recommendations on Administrative Policies for International Food and Nutrition Programs Is a Statement of the Food and Nutrition Board, Released in April 1963. The Food and Nutrition Board, Established in 1940 Under the Division of Biology and Agriculture of the National Academy of Sciences—National Research Council, Serves as an Advisory Body in the Field of Food and Nutrition.

Fundamental Principles and Problems

THE FOOD AND NUTRITION BOARD recognizes the need for effective action programs to meet urgent food and nutrition deficiencies in many developing areas of the world. Consideration must be given both to the needs of resident populations and to achieving long-range objectives of mutual interest based on improvements in agriculture, food technology, nutrition practices and public health. The recommendations developed in this statement have an obvious relationship to problems in international trade and in developing worldwide conditions that lessen the risks of war.

The quantities of food available for export from technologically advanced countries are far below the quantities needed for normal health and vigor in countries where population densities are high, agricultural practices are inefficient, and where trained personnel, equipment, arable land and transportation facilities are lacking. In many countries the rate of population increase tends to outrun or offset the slow increments in food production and improvements in economic or social structure.

Fortunately, in North America, Western Europe, Australia, Argentina and a few other sections of the world there is currently an abundance of foods for export both through regular channels of trade and on a humanitarian basis to areas where hunger and malnutrition are most severe. Although the most damaging deficiencies are in foods of high quality protein, such as milk, meat, poultry and fish, there are many countries where caloric deficiencies are serious. The caloric (energy) needs can be met at relatively low cost with supplies of grains, legumes and oil seeds, such as wheat, corn, rice, sorghum and

soybeans which are also useful sources of protein, fats, vitamins and minerals. Adequate caloric intake is an important and immediate factor in maintaining morale and work output but often does not correct the most crucial forms of nutritional health impairment.

Unfortunately, the fundamental manner in which an inadequate food supply—in terms of *either* quantity or nutritive quality—retards economic, social and political development often goes unrecognized here and abroad. When malnutrition is endemic, the low levels of vitality, poor resistance to disease, stunted physical and mental development and limited time for constructive pursuits beyond mere survival all combine to restrict progress and to create political and economic instability. Such conditions in any part of the free world impose upon other nations economic hazards and risks to peaceful relations.

Policies and programs for the utilization of foods available for export should include provision for at least three major categories of use:

(1) Commercial sales in world markets through normal channels of trade represent the major immediate and long-range goal, insofar as circumstances permit. Under present circumstances, this avenue of action, however, does not serve adequately in meeting the total situation.

(2) Special negotiations are important in soft currency areas, including such arrangements as purchase credits at low interest rates, exchange for goods or materials for which there is a need in this country and crediting food as part of contract commitments for economic development. Agreements should include specific and liberal allowance of funds for advanced training programs in agriculture, food technology and nutrition, both here and abroad.

(3) Organized and supervised programs of free distribution in disaster areas and for humanitarian purposes as in maternal and child health centers and school lunch programs are desirable, but only via well-organized national and international agencies that require joint responsibility by local agencies and provide enough surveillance to assure satisfactory programming.

There is no prospect that most of the newly developing countries will find it possible through their own resources to produce immediately enough of the foods needed for optimum health, and it is equally clear that the more advanced countries cannot produce enough to meet the entire world needs. However, our policies should vigor-

ously and honestly encourage the development of food resources within the countries that have severe deficiencies beyond their present capacity to purchase or provide. Give-away techniques or uneconomical merchandising of food commodities will not solve either their problem or ours. Start-and-stop programs are even more damaging, particularly in food, health and educational activities.

Beyond the service of supplying foods on a normal economic basis, our greatest contribution in proportion to our resources can be in terms of careful and vigorous programs of education by demonstration and sustained personnel training, supplemented by financial credits and the advisory services of carefully selected experts to improve research and practices in agriculture, human nutrition, food technology, sanitation and industrial management.

In shaping policies and in planning programs, there should be clear recognition that the segment of the population penalized most severely by malnutrition in nearly all of the developing countries is in the age range from weaning to five years. Reaching this group is extremely difficult. In many areas, up to 50 per cent of the children fail to survive to school age, directly or indirectly as a result of poor nutrition. Among those that survive, permanent physical stunting is often equivalent to two-to-three years of their most rapid growth and the central nervous system may also be irreversibly injured in degree comparable to the suppression of early growth. In the light of requirements for achieving social and economic progress, the task of assuring an adequate food supply for mothers, infants and growing children merits a much higher priority than it has had in the past. For example, it is short-sighted and tragic to go so far as to encourage increased use of land for production of cash crops for export from newly developing countries when the result of such a program is failure to adequately feed and protect the health of the population as a whole. Agricultural exports can be of immense economic advantage in establishing a favorable monetary exchange, but this goal should not cause neglect of available land, credits and education to produce essential food for low income segments in the population.

Importance of Food Technology

The vital importance of food technology to the development of countries whose economy is based largely on agriculture has not been clearly recognized. Food technology can make permanent contribu-

tions to the economy and health of devoloping countries in three broad fields:

(1) In agriculture providing improved crop selection, processing and distribution, thus stabilizing and extending outlets for farm products on a year-round basis, and by preventing waste and spoilage of temporary crop surpluses. This role of the food technologist is a key to success in agricultural production.

(2) In industry by providing employment at a higher level of production and income through an expansion of food processing and by developing products for export.

(3) In public health by improving the nutritional value of foods and by modernizing sanitary practices in food handling. For example, a very important contribution of food technology would be the development of high quality protein foods in forms that are inexpensive and highly acceptable.

Although conditions vary from country to country, an adequate program in nutrition and food technology would include such features as:

(1) Establish departments of nutrition in universities with specialists in clinical nutrition, biochemistry, physiology, dietetics and food management.

(2) Organize and support teaching curricula for training of medical students, nurses, dietitians, home demonstration agents and public health educators in nutritional science.

(3) Assist and support the conduct of dietary surveys, nutrition clinics, and research programs on problems of greatest local and national importance.

(4) Establish food technology laboratories in one or more agricultural colleges, with specialists in bacteriology, food analysis, food engineering and food management. The laboratory should include pilot plant equipment for developmental work on a semicommercial scale.

(5) Organize and support training programs in food sanitation, quality control, research and demonstrations, emphasizing the production and processing of high quality protein foods, and the shipment or canning and dehydration of local foods generally.

(6) Organize Councils on Food and Nutrition to coordinate programs and advise the Secretaries or Ministers of Agriculture, Health, Education, Commerce and Economic Development. One of the major goals in the work of such Councils should be the development of

agricultural industrial programs to serve all segments of the public on a sound economic basis.

Recommendations

(1) In view of the primary importance of nutrition and food technology to the health and economic welfare in developing countries, the Food and Nutrition Board recommends that a comprehensive program in nutrition and food technology be instituted and supported by the Agency for International Development or other federal agency authorized to meet this critical need for a coordinated and sustained program. A top-level executive should be appointed with sufficient responsibility to insure coordination of the international activities of the several government departments that have major interests in nutrition and food technology and in the related aspects of agriculture, industry, education and public health.

(2) A small high-level advisory committee or commission should be established to assist the above executive in developing and maintaining a greater degree of coordination among government, nongovernment and international agencies having major responsibilities in international food and nutrition programs. Members should be independent of other government positions and should include chiefly persons with extensive training and experience in such areas as food production, distribution and technology, human and animal nutrition, education and public health. Executive sessions should be held regularly and on call by the chairman. Administrative responsibilities apparently should be in the Federal Council of Science and Technology.

(3) Provision should be made for sustained and increased support of the Interdepartmental Committee on Nutrition for National Development and for follow-up programs to build on the opportunities created by their initial surveys. This group has completed surveys in 22 countries and has issued reports outlining both the nature of problems to be solved and programs for their solution. The surveys constitute a resource that should be developed for the mutual advantage of the countries served and the United States.

(4) Because of the severity and worldwide scope of the problem and its significance for social and economic development, a primary objective of the United States foreign policy as it relates to foods and nutrition should be the prevention of serious malnutrition among

children, with first consideration for the age range from weaning to five years. This problem should be accomplished in a manner that will not create dependency, but instead will encourage individual initiative and responsibility within the areas served.

(5) International food and nutrition programs should include a diligent regard for encouraging food production for domestic use or export, whichever is in the best interest of the total population in developing areas. Attainment of good nutrition practices within the cooperating countries should be the primary goal. This policy would encourage, rather than interfere with, a progressive development of markets in normal trade for products from the United States, but the marketing aspects should not have precedence over the protection of health and general economic progress in the developing countries.

(6) Greater flexibility and coordination should be developed in the use of Public Law 480 funds, particularly in support of research that would facilitate action programs and training of personnel to serve within the newly developing areas. Training programs should include major emphasis on nutrition and food technology, and provision for broad training in agriculture and collateral training as in economics, statistics, public health, sanitation, and food distribution.

In areas where Public Law 480 funds are not available, support should be developed from other sources such as the Agency for International Development, the National Institutes of Health, the Office of International Scientific Affairs, the Food for Peace Council, the Freedom from Hunger Foundation and the United Nations agencies. Insofar as possible, the training of professional personnel should be developed on the basis of (a) careful selection and (b) commitments by cooperating governments or their respective institutions, for placing and supporting trained personnel in positions commensurate with their training and ability. Private foundations, State Department attaches, and National Academies of Science with experience in fellowship placement should be invited to assist in this type of service.

(7) In virtually none of the newly developing countries is there a food processing and distribution industry adequate to serve the urgent year-round needs of the population. Neither do they have established programs of sanitation and pure food control. Guidance in this area of agricultural and industrial development is essential to establishing healthful conditions and a stable economy.

[The End]

The FDA Looks at Detergents Under The Federal Hazardous Substances Labeling Act

By FRANKLIN D. CLARK

Mr. Clark, Assistant to the Deputy Commissioner of the Food and Drug Administration, Addressed the Detergent and Cleaning Compounds Division of the Chemical Specialties Manufacturers Association on December 5, 1962, in Washington, D. C.

IT IS A PLEASURE to appear this afternoon on this panel in company with acknowledged experts in the field of detergents. As a lifetime employee of the Food and Drug Administration, my interest in the subject of detergents has been confined for the most part to domestic use until the passage of the Federal Hazardous Substances Labeling Act in July of 1960. Since that time your industry and the Food and Drug Administration share a common interest, and the establishment of this panel on your program today with FDA participation we believe to be entirely appropriate.

The genesis of the Hazardous Substances Labeling Act, as has been repeated from many platforms in the past two years, was the rising incidence of poisonings and other accidental injuries, especially to children, caused by common household substances. I have gone over in some detail the committee reports at hearings which led to the passage of the Hazardous Substances Labeling Act and I find almost without exception when there appears a "such as" list of common household substances that detergents are included. Although Poison Control Centers and other sources of statistical information on injuries do not show any large incidence of hospitalizations due to detergents, they do appear rather high on the list of types of substances frequently ingested by children under 5 years of age in reports from the Poison Control Centers. For instance, in 1958, 132 Poison Control Centers located in 29 states reported that a total of 464 cases

(or 4.6 per cent of the total incidents reported to them) involved ingestion of soaps, detergents, and cleaners. In 1959, the number of cases was up to 728, this being 4.8 per cent of the total. In 1960, the reported cases rose to 1,270 and included eight hospitalizations; in 1961 there were 980 cases with 11 hospitalizations. Over the past several years we have learned of two deaths of children in which a detergent has been considered the causative agent. Therefore, it is important that the status of soaps, detergents and cleaners under the Hazardous Substances Labeling Act be recognized and the problems involved in their labeling under this statute be discussed.

Why Federal Hazardous Substances Labeling Act Covers Detergents

Before going further into the matter of the status of these products under the Hazardous Substances Labeling Act, I believe it might be helpful to consider them more definitively under the Federal Food, Drug and Cosmetic Act. Soap is specifically exempted from the cosmetic section of the Food, Drug and Cosmetic Act but it may of course become a drug if therapeutic claims are made for it. Synthetic detergents if intended to be "rubbed, poured, sprinkled or sprayed on, introduced into, or otherwise applied to the human body or any part thereof, for cleansing, beautifying, promoting attractiveness, or altering the appearance" are cosmetics. If so, they are under the jurisdiction of the Food, Drug and Cosmetic Act and statutorily exempt from the provisions of the Hazardous Substances Labeling Act. Contrarily, if they do not so meet this definition for a "cosmetic" then the applicability of the latter statute must be considered. It is this consideration that I propose to discuss in the time available to me today.

There are three fundamental qualifications for coverage under the Hazardous Substances Labeling Act. The first definition is that the substance must be a "hazardous substance" because it is toxic, irritant, corrosive, strongly sensitizing, pressure generating, or flammable as defined in the statute.

Secondly, the substance is one which "may cause substantial personal injury or substantial illness during or as a proximate result of any customary or reasonably foreseeable handling or use, including reasonably foreseeable ingestion by children." This phrase, through its legislative history and I believe common understanding, includes "misuse" as well as normal and expected use.

Finally the product must be in a container "intended or suitable for household use." Although our interpretation of this clause has been subject to some criticism we believe that it is conceded that any normally packaged goods which are usually found in a household are "intended or suitable" for household use. This, we believe, covers most detergents and cleaners used for dishes, walls, and other household special cleaning tasks for which industry prepares special formulations.

The three ways in which detergents and cleaners must be considered under the definition of "hazardous substance" are toxicity by ingestion, skin irritancy and eye irritancy.

From data so far submitted to us it would seem that automatic dishwashing detergents and possibly some household cleaners, both solid and liquid, are toxic by ingestion in the high ranges of products classed as "toxic but not highly toxic" in regulation 191.1(f)(1). This audience certainly does not need to be reminded that this requirement is that products with an LD_{50} of 50 mg/kilo to 5 gm/kilo of body weight of test animal renders a product toxic by definition. This definition was one which was widely discussed at the time it was proposed. We were strongly urged to reduce the top dosage level to prevent the classification of "toxic" to many products really not dangerous. Our position was and is, and experts in the field of pharmacology and toxicology agreed with us, that the 5 gram figure is not unreasonable, and that exemption procedures provide the necessary relief when needed.

Is an Exemption Warranted?

We have been petitioned on behalf of several detergents that even though the products do meet this definition, an exemption under Section 3(c) is warranted either because of the physical impossibility of a child swallowing an injurious amount, or because of the product's built-in emetic properties which prevent any systemic absorption. We are considering very carefully this situation but I cannot at this time give you a final decision. There is some difficulty among some of us in accepting the fact that a product does not need warning labeling simply because if eaten it "only" makes a child vomit. We believe mothers in general consider that if a child vomits from something swallowed, he has been injured. We do, however, have as guiding principles the exemption provisions of the law which allows

deviations in labeling where warnings or full warnings are not required for the protection of the health and safety of the consumer.

The next issue to be met is that of the irritating properties of detergents if they accidentally come in contact with the skin in full or diluted condition. The skin irritancy test prescribed in Section 191.11 of the regulations is, we believe, a tried and tested method and in general accepted as being a satisfactory indication of reaction on human tissue. As we have so often stated, which is confirmed in Section 191.2 of the regulations, human experience does however take precedence. We should, therefore, have no difference of opinion as to how detergents should be labeled with relation to their skin irritancy properties. If they meet the prescribed test, we believe they should be appropriately labeled unless it can be affirmatively shown that human experience with the product shows no significant reaction. In this area we see very little opportunity for a decision that the health and safety of the consumer can be protected through the omission of labeling.

Possibility of Eye Irritancy

The third type of possible injury by detergents, and frankly the most troublesome one to FDA, is that of possible eye irritancy. From conversations with and questions from people in your industry we believe that this matter has also given you some concern. First I would like to mention briefly the test for eye irritancy as it is given in Section 191.12 of the regulations. We have since the issuance of these regulations received comments from investigators who indicated some difficulty in applying the judgment which classifies a product as an eye irritant, and in the light of these comments our scientists have carefully re-evaluated the prescribed test and confirmed its applicability. We believe that any modifications of it to which we could agree would probably be only minor. The problem seems primarily to be in experience in using the method. There is a question as to the physical form in which the product under test is applied. We believe that it should be applied in the physical form in which it might be "reasonably foreseeable" for it to get into the human eye.

This brings us to really the key consideration in the applicability of eye irritancy of detergents. The statutory requirements are that if a product is an eye irritant and it is "reasonably foreseeable" for such product to get in the eye of the user or of an inquisitive youngster, it should bear appropriate labeling. If the product meets the defini-

tion for an eye irritant and it is "reasonably foreseeable" that it might get in an eye, it needs labeling; if it is not "reasonably foreseeable," it does not. Whether there is a reasonably foreseeable risk of the detergent getting into the eye is a factual question on which we cannot lay down rules in advance. If the manufacturer concludes there is no such risk, he need not label the detergent for this hazard. But he does this with the possibility that we may disagree and initiate an enforcement action. We are resolving doubts in favor of consumer protection, and would urge you to do the same. Unless it is pretty clear that there is no risk of injury, the warning should be used.

FDA's Enforcement Program Under the Act

I would now like to say a few things in general about the enforcement program of FDA under the Hazardous Substances Labeling Act. I say this because the new effective date of February 1, 1963, with regard to Section 191.101 of the regulations again raises pertinent questions. On February 1, the suspension of the placement and type size requirements expire and we have no facts before us now that would furnish a basis for any further suspension of these requirements. Therefore, stocks of hazardous substances after that date which do not meet the placement and type size requirements in Section 191.101 are subject to seizure and shippers of products not so labeled after that date are subject to the criminal provisions of the law.

Changes in labeling laws and regulations are not new to FDA as we quite frequently deal with such matters under the Federal Food, Drug and Cosmetic Act. We are aware of distribution patterns and pipelines, of inventory needs, and other factors which create lags in full compliance with any change of labeling rules. We therefore do not on the effective date of a rule change automatically engage in a mammoth enforcement operation to remove all technically violative merchandise from the channels of commerce.

There is one difference here. These particular rules will have been known for 18 months on February 1, and we were assured that this was sufficient time to deplete inventories and to revise labeling. We therefore will expect to find labels of hazardous household substances substantially in compliance. Sticker labels, providing they meet with the provisions of the statute and the regulations and are firmly attached, are still permissible.

You may have noticed in the seizures consummated under this Act that actions so far have been on rather seriously misbranded

products. This quite frankly reflects the priority applied up to now to our work under this statute. On February 1, we intend a somewhat broader approach to this whole field and although we do not intend to deal in trivialities, we are going to demand progressively improved labeling of products under the statute in order that as rapidly as possible the consumers of this country may have the benefits Congress intended for them. We would, however, much rather have manufacturers and labelers develop fully satisfactory labels through consultation with our Division of Advisory Opinions than have labeling corrections brought about through conferences with our legal people after a seizure. [The End]

STANDARDS ESTABLISHED FOR ORANGE JUICE PRODUCTS

Federal definitions and standards of identity for orange juice, frozen orange juice and other orange juice products, and for concentrated orange juice products, have been established to go into effect next July 1.

The standards set the composition and names by which the products are to be called and specify the types of labeling to be used to inform consumers of what they are getting. These standards replace earlier standards that had been published by FDA in 1960 but had been set aside pending a hearing on industry objections. The hearing involved what names to use on the products, and the use and proper label designation of certain optional ingredients. The findings of fact which resulted from that hearing served as the basis of the new standards.

The standards require that labels bear information that will identify and describe the kind of product being offered. For example, regular orange juice that has been heated to destroy enzymes and microorganisms to make it keep longer must be labeled "pasteurized orange juice," or if the packer prefers, he may say "heat-processed" or "heat-stabilized" in place of "pasteurized." The standards are specially aimed at preventing the adulteration of orange juice by sugar and water and the misrepresentation of reconstituted and pasteurized orange juice as "fresh" orange juice.

Orange juice products that are sweetened by certain optional sweetening ingredients such as sugar and dextrose must carry on the label a statement such as "sweetener added to reduce tartness." The standards do not permit the use of artificial sweeteners or chemical preservatives for the consumer products, although certain safe preservatives may be used in orange juice products for manufacturing, with appropriate labeling.

Identities and standards are established for orange juice, frozen orange juice, pasteurized orange juice, heat-processed orange juice, heat-stabilized orange juice, canned orange juice, frozen concentrated orange juice, frozen orange juice concentrate, canned concentrated orange juice, canned orange juice concentrate, reconstituted orange juice, orange juice from concentrate, orange juice for manufacturing, orange juice with preservative, concentrated orange juice for manufacturing, orange juice concentrate for manufacturing and concentrated orange juice with preservative.

The Deep Pocket Rule and the Jumping Warranty: Strict Products Liability of Manufacturers

By LAWRENCE A. COLEMAN

This Paper Was Delivered at a Meeting of the Industrial Hygiene Foundation in Pittsburgh, Pennsylvania on October 24, 1963. Mr. Coleman Is General Counsel, Allied Chemical Corporation.

OUR PURPOSE is to comment upon an emergent rule of law that has profound implications for manufacturers.

It is a rule of law that is jurisprudentially "radical," as it goes to the "roots" of our law; it is morally dubious, as it would rob Peter to pay Paul; it is economically oppressive, as it casts its whole burden on a single class of businessmen; and it is wrongly ordained, as it has been enacted by the courts, not our legislatures.

We refer to the recently developed, judge-made rule that imposes an absolute liability on manufacturers for injuries sustained by others using their products, even when such products are carefully made and sold. We refer to what has been termed the "Deep Pocket" Rule.

Background of the Rule

The change in our legal order made by the Deep Pocket Rule is best appreciated against the background of the law of products liability as it stood in, say, 1950, a little more than a decade ago.

At that time, a manufacturer's products liability was typically based upon two legal theories, one developed under the law of torts (that is, civil wrongs), the other created by the law of sales.

The tort theory involved the familiar principle, applicable to us all, that a man is liable to another for injuries caused by his negligent conduct. Negligence was defined by reference to the objective standard of the ordinary care of prudent men. Consequently, a manufacturer who made or sold a product carelessly was liable for the injuries sustained by others using the product.

Justice Cardozo's Decision

Originally, this liabilty for negligence extended only to immediate purchasers of the product, persons in so-called 'privity" with the manufacturer. But in 1916 that limitation was removed, at least with respect to dangerous products, by Judge Cardozo of the New York Court of Appeals in a seminal decision,[1] and it is probably the current rule that a negligent manufacturer is liable to all who are foreseeably injured by his product.

Judge Cardozo's requirement that the product be one that would be "reasonably certain to place life and limb in peril when negligently made" [2] seems to have been more easily satisfied outside New York than within his jurisdiction, so that sofas, lounge chairs, cigarettes, and toy tops, among numerous other products, have been regarded as inherently dangerous in several of the states.[3] One is reminded in this connection of the comment of a recently appointed federal judge in the New York Southern District who, sitting for the first time on maritime tort cases, remarked that he had never imagined that there were so many "unseaworthy" vessels plying New York Harbor!

The relevant point here is that under this tort theory, it remains a condition of the manufacturer's liability that he be negligent, that he be at fault, that he be blameworthy. That is the usual tort rule of liability applicable to us all, and in theory at least the manufacturer is neither favored nor disfavored by it.

We must quickly add that there are a few special situations in which negligence is not a condition of tort liability, as under workmen's compensation statutes, or for activities like dynamiting, that subject others to extraordinary hazards. But the exceptions underscore the otherwise universal rule that men are not liable without fault. Of course, intentional wrongs are actionable without negligence, but they are hardly an exception to the rule of no liability without fault.

Warranties Made by Sellers to Buyers

The second theory of products liability was found in the law of sales, and specifically in the warranties that were made by sellers to buyers.

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[1] *MacPherson v. Buick Motor Company*, PRODUCT LIABILITY CASES 827, 217 N. Y. 382 (1916).

[2] Case cited at footnote 1, at p. 389.

[3] Frumer & Friedman, I *Products Liability* 25-26 (1960).

Dean Prosser has said that the warranty concept is "a freak hybrid born of the illicit intercourse of tort and contract." [4] It is a concept with a strange legal history, but in modern times, certainly since the general enactment of the Uniform Sales Act, the warranty has functioned much like a promise from seller to buyer guaranteeing the quality of goods sold. The promise may be expressly made by the seller, or may be implied by law. In either event, the seller is obligated to deliver goods of the promised quality. If the goods prove defective, the warranty is breached, the seller is liable for consequent damages, and it is no defense that the seller exercised the greatest care in making the product. Here the strict liability normally associated with contract breaches ensues.

"In Privity"

This is the traditional and proper result; promises must be kept. The crucial point in 1950, however, was that only the buyer who had purchased directly from the seller could sue for the breach of warranty. He was, after all, the only other party to the contract of sale, the only party, therefore, to whom the guarantee of quality could ordinarily [5] have been made. He was "in privity." If he resold the goods to a consumer, the latter, not being a party to the original contract of sale, not being in privity with the manufacturer, could not sue the manufacturer for breach of warranty; his remedy was against his immediate seller. Where fault was present, the remote consumer might sue the manufacturer in negligence under Judge Cardozo's ruling mentioned earlier, but not for breach of warranty.

Again, we must add that an exception to the no-privity-no-liability-in-warranty rule had long existed in the case of food products. Here, manufacturers seem to have had an extensive liability from the beginnings of our law. The rationale of the exception has never been satisfactorily traced,[6] but a great teacher of law has suggested a sardonic explanation of these food decisions with the comment, "The emotional drive and appeal of the cases centers in the stomach." [7]

In 1950, then, the general rules were that manufacturers, if negligent, might be held liable to all persons foreseeably injured by their

[4] Prosser, "The Assault upon the Citadel" 69 *Yale Law Journal,* 1099, 1126 (1960).

[5] Third-party beneficiary doctrine in contract law should not apply. *Restatement, Contracts,* Sec. 133(1)(b) (1932).

[6] See Dickerson, *Products Liability and the Food Consumer,* p. 26 (1951); Prosser, cited at footnote 4, at p. 1103.

[7] Llewelyn, *Cases and Materials on Sales,* p. 342 (1930); quoted in Prosser, cited at footnote 4, at p. 1103.

products; and secondly, might be held liable to their immediate customers for breach of warranty, irrespective of negligence.

Influential Opinion of 1944 Noted

About 1950, ideas that had been germinating in the minds of some of our judges began to bear fruit; one is tempted to say, bitter fruit. An anticipatory expression of these ideas is found in a concurring, but influential opinion of a judge of the Supreme Court of California. In a case appealed to that court [8] the facts were that the plaintiff, a waitress in a restaurant, was injured when a bottle of cola exploded in her hand. (I may say, parenthetically, that bottlers have contributed much to our learning in this field.) Defendant was a bottler who sold and delivered the bottles to the restaurant. No specific act of negligence by defendant was shown, but there was no evidence that any one but plaintiff had touched the bottles after delivery. On this record, the jury found the defendant bottler negligent, and the Supreme Court of California affirmed the judgment.

However, Judge Traynor rested his concurrence on broader grounds than the defendant's negligence. He said: "I concur in the judgment, but I believe the manufacturer's negligence should no longer be singled out as the basis of a plaintiff's right to recover in cases like the present one. In my opinion it should now be recognized that a manufacturer incurs *an absolute liability* when an article that he has placed on the market, knowing that it is to be used without inspection, proves to have a defect that causes injury to human beings. . . . *Even if there is no negligence* . . . public policy demands that responsibility be fixed wherever it will most effectively reduce the hazards to life and health inherent in defective products that reach the market. It is evident that the manufacturer can anticipate some hazards and guard against the recurrence of others, as the public cannot . . . the risk of injury can be insured by the manufacturer and distributed among the public as a cost of doing business. . . . Against such a risk there should be general and constant protection and the manufacturer is best situated to afford such protection."

Thus, Judge Traynor, speaking in 1944, holds that, irrespective of the care they exercise, manufacturers may be held liable for defective products even to persons, such as the plaintiff-waitress, with whom they have no contractual relations. He suggests that such

[8] *Escola v. Coca Cola Bottling Company of Fresno,* 11 NEGLEGENCE CASES 88, PRODUCT LIABILITY CASES 1053, 24 Cal. 2d 453 (1944).

liability may properly be imposed on manufacturers because they can best afford it as a cost of doing business. Dean Pound has described this view as resting on the idea "that the manufacturer can stand the loss better than the person injured." [9] Here is the "Deep Pocket Rule," full blown.

"Assault upon the Citadel of Privity"

Within 20 years, the California judge's view was to be shared by some of the most prominent courts in the country, and applied to all kinds of manufacturers. Liability without fault for manufacturers was to be accomplished by an "assault upon the citadel of privity." [10] as Judge Cardozo has put it. What happened was this: the second theory of product liability, breach of warranty, was retailored to suit the problem. A plaintiff remote from the manufacturer was permitted to base his claim on breach of warranty, notwithstanding the theory that a manufacturer's warranty is a promise to his immediate buyer only. He might recover if it were shown that the product proved defective and the plaintiff was hurt, without showing how or where the defect developed. Proof of careful manufacture would be no defense to an action for breach of warranty. The new dispensation would impose an absolute liability without fault on manufacturers generally.

To be sure, the refashioning of the warranty theory to achieve this end has met with no little conceptual difficulty.[11] A student of the subject has found about thirty different modes of legal analysis for making the warranty "jump." [12]

It has been held that the retailer is the manufacturer's agent to sell, that the retailer is the consumer's agent to buy, that the retailer assigns his warranty from the manufacturer to the consumer, that the consumer is a third-party beneficiary of the retailer's contract with the manufacturer, and so on. When this happens in a legal system, one can be fairly certain that the reasons given by judges have followed, not preceded, the desired result.

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[9] Pound, *An Introduction to the Philosophy of Law*, p. 102 (1953 rev. ed.).

[10] *Ultramares Corporation v. Touche*, 255 N. Y. 170, 180 (1931).

[11] Amram and Goodman, "Some Problems in the Law of Implied Warranty," 3 *Syracuse Law Review*, 259, 263-268 (1952).

[12] Gillam, "Products Liability in a Nutshell," 37 *Oregon Law Review*, 119, 153-55 (1957).

Judge Traynor has now made this clear. In a 1963 California opinion, writing this time for a unanimous Supreme Court, and with a battery of supporting decisions now behind him, he writes:[13] "A manufacturer is *strictly liable in tort* when an article he places on the market, knowing that it is to be used without inspection for defects, proves to have a defect that causes injury to a human being. . . . Although . . . strict liability has usually been based on the theory of an express or implied warranty running from the manufacturer to the plaintiff . . . the liability is not one governed by the law of contract warranties *but by the law of strict liability in tort* . . . We need not recanvass the reasons for imposing strict liability on the manufacturer . . . The purpose of such liability is to insure that the costs of injuries resulting from defective products are borne by the manufacturers that put such products on the market rather than by the injured persons who are powerless to protect themselves." (Italics supplied.)

We must at least be grateful for this candor. The California court tells us that we need no longer concern ourselves with the intricacies of the jumping warranty, that a new tort has emerged, and that it is specially designed for manufacturers who are without fault. It is simply called, "Strict Tort Liability."

Happily, the California decision is not yet the law of the land. There remain a very large number of states, perhaps a majority, that refuse to make the warranty jump. And the American Law Institute's new *Torts Restatement* imposes strict liability on sellers of food only.[14]

But if it is not the law, it is the handwriting on the wall. It has already received glowing approval from no less than Chief Judge Desmond of the New York Court of Appeals. Just last May, speaking for the court, he referred to Judge Traynor's concept of "strict tort liability" as "surely a more accurate phrase" for manufacturer liability.[15] This is powerful judicial backing for the new philosophy. It behooves us to examine the matter somewhat more closely.

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[13] *Greenman v. Yuba Power Products, Inc.*, 15 NEGLEGENCE CASES (2d) 35, 59 Cal. 2d 67 (1963).

[14] *Restatement, Torts* (Second) Sec. 402A.

[15] *Goldberg v. Kollsman Instrument Corporation*, CCH PRODUCTS LIABILITY CASES ¶ 5058, 191 N. E. 2d 81, (N. Y. Ct. App., 1963).

Dubious Morality of the Rule

We said at the outset that the Deep Pocket Rule, the rule of strict tort liability for manufacturers, is jurisprudentially radical, in the sense that it goes to the roots of our law. It is, we hope, now apparent that it does.

As we have observed, with few exceptions, our law refuses to impose liability without fault. That principle is firmly embedded in our legal order. To depart from it and create a special class of defendants without the benefit of its protection because of their deeper pockets, to (in effect) place manufacturers beyond the pale of law because they can afford it, is seriously to compromise our system of justice.

It is difficult to conceive of any other sector of our law in which ordinary civil liability is determined with reference to the economic status of the parties. How foreign that view is to our traditional jurisprudence is best seen in this extract from Section 406 of the Soviet Civil Code:[16] "In situations where . . . the person causing the injury is not under a duty to repair, the court may nevertheless compel him to repair the injury, *depending upon his property status and that of the person injured.*" (Italics supplied.)

Surely that is a shocking idea to Americans. A prominent teacher of jurisprudence has shown us how one's sense of justice is offended by this kind of discriminatory treatment of a defendant. He posits the case of five men arraigned before a magistrate for the *identical* offense. The magistrate acquits three, fines one five dollars, and imprisons the last. These inequalities of treatment arouse the sense of injustice because, as he puts it,[17] ". . . equal treatment of those similarly situated with respect to the issue before the court is a deep implicit expectation of the legal order."

It is assuredly a deep implicit expectation of our legal order that parties to a civil proceeding will be equally treated irrespective of their economic status. "Justice is blind," we say, and do not add (as has a wag [18]) "Blind she is, an' deef an' dumb an' has a wooden leg." If liability is to be imposed on the basis of affluence, shall we rule for the small manufacturer when the plaintiff is a giant chain store?

Clearly, we are dealing with fundamental moral questions, and it will not do to rob Peter to pay Paul. There is a close kinship between

[16] Quoted in Pound, *An Introduction to the Philosophy of Law,* 1953 rev. ed. at p. 103.

[17] Cahn, *The Sense of Injustice,* 1949 at pp. 14-15.

[18] Finley Peter Dunne.

law and morals in the principle of no liability without fault. In making moral judgments, we do not regard men as wrongdoers when they are blameless. Neither should the law.

There are, moreover, important social theories involved here. Implicit in the idea of no liability without fault is the notion that if individual men carry on their affairs with reasonable care, society will not penalize them; indeed, that society encourages the energetic, imaginative exercise of individual free will when done carefully. And conversely, each of us must bear the risks of some injuries that are inevitable in society when no one is at fault.

The Deep Pocket Rule takes a very different view of society. It conceives that a life free of economic risks is now to be guaranteed everyone by the law, by making Good Samaritans out of manufacturers. There are to be no more luckless victims.

It is not our purpose to examine the relative merits of these two social theories. The point here is that the Deep Pocket Rule presupposes a view of society that sharply diverges from the theory that has reigned heretofore.

There is, finally, an economic assumption under the strict liability theory that is disturbing.

Economic Validity

The California court held that the manufacturer is properly the victim of the Deep Pocket Rule because he can insure his liability and transfer his costs to ultimate consumers. Passing the question whether the consuming public *should* pay for the plaintiff's injuries, how valid is that assumption as a matter of economics?

There are about 165,000 active manufacturing corporations in the United States. Of these, 90 per cent are corporations with total assets of less than $1 million.[19] The nameless, typical manufacturer, therefore, is overwhelmingly in the category of small business. In the absence of insurance, ability to withstand product liability claims is plainly limited, for judgments in this area are not uncommon in five and six figures.

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[19] *Quarterly Financial Report for Manufacturing Corporation, First Quarter* 1963 (FTC-SEC) at p. 61. Figures are based on corporation income tax forms filed in 1960-61. Manufacturing partnerships and single proprietorships are excluded, but would probably increase the stated percentage.

The Question of Insurance

May insurance be expected to solve his problem?

It seems clear that complete insurance coverage of strict liability would require that insurers guarantee the quality of a manufacturer's research, the efficiency of his manufacturing and packaging techniques, and the warranties printed on his labels or uttered by his salesmen. Coverage of this scope is not now available, and, in view of the enormity of the risk entailed, will probably not become available in the foreseeable future.

What is normally available, therefore, does not fully meet the risks involved. The text of a given policy may fail to include particular risks from coverage, because heretofore they were not considered the reasonable subject of liability. Similarly, as any verdicts increase in amount, a manufacturer may well find himself uncovered for substantial sums.

The costs of this insurance cannot be lightly dismissed. A small manufacturer of a general line of chemicals with sales of, say, $10 million a year, desiring reasonable coverage, might well be paying an annual premium of $30,000. If his sales were chiefly of products with the special risks of bodily injury, his premium might be $45,000. For large chemical companies, premiums may be in the order of half a million dollars, depending on experience. And, of course, as the courts broaden the scope of liability and juries bring in ever larger verdicts, premiums will climb.

Will Higher Prices Be the Result?

Can these insurance costs be passed on to customers as higher prices, as the courts assume?

A recent study of the pricing policies of 200 companies sponsored by the National Industrial Conference Board [20] suggests not. The determinants of price are shown to be multiple; costs may be one of these, but are rarely controlling, frequently are of little importance, and, indeed, are often unknown. Rather, the economic characteristics of a product, whether new or old, whether capital goods or consumer goods, whether differentiated goods or standardized goods; the type of firm involved, whether multiproduct or single product; the extent of competition, domestic and foreign; the role of demand in relation

[20] Backman, *Pricing: Policies and Practices* (1961).

to the availability of substitute products, consumer purchasing power, and habits and tastes; public relations considerations, and other forces; any and all of these may, for a given company and product, be more crucial than costs in determining price. The report concludes:[21] ". . . it is clear that the role of costs in pricing has been considerably exaggerated. Certainly, costs cannot be ignored in pricing. But neither can the many other factors discussed in this analysis. While cost-price relationships may be important, it does not follow that cost determines price. On the contrary, under many circumstances the flow is in the opposite direction. The price that can be obtained under prevailing conditions of demand and the pressures of competition often determines the costs that a company may profitably incur."

Thus, in the many cases in which a manufacturer's price is determined by noncost factors he cannot pass on his increased costs. He may, in fact, be locked into a given price by external economic forces so that increased costs of product liability come out of his pocket. And if, as is probable, he is a small manufacturer, his pocket is not very deep.

"Bad Government for the Courts"

Which brings me to my final point. We have indicated that the Deep Pocket Rule is an expression of radical jurisprudence, dubious morality, novel social theory and bad economics. Apart from the merits of each of these criticisms, and mindful only of the magnitude of the change that the rule effects, surely it is bad government for the courts, rather than the legislatures, to have enacted it.

In the first place, the ordinary, adversary judicial proceeding is not a very suitable mechanism for the consideration of so complex a question of "political economy." One can fairly assume that in none of the cases in which the Deep Pocket Rule was adopted was evidence adduced on the question whether the defendant-manufacturer's increased costs were transmissible to his customers. That is not the kind of question courts look into, despite its obvious relevance to the premises of the rule. Such economic evidence would, however, constitute the heart of legislative consideration of the matter.

Secondly, it is far more consistent with democratic theory for so sweeping a change in public policy to be made by the legislatures. It was, after all, an assumed public policy that prompted the California court's statement of the rule. However, we have no assurance that

[21] Work cited at footnote 20, at p. 39.

it was reflecting a wide social consensus. I believe that the sweep of the rule requires such a consensus, expressed through our legislatures, for its legitimation.

Curiously, the legislature of more than half the states, in enacting the new Uniform Commercial Code, had an opportunity to deal with the matter and declined to do so, probably because of the bulk of other problems presented by the Code. They did see fit to extend the manufacturer's warranty to a limited circle around the buyer, but final resolution of the manufacturer's liability was deferred to the courts, in a reversal of roles.[22] Nevertheless, one returns to Dean Pound's incisive question,[23]

"If I am not to be my brother's keeper but am to be his insurer, should not so radical a change in the social order come through legislation rather than through judicial decision?" **[The End]**

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

1. Date of filing: Oct. 1, 1963. 2. Title of publication: Food Drug Cosmetic Law Journal. 3. Frequency of issue: Monthly. 4. Location of known office of publication: 4025 W. Peterson Ave., Chicago, Cook, Illinois 60646. 5. Location of the headquarters or general business offices of the publishers: Chicago, Illinois 60646.

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7. Owner: Commerce Clearing House, Inc., Chicago, Illinois; names and addresses of stockholders owning or holding 1 percent or more of total amount of stock: C. T. Corporation System, Wilmington, Delaware; The Corporation Trust Company, (Del.), Wilmington, Delaware; The Corporation Trust Company, (N. J.), Jersey City, New Jersey; The Corporation Trust Company, (N. Y.), New York, New York; Chetco, Boston, Massachusetts; Eddy & Company, New York, New York; Hurley & Company, New York, New York; The Millbrook Tribute Garden, Inc., Millbrook, New York; Justus L. Schlichting, Toms River, New Jersey; Sigler & Company, New York, New York; Smith Barney & Company, New York, New York; Bertha Palmer Thorne, Bar Harbor, Maine; George T. Whalen, as Trustee under the will of Oakleigh Thorne, Millbrook, New York. 8. Known bondholders, mortgagees, and other security holders owning or holding 1 percent or more of total amount of bonds, mortgages or other securities: None.

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[22] Uniform Commercial Code 2-318, Comment (3).

[23] Pound, cited at footnote 16, at p. 102.

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