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Food-Drug-Cosmetic Law JOURNAL

Charles Wesley Dunn Lectures: The Ultimate Responsibility . . . . .

by GEORGE Y. HARVEY

The Philosophy of Enforcement of the Federal Food, Drug and Cosmetic Act

by FRANKLIN M. DEPEW

The Latin-American Food Code: Chapters I, II, III and V

A COMMERCE CLEARING HOUSE PUBLICATION
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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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REPORTS

TO THE READER

Charles Wesley Dunn Lectures.—This month's JOURNAL is pleased to present two of the Charles Wesley Dunn Lectures. These lectures, sponsored by the Pharmaceutical Manufacturers Association, were created in honor of the late Charles Wesley Dunn who was one of the founders and first president of The Food Law Institute, Inc.

Franklin M. Depew, the current Food Law Institute president, pays tribute to "the inspiration and foresight of the man, Charles Wesley Dunn. . . . Mr. Dunn became interested in the food and drug law early in his career. Prior to the passage of the 1938 Act I think I can safely say he was the only lawyer who devoted any substantial part of his professional time to this field. It was through Mr. Dunn's efforts that attorneys practicing in this field were brought together on a professional basis in the American Bar Association, the Inter-American Bar Association and the New York State Bar Association."

Mr. Depew spoke at the University of Southern California on April 4, on the subject of "The Philosophy of Enforcement of the Federal Food, Drug and Cosmetic Act." He points out that this act is the only federal law which affects our daily life and well-being so intimately. Because of this it is important that those who are responsible for compliance with its requirements in industry and government should be exceptionally well-trained, responsible and competent. "Patience and tolerance must be more than ideals on the part of both—they must be living realities," declares Mr. Depew. This article appears at page 185.

The Chairman of the Citizens Advisory Committee, *Dr. George Y. Harvey,* presented the second lecture at the New York University School of Law on March 26. His paper, which appears at page 173, discusses the objectives of the Second Citizens Advisory Committee Report which was released in October, 1962. He states that it is a plan for development, rather than a definite blueprint for immediate and drastic action. It is the responsibility of the Secretary of Health, Education and Welfare to follow as he sees fit. However, he maintains that the ultimate responsibility for a government of our kind lies with the legal profession. "A legislature adopts rules of action to carry out new theories of government as desired by the electorate, but only a court of law can declare the principles which make such rules of action effective, and thus, articulate the will of the people. Here is the fiber of government. Here is the majesty of the law. Here is the future of America and it is in this context that we measure the great and lasting contribution made by such men as Charles Wesley Dunn."

Latin-American Food Code.—This JOURNAL contains Chapters I, II, III and V of the Latin-American Food

Code which were translated from the original Spanish by Ann M. Wolf of New York. Chapter I contains the "General Provisions." Chapter II discusses "General Requirements for Food Factories and Food Outlets." "The Storage, Preservation and Processing of Foods" is the subject of Chapter III. "Labeling" regulations are set forth in Chapter V.

The translation, which begins on page 194, is based on the 1960 edition of the Code published in Buenos Aires, as subsequently amended by the Latin-American Food Council. Other parts of the Code have appeared in the following issues of the JOURNAL: October, 1960 (Introduction to the Code and Index); February, 1961 (Utensils, Receptacles, Containers, Wrappers, Machinery and Accessories); May, 1961 (Sugar and Sugar Products); November, 1961 (Correctives and Improving Agents —Additives); and June, 1962 (Nonalcoholic Beverages and Refreshing Foods and Drinks).

Testing New Drugs on Humans.— *Michael F. Markel* discusses the legal considerations in experimental design in testing new drugs on humans in a paper which appears at page 219. "It may come as a surprise to some of you," he notes, ". . . to learn that no statutory code is in existence today anywhere which outlines a required procedure and course of conduct for those concerned with the evaluation of the safety and efficacy of drugs. The one exception to this general statement, to the extent that it is an exception, is the Drug Amendments of 1962 as this law will be implemented by administrative regulations governing 'investigational drug research' along the lines indicated in the proposed regulations. . . ." However, the courts have established basic principles which must be observed by those who would experiment on humans. He concludes his remarks by suggesting that the doctor, whether he be a medical investigator, a specially qualified clinician, or a general practitioner, who follows his professional code of ethics conscientiously has nothing to fear from the law, both statutory and common law. Mr. Markel is the present Chairman of the Division of Food, Drug and Cosmetic Law of the American Bar Association.

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Food·Drug·Cosmetic Law
Journal

The Ultimate Responsibility

By DR. GEORGE Y. HARVEY

This Charles Wesley Dunn Lecture Was Delivered at the New York University School of Law on March 26, 1963. George Y. Harvey, LL.B., LL.D., Is Assistant to Dean, Extra-Divisional Administration, Lecturer in Political Science, School of Business and Public Administration, University of Missouri, Columbia, Missouri.

IT IS ALWAYS A SIMPLE MATTER to make a speech if all one does is to string together the cliches of history and run the flag a little higher on the pole. No one will ever get into trouble talking about this government of the people, by the people, for the people, and this government of laws and not of men.

It is quite a different thing to call attention to the fact that government of the people by the people does not mean government of a lot of people by a few people or that a government of laws cannot rise above the human beings who administer those laws.

Moderate Approach Difficult

It is also easy to make a speech if one merely selects the most horrible example of an obvious evil and inveighs against it with vigor and enthusiasm. The difficult position is the moderate approach. He who chooses to travel in the middle of the road may be killed in the traffic, but let it be said that he died sportingly.

This is the most successful, most sophisticated, structured society in the history of man and government is only a part of it. In fact this government has been less a part of structured society than any other government in history and herein lies the secret of its success. Political power always has been resented in America, but political leadership

Dr. Harvey Is Chairman, Citizens Advisory Committee, Food and Drug Administration.

has been willingly accepted with the right to change leaders jealously preserved. This proudly hailed sophistication, however, is a very thin and hastily applied veneer. Less than 80 years ago it was said there was no law west of Dodge City and no God west of Carson City and, if the television audience is any criterion, most of America looks wishfully back to that period.

By the end of the nineteenth century it became apparent that things had to change. A growing, settled, population and an industrial economy required a different outlook. The lusty and lustful mores of the frontier characterized government, politics, and practically every other form of social and economic inter-action. Reform became the order of the day. Demons were driven from the land. The demon "rum" was driven a little too far and had to be recalled.

Regulation of Business Born

By and large these reforms were born of very real necessity. One of these was the regulation of business. The business community itself needed regulation for its own protection as well as for the protection of the general public. In that early period the general philosophy, even east of Dodge City, seems to have been that the law was applicable only to those who were caught.

Of course, human nature has not changed, but cooperation with the inevitable is a human characteristic. Doctor Benjamin Friedman, a life-long student of food and drug protection, has said that in the enforcement of the early federal laws, Harvey Wiley had to make cases because he could not make policy. It must be stated as incontrovertible fact that it is possible to make policy only after it is definitely established that cases can, have been, and are going to continue to be prosecuted.

Basis of Report of Citizens Advisory Committee

This is the basis of the report of the Citizens Advisory Committee on Food and Drug Law Enforcement. The report states that the police powers of the Food and Drug Administration are the source of its authority and its influence.

The *St. Louis Post Dispatch,* in commenting editorially on the Committee's suggestion—renewed from the report of the first citizens' committee in 1955—that more emphasis should be placed on preventive measures stated: "This objective may be too idealistic to be realized in full, but it is both the fair and practical goal to strive toward."

This statement is a compliment to the committee. Any study of this kind must be, to a degree, idealistic. Unless it explores ideas beyond the realm of immediately possible translation into action, it will have fallen short. The 16 members of the committee gave a great deal of time and attention over the period of a year to an examination of the problems involved. Each came to the task with a different point of view. Some of us were concerned only from the viewpoint of the consumer. Others, with basically a consumer point of view, were qualified from a highly technical and scientific standpoint. Some were more knowledgeable in the field of management of the regulated industries. Each had the basic interest of humanity first in his heart.

Regulation of business is a cold subject as related to the manufacture of machinery or in some other wholly inanimate area, but, when the safety of the food and drug supply of a large part of the world is at stake, it becomes a living, vital thing, and the financial and personal interests of stockholders, board chairmen, and attorneys, as well as the prestige interests of government officials, are secondary considerations.

Entrance of Government by Invitation Only

Government has never entered the field of regulation of business except through invitation. Once business by its attitude toward the public—neglect of its public responsibilities—makes it necessary for government to intervene, it is never able thereafter to purge itself sufficiently to be released from control. There is no indication of the desirability of relaxation of present controls in the food, drug, and related industry fields and no one suggests it. However, there are other types of controls, other methods of enforcement which ought to be explored and wherever practicable introduced to this field. To some extent it may be that these methods can be developed to provide

in some areas a better and more certain protection for the consumer. They should be considered as alternatives to current procedures, however, only where this is demonstrably possible.

Government Protection Needed by Both Consumer and Business

Attention should be given to developing protective measures in situations which seem to be beyond the reach of traditional methods. In any event there must be a constant re-examination of enforcement techniques and procedures and a special alert maintained for new enforcement problems. By its very nature American business is always in a great hurry. Profits just around the corner prompt honest men to take chances. With the volatile materials with which they deal today, the government must be ready and capable and adequately forewarned to deal with health hazards before they are found in the market place. The consumer and business both need the kind of protection that can be afforded only through government leadership.

In the past, new laws and regulations usually have been written in the heat generated by dramatic episodes. Surely we have reached the stage where it is not necessary to have a horrible example before action can be taken. Public opinion has charged government with responsibility for protection of the nation's food and drug supplies and will support any new law or regulation which may be needed. As a matter of fact, the public's ready answer—and usually it is an effective answer—to any abuse of privilege under this form of government is "enact a law." It is sometimes very easy to enact a law, particularly in the presence of an open grave.

Successful administration of a government of the people by the people depends on the assumption of each element in society of the burdens of government as applied to it. Where the business community is concerned, particularly those businesses having to do directly with the safety of food and drug, the alternative will be intrusion of government into the management of business to a degree heretofore undreamed of.

But no one business firm can do the job alone. Those willing to gamble with human life—and there are always a few—win just enough of the time to milk profits away from cautious operators and soon gambling becomes too commonplace. Only government working with those businesses who desire to maintain their reputations in a free market place can furnish the leadership necessary to isolate the

gamblers and deal with them in the harsh terms which will make gambling with human life an unprofitable venture. Perhaps this is idealistic—wishful thinking—but the American ideal requires that every effort be made to find ways and means of protecting the consumer with minimum interference in the internal affairs of business, though adequate protection will remain the responsibility of government.

Necessity of Alert Enforcement Unit

As pointed out in the committee's report, it will always be necessary to maintain an alert enforcement unit. It must be completely protected in its function of finding and bringing to time the willful violator and the chance taker. The honest mistake will not be repeatedly tolerated. He who returns to the confessional too often must be regarded as a willful sinner.

It is impossible these days to discuss any important question without making some reference to this new scientific world and its new problems. More than anything else this was the concern of the advisory committee. The avalanche proportions of the developments of the last half century have created problems for both government and industry which are not going to be solved overnight, and these problems are not isolated. Too frequently they are not separable, one from the other. As an example, protection of the food supply of man is now directly related to and bound up with the food supply of food supplies, both animal and plant. Over 80 per cent of animal feed today is medicated and this carries through to the meat in the market. This is a development of the last 15 years. Scientists at the colleges of agriculture long concerned only with better fertilizers to increase bushels per acre now have developed a very real concern for the health of man in relation to their fertilizer experiments.

The "Generalist" Created by Age of Specialization

Many different agencies of government at all levels are concerned with problems affecting the food and drug supply of the nation as well as affecting general health. Municipalities now commonly use pesticides over wide areas. Researchists in government scientific agencies and at universities have helped industry in developing new pesticides often without sufficient regard for toxic effect on humans. Scientists have been inclined themselves to pursue their own special interests without regard to tangential or concomitant but definitely related considerations. Fortunately there are many people in the

sciences who now are learning that they cannot turn their new knowledge loose on an unsuspecting world without exploring long-range and corollary effects. There is a new awareness of the interrelationship of various fields of endeavor and a great deal of time and effort is being expended to bring about a common understanding and coordinated approach to health, economic, social and political problems. Academics are faddists too. For many years proliferation of disciplines and curricula within disciplines has been the trend. Now, however, there is much discussion of inter-disciplinary approaches and recently the term "multi-disciplinary" is creeping more and more into the conversation. It seems that the age of specialization is about to create the final specialist: the "generalist." The problem soon will be to avoid carrying this trend so far that no specialists will be around to train the generalist in the specialties on which he is supposed to generalize.

In any event no agency of government, no agency with a public responsibility, can hope or expect to be a completely self-contained unit if it is to keep abreast of any segment of the problems of the health of the nation or of the social and industrial developments so rapidly occurring. Just as certainly no single agency can expect to keep up with all such problems and developments.

Controlled Science, Business and Government Interrelationship Vital

Many years ago some reference was made to the course of history having been determined on the cricket fields of England. Now the graduate and professional schools of American universities have supplanted the cricket fields of England in affecting the future course of events. Controlled interrelationship of science, business and government is vital to future development and the protection of society.

American business in its usually ingenuous fashion seized upon the new scientific approach of this generation and in true American fashion has exploited it to the limit. Investment counsellors today are often more concerned with the activity of the research branch of a business than with the financial wizardry of the board or the energy of the sales department. And, as usually is the case, government has fallen behind. This is normal in the American system. America has never moved its government into any field of endeavor until the needs of humanity required it. It is unfortunate but nonetheless true that government officials frequently must absorb considerable punishment for not having acted before they dare to act. Interrelationship of the

various agencies in and out of government with facility of communication among them will furnish the only assurance of protection for the public.

Health Problems Presented by Use of Old Chemicals Also

The use of old chemicals for new purposes and the use of new chemicals for old purposes have presented health problems far beyond the imagination of those who developed early controls and control methods. One small example: A generation ago paint remover was a product known to only a few. Today the old furniture craze has developed a market so important there is vigorous competition among the manufacturers. Large numbers of people are using these various products every day and the toxic effects may be extremely serious.

A larger example: The drug business of today is almost entirely a new business and is still changing rapidly. It is estimated that 90 per cent of prescriptions today call for drugs that were not on the market ten years ago and 45 per cent were not available five years ago. The drug industry is falling over its own feet like a growing boy. On the other hand, there is no way of measuring the benefits man has derived from the new products brought out by the drug industry. The developments in the drug field have presented acute problems to which adequate and early solutions must be found. One of these is communication with the practitioners of the healing arts through some more objective channel than self-serving advertising media. It is a responsibility of both government and the industry and also of the medical profession. Very simply it is the joint responsibility of all three.

The very necessary strictures and inhibitions of the anti-trust laws make the positive leadership of government necessary in a situation of this kind if the consumer is to be accorded vitally necessary protection and the business community is to continue to enjoy the freedom of the market place, a cornerstone of the American system.

Here again the easy answer is not adequate. Where life and death of people—persons—you and me—our children—are concerned, the rules developed to control purely economic considerations will rarely suffice and yet the principles of the anti-trust laws are sound and must be maintained.

Consumer Must Protect Himself

The most difficult problem in the whole area of consumer protection is to persuade the consumer to protect himself. Much has been

said about improved labeling. Printed labels are of no value to an illiterate public, and people who can read but won't read are just as illiterate as though they had never been to school. By this definition the illiteracy rate in the United States is extremly high. The importance of understanding methods and conditions of use, as well as dangers of ingredients present in a new product, must become the responsibility of the individual. A continuous educational effort to achieve this end must be maintained though it is doomed to be always less than completely successful.

Two-Fold Educational Requirements in Food and Drug Fields

One of the fundamental responsibilities of government is the dissemination of information among the people. Probably the single greatest accomplishment of the United States is the development of free public education. The federal government now has a Department of Health, Education and Welfare. Education no longer ends with the distribution of diplomas at the end of a formal period in youth but extends throughout life, and the public universities carry on extensive programs of educational conferences and short courses for professional as well as lay organizations to keep the adult population abreast of the times. Through normal news media much adult education can be accomplished but a more formal and intense approach is often necessary, particularly where technical fields are involved. The educational requirements in the food, drug and related fields are two-fold: general information for the consuming public and more technical information for specialized users.

All the protective devices of government can never help the person who ignores the warning of danger. Whether concerned with automobiles, appliances, food and drugs, hardware or whatever, too many people have the impression that government should guarantee safe passage through the market place. No matter how diligent the effort, no matter how many thieves have been sent to jail, always a new one turns up on the loose. There is real danger in permitting the populace to believe that it is even possible for the government to accomplish this result. Consumer education, of course, is a much broader field than just food and drug. Perhaps the Department of Health, Education and Welfare can utilize some of its talents and facilities outside of the Food and Drug Administration for a broad approach in this field.

Present Advertising and Sales Promotion Schemes Similar to Old Medicine Show Pitch Man

One of the great difficulties about America is that nobody has ever stopped to develop it. America has been exploited. This was early described and is still regarded as a land of quick wealth. Now that the day of quick profit from exploitation of natural resources is at an end, the quick dollar crowd think they have found a gold mine in the credulity of man. Present advertising and sales promotion schemes smack of the methods of the old medicine show pitch man. Great product names are being dragged before the public in disgrace because the sales department put on too much pressure or indulged in little deceptions for short-range profits. These people should give sober thought to the fact they do not enjoy the privilege of the old medicine show to pull stakes, get out of town before daylight and vanish into the hills. At the present rate of exploitation man's credulity will soon be as mined out as the coal fields of West Virginia.

Henry Ford, II, speaking at Minneapolis on April 20, 1961, said:

> I think it may be no exaggeration to project the 1960's as the most critical and far-reaching ten years in the history of the world. In such a decade, America needs more than ever before an atmosphere of mutual trust and confidence among such major elements of our society as industry, labor, and government.

and a little later on he adds:

> I, for one, don't believe America can afford the ludicrous spectacle of old-fashioned guerrilla warfare between business and government.

The interesting point here is that a great business leader will call warfare with the government old-fashioned. Not many years ago most business leaders regarded warfare with the government as the normal way of life and, unfortunately, some still do. However, there is no doubt that this attitude is changing and that a very large segment of the business community is willing to work cooperatively with the government in the public interest. Particularly is this true where health and safety are concerned. Long since, thinking people in modern society accepted the fact that inescapably each is his brother's keeper.

A year and a half ago, at the Food Law Institute dinner in Washington, I raised this question about regulatory law:

> Have we really examined these new fields from a philosophical standpoint in an effort to develop basic principles? All this new field of regulation which intermingles the legislative, the executive and judicial functions under one hat has presented some difficulties which we seem to have handled on a short-range basis. Have we been doing business with too much heat and too little light? Should we not now begin to look at the basic nature of the problems involved?

The establishment of the Food Law Institute and the work it has been doing are laudable efforts in this direction. As the Committee report stated, the whole structure stands on a foundation of law and the enforcement thereof. But it is for the law—the lawyers—to develop that atmosphere in which the honest conscientious businessman can learn to live within the law and continue to furnish safely to the public that to which the public is entitled: the fruits of new knowledge. It is in the framework of such agencies as the Food Law Institute and under the tutelage of men like its great leader, Franklin Depew, that new ideas and new concepts can be considered, molded and adapted to the needs of the public.

No one with any responsibility for either business or government can afford the demagogic luxury of equating dishonesty with the man across the street just because he is across the street. The best interests of the public will be served through the cooperative efforts of government and conscientious businessmen wherever possible. The outright crooks will remain the primary responsibility of the government but the government will have more time to devote to them if much of its business can be handled through willing cooperators and the consumer, out of all of it, will receive maximum protection.

Report of Advisory Committee a Plan for Development

There is nothing that is very new in the report of the Advisory Committee. Every suggestion that was made was based on previous experience in the Food and Drug Administration itself, or in other governmental agencies.

The report should not be regarded as a definite blueprint for immediate and drastic action. Rather, it is a plan for development. It contains many recommendations but calls attention to the fact that these recommendations are only the best ideas on which the Committee could reach accord.

It is now the responsibility of the Secretary of Health, Education and Welfare to use the report to his best advantage; to use those portions of it which to him seem desirable; to follow the concepts of the report if he sees fit, but to use other methods than those proposed if in his judgment other methods are better. Whatever course of action he may choose, the members of the Committee have pledged such assistance and support as he may require of them.

Forms and structures of government change from time to time, from country to country, from era to era, from decade to decade. The Department of Health, Education and Welfare is less than ten years

old and its constituent units, all older than the Department itself, have been reorganized and regrouped many times in the course of their history. An examination of institutionalized government over a quarter of a century will disclose little resemblance between the beginning and the end. No organization of government exists because God ordained it.

New Professional Responsibilities of Physicians and Lawyers

Man is born with two basic problems: his health and trouble with his neighbor. Two professions grew up over the centuries to deal with these problems: the physicians and the lawyers. They are a natural part of society without regard to forms of government. The medical profession has grown in its capabilities and in the breadth of its knowledge, but its responsibiltiies have grown also. As his life has changed and become more complex—while he lives longer and is far better protected against disease—man's health is increasingly endangered by the environment in which he finds himself and against which only organized society can protect him. Here is a new responsibility of and a new role for the medical profession that calls for collective action. The medical profession finds itself in a situation where many of its members are giving their time and attention to community problems rather than treating individual patients. This requires a new philosophy, a new attitude, working with government and for government, in order to meet these new health needs of man. It requires cooperative efforts with other professional and academic groups. Many persons in the medical profession in and out of government, on the campuses and in industry are aware of this new and different professional responsibility and are making real efforts to meet it.

The legal profession from the gratuitous advocates of early Rome has had the responsibility of protection of man in his person and his property. This responsibility has grown and enlarged through the centuries and reached the zenith of its importance in the American system where government exists only for the purpose of enabling man to deal peaceably and honorably with his neighbor.

John M. Zane, in his "Story of the Law," says, "The history of the law teaches that without a professional class of lawyers, a reign of law is impossible."

In a government of laws the exponents of the law carry the true burden of government. It is the legal profession which must maintain the necessary balance between institutionalized government and other elements of society. From time to time it will be necessary for one

professional group or another to take over an important role. At all times it will be necessary to maintain a flexibility of the formal structure of government which will permit the infusion of new ideas, new knowledge, new interests. This can be accomplished only through the philosophical continuity passing from one generation to the next in a profession of dedicated men whose concern is the welfare of humanity itself rather than in the power of government or the control of society.

A leading member of the American bar said, about 40 years ago, that few lawyers are philosophers and fewer philosophers are lawyers. The Food Law Institute recognizes a special field of the law where community health problems may be studied from the lawyers' standpoint. There is a field of importance above and beyond the individual client relationship. Perhaps there is reason for the legal profession to seek a role in the multi-disciplinary approaches now in vogue. At the University of Missouri we are now cross-listing several law school courses for graduate credit in the Political Science Department. Perhaps the law schools can utilize some of the modern research techniques to study legal systems, particularly in America, in the light of and in their relation to political systems.

Chief Justice Fuller once said: "It is with governments as with religions—the form often survives the substance of the faith."

Constant re-examination of the rules and forms of government is the price to be paid if the faith is to be sustained in the light of new knowledge and new needs. A good many centuries ago the writer of *Ecclesiastes*, took the completely pessimistic view that "he that increaseth knowledge increaseth sorrow." This is true only to the extent that man fails to learn how to manage his knowledge and direct it to his benefit.

In this government of laws and not of men the resources of government, the management of its enterprises, the vitalization of its principles through human action and relationships logically and inevitably fall within the purview of the law. The ultimate responsibility for such a government is with the legal profession. A legislature adopts rules of action to carry out new theories of government as desired by the electorate, but only a court of law can declare the principles which make such rules of action effective and, thus, articulate the will of the people. Here is the fiber of government. Here is the majesty of the law. Here is the future of America and it is in this context that we measure the great and lasting contribution made by such men as Charles Wesley Dunn. **[The End]**

The Philosophy of Enforcement of the Federal Food, Drug and Cosmetic Act

By FRANKLIN M. DEPEW

This Charles Wesley Dunn Lecture Was Delivered at the University of Southern California on April 4, 1963. Mr. Depew Is President of the Food Law Institute, Inc.

THE FEDERAL FOOD, DRUG AND COSMETIC ACT of 1938[1] is our most important federal law in the commercial field. It is the federal law which regulates the manufacture and sale of our vital daily necessities, to assure their safety, purity and integrity, and to require their honest and informative representation, in order to prevent the consumption of any that may kill or injure and the purchase of any that may deceive or defraud. A major portion of producers and distributors foresaw the practical worth of this law to producer and consumer and have worked diligently and productively to enhance its potentialities. The philosophy of its enforcement throughout the years is a subject which suggests many interesting considerations of a political, social and economic nature.

The Act is one which intimately affects the daily life and well-being of all of us, as no other federal law does. Not only does it regulate the sale and distribution of articles with which we come into intimate bodily contact, but it extends the protection of the federal power right into our homes.[2] For this reason it is important that those responsible for compliance with its requirements, both in government and industry, should be unusually devoted, well-trained, responsible and competent, with the vision to work toward the accomplishment of the law's basic purpose of supplying the American public with the

[1] 52 Stat. 1040, 21 USC 301 and the following.

[2] *United States v. Olsen*, 161 F. 2d 760 (CA-9 1947).

most abundant, most safe and most nutritious foods and the best and safest drugs and cosmetics. Patience and tolerance must be more than ideals on the part of both—they must be living realities.

The provisions contained in the Act relating to food are a recognition of the unusual responsibility the nation ascribes to those who produce and handle its life sustaining foods. The food sections of the law run like a thread through every activity from harvest to grocery shelf to consumer. No other commodities except drugs have been surrounded with such comprehensive and carefully designed safeguards.[3]

Implicit Common Denominator

This underlying concept of public trust is an implicit common denominator in every legal question on which a food or drug manufacturer seeks legal advice. Thus, lawyers who are privileged to practice in this field are in many respects in a unique position. They are presented daily with important legal questions requiring constructive study to assure proper and responsible interpretation. It is important that both counsel and their clients should be guided in their actions by this concept of public trust in order to assure the law's orderly operation and progress. In addition, it is important that they should recognize that while this law has operated to advance our free enterprise system to an unprecedented degree,[4] to the benefit of all, it will not continue to do so unless consumer wishes are satisfied in a manner which will avoid new legislation imposing an undue degree of administrative determination of business policy in the food and drug field.

I suggest that this problem of consumer satisfaction as posed by various representatives of women's organizations is one of the most difficult presently faced by industry. Despite the fact that the housewife's table today looks like an international feast, at costs relatively less than those of ten years ago,[5] many consumers and consumer organizations express dissatisfaction. The housewife has no laboratory at her disposal and is not a chemist; she cannot see through many of the packages to examine their contents nor the extent of their fill. Therefore, in this field, she wants government to act as a watch-

[3] C. W. Crawford, "Ten Years of Food Standardization," 3 FOOD DRUG COSMETIC QUARTERLY 243.

[4] Clarence Francis, "Its (The Food, Drug, and Cosmetic Act's) Basic Value to Food Industry," 1 FOOD DRUG COSMETIC QUARTERLY 379; S. DeWitt Clough, "Its Basic Value to Drug Industry," 1 FOOD DRUG COSMETIC QUARTERLY 387; H. Gregory Thomas, "Its Basic Value to Cosmetics Industry," 1 FOOD DRUG COSMETIC QUARTERLY 401.

[5] Index of Primary Prices of Processed Foods, U. S. Department of Labor, Bureau of Labor Statistics, as reported January, 1963.

dog for her. The problem is to find the point of maximum justice to both producer and consumer. Presumably there is some golden mean between the interests of the two, but the process of reaching it has become one of increasing conflict as reflected in the hearings conducted in Congress and the legislation introduced and passed therein. One dfficulty has been that a large percentage of industry's zeal for consumer protection is discounted. The suggestions of industry are frequently looked upon with suspicion, the feeling being that because industry advocates something there must be a selfish reason. Some of industry's efforts to present its point of view have been characterized as a "flood of propaganda as illogical as it was vigorous." [6] Thus, it seems clear that the potentialities of this law in advancing our free enterprise system and in getting the produce of our farms to the consumer in increased variety and abundance, will only be fully realized if consumer, government and industry work responsibly together to this end. In order to accomplish this they will have to deal frankly with each other and listen to the others' point of view with some freedom from prejudice and emotion.

It will be the purpose of these remarks to give some of the highlights of developments to date and to endeavor to draw some conclusions therefrom as to what we may expect in the future in developing the potentialities of this law in the light of the present philosophy with respect to its enforcement.

Men Active in the Adoption of the Act

Our country was fortunate indeed in that the men who were active in furthering the adoption of the 1938 Act were men not only aware of the consumer interest but also of our country's basic belief in the free enterprise system, including the desirability of separating the legislative and executive powers: Among these in addition to Senator Royal S. Copeland, were David F. Cavers, now Associate Dean, Harvard University School of Law, who acted as adviser to the Department of Agriculture with regard to food and drug legislation in 1933 and 1934, and Assistant Commissioner of Food and Drugs, Charles W. Crawford, to whom much credit must be given for keeping the consumer protection point of view before the legislative committees. Another who shared actively in the drafting work was Ole Salthe who had been in charge of food and drug law enforcement

[6] Saul Nelson, "Representation of the Consumer Interest in the Federal Government," *Law & Contemporary Problems*, a quarterly published by Duke University School of Law, Vol. VI, No. 1, p. 151 et seq., at p. 154.

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under Senator Copeland when the latter was Health Commissioner of New York City. Mr. Salthe, acting as adviser to Senator Copeland, brought to the task a realistic knowledge of industry and enforcement problems and a lively interest in consumer welfare.

Three Basic Principles Behind the Act

The statesmanlike approach of our Congress to the problems posed by the proposed legislation must also be acknowledged. The statement contained in Senate Committee Report No. 91, February 15, 1937,[1] which accompanied the bill, S. 5, which later became the 1938 Act, analyzes the conflicting points of view and synthesizes them into this statement of principles:

> This bill has been prepared with three basic principles in mind: first, it must not weaken the existing laws; second, it must strengthen and extend the law's protection of the consumer; and third, it must impose on honest industrial enterprise no hardship which is unnecessary or unjustified in the public interest.

If we take this statement as our lodestar and weigh carefully whether proposed legislation or regulations measure up to its standards, I think we will not go far wrong. This will require us to consider with care whether those factors of consumer protection sought to be secured by a proposal are of sufficient importance that they should be secured by legislation or regulation which restricts in some degree our freedom of action, or which makes it more difficult for small companies to compete, curbs innovation or curtails variety, freedom of choice, or production.

Principal Amendments to the Act

How do the principal amendments to the 1938 Act measure up against this original statement of aims? The Pesticide Chemicals Amendment provides that before a pesticide may be sold it must be registered with the Department of Agriculture as an economic poison and a petition must be filed with the Food and Drug Administration, (FDA), which requests that a tolerance be established for the chemical or that it be exempted from the requirement of a tolerance. Upon the basis of this information the FDA establishes by regulation a tolerance, which may be zero, or exempts the substance from the necessity of a tolerance. The Food Additives Amendment requires the prior approval by FDA of all food additives; which are basically

[1] Charles Wesley Dunn, Federal Food, Drug, and Cosmetic Act (1938) p. 675 et seq.

defined to be substances, intentionally or incidentally, added to food, except one already approved under existing law or one which is generally recognized among experts competent to evaluate its safety as having been adequately shown to be safe. The Color Additive Amendments involve a government permission control law which provides for the separate listing of suitable color additives safe for use in food, drugs, or cosmetics, under such conditions, including tolerance limitations, as the FDA may find necessary to assure the safety of the uses permitted. The Drug Amendments of 1962 increase the factory inspection authority of FDA in respect to prescription drugs and authorize the federal courts to enjoin refusal to permit any plant inspection authorized by the Food, Drug and Cosmetic Act. They provide additional FDA authority with respect to clinical investigations and require reports on experience with respect to new drugs. This Act also amends the 1938 Act with respect to clearance procedures for new drugs and requires the affirmative approval of the FDA before a new drug application becomes effective. Such drugs must under its provisions be shown effective in addition to being safe. The Act further provides the basis for a system to standardize nonproprietary drug names and requires prescription drug advertising to show the name of the drug and some information about it. Finally, the law requires the registration and periodic inspection of all domestic drug manufacturing establishments regardless of whether they are engaged in interstate or intrastate commerce.

Regulation by License or Administrative Expertise

From the foregoing very brief descriptions of these important amendments you will have noticed that there has been a trend away from the philosophy of a regulatory statute which (1) separates judicial and legislative powers and, which, (2) establishes an objective standard of conduct, which may be tested in the courts; to the philosophy of regulation by license or administrative expertise. However, I should point out that these amendments were fashioned into final form in accordance with the best American tradition of industry-government cooperation. The food and drug industries supported many of the FDA's requests and proposals for increased powers as in the public interest. Some of the provisions of these laws were the outgrowth of proposals either advanced or advocated by industry. The factors of consumer protection were found to be of such overriding importance as to warrant the imposition of these restrictions

on the freedom of action of the industries involved. It was recognized that life in our complex society required an additional concession of part of industry's freedom of action for the good of the common order. The amendments as passed maintained to a degree the fine balance between public protection and the preservation of our private enterprise system.

The difficulty facing industry today is that these enactments may be taken as precedent for a further exaltation of executive power in respect to other circumstances where the factors of consumer protection do not merit these restraints on our freedom of action—that splendid thing called independence—so essential to the kind of world in which we want to live.

The Public Interest Is Main Concern

My own belief that FDA does not seek increased administrative authority with broad quasi-judicial and quasi-legislative powers except where really needed in the public interest, finds support in the remarks of Messrs. Daniel P. Willis and William W. Goodrich, attorneys with the then Federal Security Agency, made back in 1948.[8] They then said:

> Despite the ups and downs that go with litigation—the elation one naturally feels when a particularly difficult case is won and the disappointment that comes from the denial of certiorari or an adverse decision not even accompanied by an opinion—experience under this Act shows that this regulatory statute, in which courts and juries serve as agents of enforcement, can and does work. The courts have not neglected the responsibilities entrusted to them as a coordinate arm of enforcement; their opinions continue to breathe life into the Act; and the public interest has been the guiding principle of decision.

Based on past history, then, we can cautiously hope that the Congress will consider the legitimate needs of industry to be free of undue restraints in drafting and passing new legislation in this field. Can we express this same confidence that the FDA, in writing the regulations and interpretations under the tremendous power granted this agency by these amendments to the 1938 Act, will give adequate consideration to industry views?

Once the legislative choice is made, many administrative and regulatory questions remain to be answered, with respect to which there are bound to be a great many differences of opinion. It seems

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[8] Daniel P. Willis and William W. Goodrich, "Judicial Progress Under the Federal Food, Drug and Cosmetic Act." 3 FOOD DRUG COSMETIC QUARTERLY 16, 34.

obvious that there are many problems posed by the existing laws relating to pesticide chemicals, food additives, color additives, new and investigational drugs, and so forth, that may act as a profoundly deterrent factor to technological research and development unless FDA approaches them responsibly and sensibly. It is my belief that if industry keeps its business and professional houses in such order that it can make a frank and fair disclosure of the facts, in a spirit of mutual confidence and respect, it may expect FDA to solve most of these problems without either unduly impairing American enterprise or endangering the health of the consumer. The need for this understanding attitude on the part of FDA is clearly shown by the Report of the Second Citizens' Advisory Committee, filed with the Honorable Anthony J. Celebrezze, Secretary of Health, Education and Welfare, on October 25, 1962.[9] That this need is recognized by the Department of Health, Education and Welfare is shown by the formation of a Departmental Committee for Consumer Protection, headed by Miss Mary E. Cunningham as Special Assistant to Secretary, to carry forward the consumer's rights to safety, to be informed, to choose and to be heard. It is further shown by the remarks of Mr. Boisfeuillet Jones, Special Assistant to the Secretary, on the occasion of the FDA-FLI Conference, November 26, 1962.[10] His remarks indicated that the Department had a lively awareness that the administrative and scientific problems inherent in these legislative schemes could not be resolved in the public interest, without the support of the industries involved. That Commissioner of Food and Drugs, George P. Larrick, realizes the tremendous need for mutual understanding and respect between FDA and industry is made clear by his remarks before the Section of Food, Drug and Cosmetic Law, of the New York State Bar Association, on January 22, 1963, where after mentioning the legislative trend toward prior approval before marketing a product, and commending The Food Law Institute program of education, he concluded his remarks by saying:

> It has been the objective of the administrators of the Food, Drug and Cosmetic Act from the very beginning to administer the statute in such a way as to prevent violations of the law rather than to punish violators after they occur. We will always, in my opinion, need to employ the sanctions of the statute to effectuate its purposes, but recent developments, both in the amendments mentioned as well as in the reviews of our administrative programs by the Citizens Advisory Committee and others, have emphasized that ad-

[9] The Second Citizens Advisory Committee Report, 17 FOOD DRUG COSMETIC LAW JOURNAL 581.

[10] Boisfeuillet Jones, "Consumer Protection Activities," 17 FOOD DRUG COSMETIC LAW JOURNAL 808.

ministrative actions designed to implement preventative enforcement should be undertaken at an accelerated pace. This we plan to do. We welcome your constructive suggestions and participation in this endeavor.

The FDA Conference on the Drug Amendments and Proposed Regulations, held on February 15, 1963, is the most recent evidence of the desire of FDA to cooperate with industry in solving problems under this law. It was held because FDA believed that the public interest would be served by affording an opportunity for an open exchange of views among all persons interested in the new law and the regulations to be adopted for its administration. The views expressed in the prepared statements and answers to questions showed a solicitous desire to enforce the law, with due respect to its requirements, but with fairness to industry and without unduly stifling research.

I should add that these amendments have imposed an ever increasing burden on the already overtaxed scientific, medical, and enforcement manpowers of the FDA. The responsibilities placed on FDA by the Drug Amendments may be expected to increase the agency's work load to truly staggering proportions. We cannot expect those administering the FDA to fulfill their obligations under the law unless they are able to engage competent and devoted people for all positions, from top to bottom, throughout the agency. Faced with these many problems the FDA needs to enhance its stature and to increase the morale of its personnel. Based on past experience, and the guidance afforded by the Second Citizens' Advisory Committee Report, we can expect Commissioner Larrick and his aids to do their utmost to build a highly qualified staff, which is familiar with the latest thinking in the scientific, medical and sociological fields. In order to do this FDA needs sufficient funds; and industry and consumers should urge the Congress to provide adequately for these needs.

To sum up, I have a conviction that this law and its amendments to date have served to contribute to our faith in our government. They have helped build up in the mind of the consumer, a respect for our commercial institutions. They have added to our belief in the fairness and justice to be found in our representative form of government. They have demonstrated the virility of our indefinable fusion of popular government and free enterprise.

The foregoing forecasts the horizons that lie ahead, and presents a challenge to all—in government, in industry and in education—to dedicate ourselves to work together to secure an even better and

more efficient administration of this important law. This should include continuing encouragement of industry to provide for itself standards for consumer protection consistent with the requirements of the Act. This should also include with a high priority the development of a program of education for statesmen, legislators, budget officials, the medical and legal professions, consumer organizations, and, most importantly, the President's Consumer Advisory Council, which has made such a splendid beginning,[11] where the emphasis is on the importance, need and value, rather than on the possible dangers, of foods, drugs and cosmetics to the health and welfare of the public. We in The Food Law Institute are working to this end and hope that all of you will join with us in creating a better public understanding of this law and of the continuing need for its fair and efficient administration by both government and industry.

Tribute to Mr. Dunn

I cannot close without paying a brief but warm tribute to the inspiration and foresight of the man, Charles Wesley Dunn, in whose honor these lectures have been established through the generosity of the American Pharmaceutical Manufacturers Association. Mr. Dunn became interested in the food and drug law early in his career. Prior to the passage of the 1938 Act I think I can safely say he was the only lawyer who devoted any substantial part of his professional time to this field. It was through Mr. Dunn's efforts that attorneys practicing in this field were brought together on a professional basis in the American Bar Association, the Inter-American Bar Association and the New York State Bar Association. Mr. Dunn was also instrumental in helping to found The Food Law Institute in 1949. His enthusiasm stirred me to take an active part in The Institute's program shortly thereafter, and I had an inspiring association with him until his untimely death in 1959.

Mr. Dunn never deviated from the faith that guided him in his every action—the concept that the food and drug laws place a public trust on those responsible for their enforcement and development—and he endeavored throughout his lifetime to instill this faith in others. In addition he had the priceless quality of utmost sincerity and absolute devotion to his work, associates and friends, which won their affectionate respect. **[The End]**

[11] Press Release on Meeting of Consumer Advisory Council, January 31, 1963.

The Latin-American Food Code: Chapters I, II, III and V

The Following Chapters of the Latin-American Food Code Were Translated from the Original Spanish by Ann M. Wolf of New York. The Translation Is Based on the 1960 Edition of the Code Published in Buenos Aires, as Subsequently Amended by the Latin-American Food Council (Formerly Called the Latin-American Food Code Committee), up to February, 1963. The English Translation of the Introduction to the Code by Dr. Carlos A. Grau and the Index Were Published in the October, 1960 Issue of the FOOD DRUG COSMETIC LAW JOURNAL; the Translation of Chapter IV (Utensils, Receptacles, Containers, Wrappers, Machinery and Accessories) Appeared in the February, 1961 Issue; the Translation of Chapter X (Sugar and Sugar Products) Was Published in the May, 1961 Issue; the November, 1961 Issue Contained the Translation of Chapter XVI (Correctives and Improving Agents—Additives); and Chapter XII (Nonalcoholic Beverages and Refreshing Foods and Drinks) Appeared in the June, 1962 Issue.

CHAPTER I—GENERAL PROVISIONS

Article 1—Any person, commercial firm, or establishment that manufactures, packs, holds, transports, sells, exhibits or handles foods, household articles, or raw materials used for such products shall comply with the provisions of this Code.

Article 2—Any foods and household articles, and the raw materials used for the same, which are manufactured, packed, held, transported, sold or exhibited shall meet the requirements of this Code, and their sale shall be licensed by the competent health authority, not in any case by police authorities or entities organized under private law.

Article 3—Any operation not mentioned in this Code as either regular or optional shall be lawful, provided that it does not modify the composition of the product, or does not introduce undesirable or prohibited extraneous elements capable of endangering the consumer or of diminishing the nutritional value of the product, and provided further that it does not change the constituent elements to an extent exceeding that of natural causes.

Article 4—Any term defined in one section of this Code shall have the same meaning in all other sections of this Code in which it is used.

Article 5—The following definitions are hereby established for the purposes of this Code:

1. *Consumer:* Any person, group of persons, firm or institution that procures foods for personal consumption or for consumption by third persons.

2 *Food:* Any natural or artificial, processed or unprocessed product which, when ingested, supplies the body with the materials and energy it requires to perform the biological processes. By extension the term "food" shall apply also to any substances which, regardless of whether or not they have nutritional qualities, are added to foods and dishes as taste correctives or additives, or the consumption of which is customary or pleasurable and takes place with or without a nutritional purpose. Therefore, whenever reference is made in this Code to *"foods,"* the term means not only solid, liquid or gaseous food products, but also the raw materials used in the same and any *additives* added to improve their appearance, color, aroma, preservation, etc., such as acidulants, alkalizers, agents preventing violent boiling, antioxidants, aromatics, colors, sweeteners, emulsifiers, thickeners, stabilizers, foam producers, anti-foaming agents, hydrolizers, preservatives, flavors, etc.

3. *Genuine, Standard or Legal Product:* This term when applied to a food means any product which, meeting the regulatory specifications, does not contain any unauthorized or added substance representing an adulteration and is sold with its legal name and labeling without any legends, signs or designs which may be misleading with respect to its origin, nature or quality.

Such products are prohibited from being called "pure."

3a. *Natural Product,* or *Product in its Natural State:* These terms mean any food of animal, vegetable or mineral origin, from which no constituent element has been removed and which presents its original appearance, without any changes in composition.

4. *Deteriorated Food:* This term means any food the intrinsic composition of which has suffered damage, deterioration or injury as a result of natural causes, such as humidity, temperature, air, light, enzymes, micro-organisms, or parasites.

5. *Contaminated Food:* This term means any food manufactured, handled or packed under insanitary conditions, or containing mineral

or organic impurities which are undesirable, obnoxious or poisonous. It also covers any food manufactured from animals affected with a disease the agents of which may be present in the product, except in cases specifically authorized by the official veterinary inspection authorities.

6. *Adulterated Food:* This term means any food the valuable constituents or characteristic nutritional principles of which have been abstracted, in whole or in part, and replaced by inert or extraneous ingredients, or foods to which an excessive amount of water or other filler has been added, or which have been artificially colored or artificially treated in order to conceal deteriorations, objectionable manufacturing processes, or inferior raw materials, or to which unauthorized substances have been added, or the composition, quality or other characteristics of which do not correspond to the denomination and description under which the product is sold.

"Extraneous elements" or *"extraneous substances"* in a food ready for consumption are any substances which, under this Code, are neither constituent elements nor harmless ingredients. (Technical additives used to stabilize, preserve, flavor, aromatize, or color.)

7. *Misbranded Food:* This term means any product which has the appearance and general characteristics of a legitimate product, regardless of whether or not the same is protected by a registered trademark, which is not the genuine product but sold as such, or does not come from the true manufacturer and zone of production known and/or declared.

Article 6—The term *"food poisoning"* means a pathological process caused not only by spoiled food, but also by the ingestion of foods which, notwithstanding their normal appearance, contain products injurious to the body, which may be of vegetable, animal or mineral origin. Physicians who treat such cases of poisoning are held to report them immediately to the local health authority in order that the same may adopt the necessary measures, for which purpose it shall be given whatever information it deems necessary.

Article 7—Articles prepared in one country which imitate products of another country shall be prepared in accordance with the processes used at the place of origin * and shall meet the characteristics of the original products (Port, Malaga, Marsala, etc. wines; Roquefort, Gruyère, etc. cheeses).

* Note of the translator: Not too clearly expressed.

Article 8—In advertising food products (by word of mouth, over the radio, or in writing) the definitions and other requirements of this Code shall be respected.

The composition, properties, qualities, effects and nutritional value of dietetic products may be advertised only with the written approval of the competent authority.

Advertisements directed to alcoholic beverages are prohibited from recommending their consumption as providing stimulation, well-being or other sensations, in the same manner as the smoking of filter cigarettes or the use of filter cigarette-holders is not permitted to be encouraged by favoring the belief that they are harmless in this way.*

Article 9—Any countries which adopt this Code shall issue broader supplementary local provisions in a body of regulations which may be named a "Food Code" or "Bromatological Code."

Persons who prepare foods and beverages intended for export may add to the same substances not authorized by this Code, always provided that they can prove that such substances are permitted in the country of destination.

Article 10—The presence of the metals and metalloids (*incidental or residual additives*) listed hereinafter shall be tolerated in foods (with the exception of drinking water, fish and shellfish), provided that they are kept within the following limits:

Aluminum	Maximum:	250 parts per million
Antimony	Maximum:	2 parts per million
Arsenic:		
Liquid	Maximum:	0.1 part per million
Solid	Maximum:	1 part per million
Barium	Maximum:	500 parts per million
Boron	Maximum:	100 parts per million
Cadmium	Maximum:	5 parts per million
Zinc	Maximum:	100 parts per million
Copper	Maximum:	10 parts per million
Tin	Maximum:	300 parts per million
Fluorine	Maximum:	1.5 parts per million
Mercury	Maximum:	0.05 parts per million
Silver	Maximum:	1 part per million
Lead:		
Liquid	Maximum:	2 parts per million
Solid	Maximum:	20 parts per million
Selenium:		
Liquid	Maximum:	0.05 parts per million
Solid	Maximum:	0.3 parts per million

* Note of the translator: This apparently means "that the filter renders the tobacco harmless."

With regard to the amounts of pesticide chemicals tolerated in foods, see Articles 739, 740 and 741 of this Code.

In special cases, the health authorities may allow exceptions to the limits fixed above when the food is not consumed in its natural state (boron in cacao beans), is consumed in small quantities (copper in nuts and pepper, lead in oysters, etc.) or during processing undergoes transformations which render it less harmful.

The presence in a canned food of an abnormal amount of iron caused by contact with the container shall not be objectionable, provided that the container is not swollen and that the product is in its normal condition and suitable for consumption.

CHAPTER II—GENERAL REQUIREMENTS FOR FOOD FACTORIES AND FOOD OUTLETS

General Rules

Article 11—The name *"Food Factory"* means any establishment in which foods are processed, manufactured, or packed.

The name *"Food Outlet"* means any business enterprise in which foods are held, packaged, or sold for consumption by the public.

Article 12—Food factories and food outlets may be installed and operated only after a license has been obtained from the competent health authority, which license shall be renewed whenever the factory or outlet is moved; when expansions take place which entail fundamental changes; and when there is a change in the name of the proprietor or company.

Article 13—As a general rule, foods are prohibited from being extracted, processed, manufactured, handled, stored, repacked or sold on premises which, because of their size, temperature, lack of light, ventilation, or other hygienic conditions, are unsuitable for such purposes.

Such premises shall meet the following general sanitary requirements:

1. They shall be kept perfectly clean at all times and may not be used as dwelling or sleeping quarters, or as passageways leading to dwelling or sleeping quarters.

2. Smoking is not permitted in factories and rooms in which foods are handled, nor may such premises be used to keep products that yield odors susceptible of being absorbed by foods.

3. In rooms used to handle or store unpackaged foods which connect with the outside and which for this reason cannot be kept insect-free, all openings shall be provided with devices preventing the entry of insects.

4. Finished products, raw materials, and containers shall be kept on adequate stands or shelves, and stacked products shall be placed on stands or raised platforms.

5. In rooms in which foods are processed, only the raw materials necessary therefor may be kept, but no other products, articles, implements or materials.

6. If products returned to a plant because of faulty processing or poor preservation are kept there for more than 48 working hours, their presence will be interpreted as an intention to use them (reprocessing, correction, re-sterilization, etc.). No argument will be accepted to justify it, for which reason their possession will always be penalized, without prejudice to the confiscation and destruction of the products.

7. Companies which own establishments, plants and factories shall be liable for any product released for sale with manufacturing defects or in defective containers and shall be held to take such precautions as may be necessary to prevent such occurrences. If the same can be proved, no excuse intended to reduce or shift this liability will be accepted.

Companies shall also make sure that the processes or methods used to prepare food products are satisfactory from the sanitary point of view, with the proviso that any batch of merchandise proved to have been prepared under unsatisfactory sanitary conditions, or in violation of the provisions in force, shall be seized forthwith.

8. Establishments, plants, factories, warehouses, wholesale and retail groceries and shipping depots handling food products which are located within city limits are not permitted to communicate directly with stables for horses, animal breeding places or other similar establishments which are considered as jeopardizing the safety of the foods.

9. All basements shall be sufficiently ventilated and lighted and shall be easily and safely accessible. Their walls, floors, and ceilings shall be protected against humidity by a waterproof material.

10. Foods may not under any circumstances be stored on premises which do not comply with the requirements fixed for such purpose.

11. Companies which own establishments, plants, factories, warehouses, wholesale and retail groceries and shipping depots for food products must fight the presence of rodents and insects on such premises. Negligence in this connection will be subject to penalties.

12. All premises occupied by establishments, plants, factories, warehouses, wholesale and retail groceries and shipping depots for food products shall be equipped with faucets for drinking water, with the sinks necessary to wash containers, etc., and with drains connected with the sewer system or regulatory cesspools. They shall always be kept in a state of good repair, appearance, and cleanliness and shall have waterproof floors. The health authority may order the premises to be cleaned, whitewashed or painted whenever it deems it advisable, and wherever necessary may also order the walls to be waterproofed up to a height of 1.80 meters. All machinery, utensils, and other materials shall likewise be kept in a satisfactory sanitary condition.

13. All food outlets selling products easily spoiled by heat shall have refrigeration equipment for their preservation.

14. Foods packed in bulk may be repacked only at the time of sale, directly from the original container and in front of the purchaser.

15. Kerosene, soap, disinfectant fluids and similar products packed in bulk containers shall be kept in adequate places, separate from foods, even if they are sold in their original containers.

Article 14—All workers and employees of food factories and food outlets shall at all times take good care of their personal hygiene, to which end the owners of such establishments shall provide the necessary installations and equipment such as: wardrobes and wash basins with soap; drinking water dispensers (fountain, tank, barrel, etc.), the number and capacity of which shall be proportionate to the number of persons using them; toilets, separated from the work rooms, with waterproof floors and walls waterproofed up to a height of 1.80 meters. Hands shall be washed with water and soap and dried hygienically every time the toilet is used; employees shall be so instructed by permanently posted signs.

Persons employed in food factories and food outlets, no matter in what capacity, shall be permitted to enter and work in such establishments only if they are in possession of a health certificate issued to them by the competent authority. This obligation applies also to owners who participate in person in the activities of the establishment, regardless of the type of activity in which they engage. All

health certificates shall be kept in the administrative department of the establishment and be available for exhibition to the official inspectors upon request. This requirement does not apply to employees who work outside the establishment, who shall always carry their health certificates with them. These certificates shall be valid for one year, and the initial certificate shall state the results of the chest X-rays and examination of the faeces.

In addition, any persons employed in the handling and conveying of foods in grocery stores, bakeries, pastry shops, pantries, delicatessens, dairies, beverage stands, bars, candy shops, restaurants and similar establishments, pizzerias, kitchens, factories making fritters, meat pies and sandwiches, milk bars, ice cream parlors, etc., shall wear uniforms (blouses, smocks or aprons) and white or cream colored caps which are washable; in butcher shops, vegetable shops, fruit shops, markets and food and beverage factories (canned foods, jams, biscuits, sausages, etc.), the wearing of white aprons or smocks and caps is compulsory. In special cases, the use of dark aprons or gray, blue or khaki overalls may be permitted. These pieces of clothing must at all times be kept in a perfect condition of repair and cleanliness.

Moreover, female employees shall use hair nets and are not permitted to use nail polish or wear jewelry of any kind.

Ambient Air

Article 15—The composition of the ambient air in closed premises which are inhabited or occupied by humans shall meet the following specifications:

Carbon dioxide	Maximum:	1,500 parts per million
Carbon monoxide	Maximum:	200 parts per million
Hydrochloric acid	Maximum:	100 parts per million
Fluorine	Maximum:	2.5 parts per million
Ammonia	Maximum:	50 parts per million
Hydrogen sulfide	Maximum:	0.15 parts per million
Sulfur dioxide	Maximum:	20 parts per million
Chlorine and bromide	Maximum:	2 parts per million
Carbon sulfide	Maximum:	0.1 part per million

Other harmful substances: none.

Kitchens and Dining Rooms

Article 16—*Kitchens:* The kitchens of bars, chophouses, canteens, eating houses, guest houses, clubs, grills, restaurants, boarding houses, hotels, inns, etc. shall be of a size proportionate to the size of the establishment and shall meet the following requirements:

1. They shall be well aired and ventilated; floors shall be made of a waterproof material approved by the competent authority and walls shall be covered with a similar material up to not less than 1.80 meters.

2. All openings shall be equipped with automatic shutters and metal or plastic screens to prevent the entry of insects.

3. All brick ranges or ovens shall be covered with a suitable material, except for their upper part (called top) which may be made of steel, colored tile of the type known as "Marseilles tile" or a similar material.

4. They shall have a sufficient number of sinks satisfactory in size to wash the working utensils, with the necessary running water supply, and the drains shall be connected with the sewer system or regulatory cesspool and open sewers. Each sink shall have two drain basins, one for pots, dishes and other dirty utensils, and the other for clean material. The sinks may not under any circumstances be used to launder clothes. With regard to the utensils, see Articles 51 to 70.

5. Chimneys, ranges, and ovens shall be installed and operated in accordance with the provisions in force on this subject matter.

6. No objects other than kitchen utensils, working gadgets, and the products required for the daily meals may be kept in kitchens, where they shall be arranged in a manner safeguarding their sanitary condition.

7. All products intended for the preparation of meals shall be stored in a separate suitable place; vegetables shall be kept on racks protected by metal or plastic screens; meat shall be kept in insect-proof containers ("fiambreras"), refrigerators, or refrigeration chambers, and fish and shellfish shall likewise be kept in a storage place of this type.

8. During the hours when meals are prepared, no sawdust may be on kitchen floors, except for small quantities around the stoves.

9. When the ambient air in kitchens does not meet the requirements fixed in Article 15 of this Code, exhaust fans shall be installed in sufficient numbers, this being compulsory in tropical climates.

10. Garbage and trash shall be placed in suitable cans provided with lids, to be emptied with the necessary frequency. Raw garbage may not be used to feed hogs.

11. All persons working in kitchens, pastry shops, and ice cream parlors shall wear clothing suitable for their jobs, which clothing shall be kept perfectly clean at all times. In no case, and under no circumstances, may clothes be changed in said work rooms. Bus boys, waiters, and kitchen personnel are prohibited from carrying cleaning rags under their arms or on their shoulders. Employees who wait on the public or handle food may not be employed to clean the premises, urinals, toilets, floors, furniture, spittoons, etc., the cleaning of which shall be left exclusively to the cleaning men.

Article 17—In establishments in which meals are prepared, such meals once prepared may not be kept for more than 24 hours. Left-overs may never be used to prepare new dishes, but shall immediately be thrown into the garbage cans. The term "left-overs" means any remnants of food not eaten by patrons which go back on the plates. Portions of food which come back from the tables may not be used to be served to patrons; if they are to be kept for other purposes, this shall be done in a separate room, set aside for this purpose.

Dishes which are usually kept semi-cooked (spaghetti, rice, boiled vegetables, etc.) shall be consumed within 24 hours after cooking time. Only raw materials to be used in the kitchen (meat, fruits, eggs, milk, butter, cold cuts, etc.), mayonnaise and similar products, as well as dressings (except "tuco" *), and beverages may be kept in refrigerators. Any products found to be in violation of this article shall be destroyed forthwith, without prejudice to the imposition of the respective penalties.

Article 18—Kitchens of first and second class hotels and restaurants shall have the following facilities:

1. A refrigeration chamber and antechamber meeting the conditions set forth in Articles 33 ff. of this Code.

2. Separate rooms which meet the legal requirements to pluck fowl, clean vegetables, and prepare pastry, ice cream, coffee, and serve as pantry.

3. Garbage incinerators wherever the city or state does not provide for garbage collection.

Kitchens are prohibited from being installed in basements, with the proviso that basement kitchens existing upon the entrance into effect of this Code may remain in use.

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* Note of the translator: Type of spaghetti sauce.

Kitchens built on the ground floor of buildings may not have openings to the street. Such kitchens may receive light from the street side only through sealed windows.

Article 19—*Dining rooms:* Any rooms to be used as dining rooms in hotels, clubs, guest houses and other establishments as mentioned in Article 16 hereof shall have sufficient natural ventilation, space, and light to meet the requirements of this Code. Walls must be plastered, whitewashed, painted with oil paint, or covered with stucco. The use of wallpaper shall be permitted, provided that the wallpaper is attached directly to the plaster above a panel of wood, or another suitable material, not less than 1 meter high. Floors shall be covered with mosaic, tile, linoleum, plastic tiles, parquet, or another authorized material. Ceilings shall be made of cement, plaster, metal, fiber-cement, plastered arches, masonry, or another authorized material.

Toilets shall be separate for each sex, in numbers proportionate to the number of tables of the establishment. They shall be provided with toilet paper, comply with all other requirements, and be kept perfectly clean at all times. The wash basins shall be supplied with liquid soap and paper towels, or another type of dryer, the use of another type of soap being prohibited.

Article 20—Products which violate this Code in their composition, make-up, labeling, or for any other reason, are prohibited from being kept and/or used in restaurants, eating houses, confectionery shops, bars, and similar establishments. Any products found to violate this Code in this respect will be seized forthwith, without prejudice to the imposition of the respective penalties.

Article 21—Waiters and other persons who wait on the public shall wear clean and proper clothing and enjoy good health, which must be evidenced by an official certificate. They may not carry cleaning rags on their shoulders or under their arms or use the same to wipe off perspiration.

Employees who wait on the public, handle foods and beverages, or wash dishes may not be employed to clean the premises, urinals, toilets, floors, spittoons and furniture, the cleaning of which shall be left exclusively to the cleaning men.*

Minors are not permitted to be hired to wait on patrons in factories, kitchens, diners, luncheonettes, and similar establishments.

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* Note of the translator: Repetition of provision contained in Article 16, No. 11.

Open-Air Markets

Article 22—Products sold at open-air markets shall be grouped by kinds, exhibited on wood or metal stands or platforms and maintained in a state of good preservation and cleanliness. They are definitely prohibited from being kept on a level with the sidewalk or street and from being exposed to the sun and flies. Moreover, at least one pair of scales shall be available to the public to permit it to check the weight of the merchandise purchased by it.

Live fowl sold at stands shall be kept in cages large enough to prevent the birds from suffering, and a supply of clean water shall be held available to them.

Injured, diseased or dead birds shall be taken out of the cage and may not be sold for human consumption.

Article 23—All sales personnel shall wear white blouses or dusters, and aprons which shall be kept perfectly clean and shall, as the products, comply with the other requirements of this Code.

For reasons of hygiene (contamination by street dust, handling, etc.), articles packed in bulk which are ingested without previous washing or cooking, such as butter, cold cuts, canned tomatoes and jams are prohibited from being repacked at open air markets, but shall be taken to the market already packaged in accordance with the regulations. Fruit stands shall display signs reading: "For reasons of hygiene, please do not touch the fruit."

Kiosks and Stationary Vehicles

Article 24—The terms *"Kiosk"* or *"Cart"* mean small retail stands or counters set up in booths, halls that open to the street, and hallways, or as annexes to business establishments of various kinds.

Such *Kiosks* and *Stationary Vehicles* may sell foods in their original get-up, beverages prepared by licensed plants, shellfish, cigarettes and other merchandise, such sales to be handled by different vendors for different types of goods. Stands that sell meat pies, fritters and hot sandwiches shall be provided with the devices required to prevent the smoke and odors from reaching the public. Stands which sell fruit juices or fruit sections shall not be permitted to keep them for periods of more than 24 hours from the time of their preparation and shall sell them in wax paper cups, to be kept in sanitary tubes or a similar device that protects them from contamination. The water supply and elimination system for such *kiosks* and stationary vehicles shall be governed in each case by local bromatological or sanitary

regulations. They shall also satisfy the other requirements of this Code. Persons who fail to comply with these requirements shall be subject to the respective penalties.

Markets and Groceries

Article 25—Markets, Supermarkets, and Groceries shall comply with the following requirements, in addition to the general rules provided for in this Code:

1. They shall be large enough to accommodate the greatest prospective number of patrons.

2. They shall have the regulatory installations for the different sales stands; separate garbage deposits, and a running water supply and drainage system, all of which shall be kept in a state of good repair, painting and cleanliness.

3. Indoor aisles and indoor and outdoor sidewalks shall have waterproof floors.

4. Products, the preparation of which requires frying or cooking on stoves, are prohibited from being prepared indoors.

5. The premises of the market are prohibited from being used as sleeping or dwelling quarters.

Public Auctions of Food Products

Article 26—Public auctions or sales of food products, the bromatological conditions of which are regulated by this Code, shall be subject to the following requirements:

1. All products shall first be inspected and approved by the competent health authority; otherwise, they will be withdrawn from the sale or confiscated, without prejudice to the imposition of the respective penalties.

2. Applications for the inspection provided for in the preceding paragraph shall be accompanied by an itemized inventory of the merchandise to be sold that specifies the brands of products, their nature and quantities for each lot, stating the different container sizes if the products come in containers.

3. While the auction goes on, a copy of the inventory referred to in paragraph 2 hereof shall be exhibited to the public. This copy shall be signed by the person responsible for the sale and bear the stamp of approval of the health authority with a statement that the merchandise is suitable for consumption by the standards fixed in this Code.

4. The premises on which public auctions of food products are held shall be kept in good sanitary condition.

5. The products to be auctioned are prohibited from being repacked or refilled on the premises referred to in the preceding paragraph.

Itinerant Distributors and Vendors

Article 27—In general, foods and beverages are prohibited from being sold by itinerant vendors with the exception of fruits, vegetables, and the following products: candy bars, peanuts, corn, almonds, soft drinks, pastries, crackers and cookies, meat pies, sandwiches, hard candy, chocolates, wafers and ice creams, provided that said products are sold in their original factory get-up, that their sale has been authorized by the health authority, and that they come from inspected factories.

Fruit juices, coffee, tea, mate, milk and cocoa may likewise be sold by itinerant vendors provided that the beverages are kept in refrigerators or thermos containers and are dispensed in wax paper cups or similar containers which shall be kept in sanitary tubes. The cups shall be destroyed after use. The health authority may also, in special cases and at its discretion, permit the sale by itinerant vendors of other products, such as fish, etc.

All vendors shall wear uniforms (blouses, dusters and aprons, preferably white) which shall be kept in a state of perfect cleanliness. They shall display on their uniforms the badge issued to them by the health authority as proof of their being licensed vendors, without which they are not permitted to sell any merchandise. In addition they shall hold a health certificate from the health authority, which they shall carry with them at all times and present to the inspectors whenever asked to do so. Said health certificates can never be valid for more than six months.

Article 28—In the interest of hygiene and the better protection of the consumer, deliverymen making home deliveries of foods and beverages shall carry the same in the original wrappers used by the firm for which they work. As itinerant vendors, they shall wear uniforms (blouses, aprons and dusters) and caps (preferably of a light color) which shall be perfectly clean, and they shall also hold health certificates issued to them by the health authority, on the same conditions as set forth in the preceding article.

Article 29—The carts, baskets, cases, hampers and other receptacles used by deliverymen and itinerant vendors of foods and

beverages shall not only be suitable for the use made of them, but shall also at all times be in a state of perfect repair and cleanliness and be provided with the devices required to protect the merchandise (canvas, cover, lid, closure, etc.). The health authority may require itinerant vendors to have storage rooms for their products if the nature of their products makes this advisable.

Home Deliveries of Meals

Article 30—The preparation of meals for delivery to homes shall take place under perfect hygienic conditions, using products which, in accordance with this Code, are suitable for consumption, a staff provided with health certificates, and thermos equipment or food carriers made of a suitable material and kept in a state of perfect repair and cleanliness.

Article 31—Families who prepare in their private homes, for delivery to outsiders, a number of portions not exceeding six a day (or 12 meals) shall not be considered as conducting *eating houses*, but shall report to the health authority that they engage in the supply of cooked food for pay. They shall permit the health inspectors to enter their homes in order to inspect the kitchen and to check whether the persons engaged in the preparation of foods and the raw materials used in the preparation of meals comply with the requirements of this Code.

Article 32—*Eating houses* and *boarding houses* shall register with the health authority.

Article 33—Eating houses, boarding houses, inns, restaurants, grills, hotels and private individuals engaged in the preparation of meals for home delivery shall make sure that the transportation of the food takes place under hygienic conditions, by deliverymen who satisfy the requirements of this Code. They shall be liable to the health authority for any violation proved.

CHAPTER III—THE STORAGE, PRESERVATION AND PROCESSING OF FOODS

Article 34—Foods may be preserved by physical methods (heat, refrigeration, filtration, acoustic, electric or neon waves, radiation); physico-chemical methods (smoking and the action of certain metals, such as silver); chemical methods (elimination of air and substitution by inert gas, authorized anti-fermentation agents, such as common

salt, oil, vinegar, ethyl alcohol, antibiotics) and biological methods (antibiotic or antagonistic bacteria). Any product sold as *pasteurized* or *sterilized* must have undergone this type of preservation process after having been packed at the place of origin in a hermetic container.

The term "antibiotic" means any nontoxic substance, minimal quantities of which are capable of inhibiting the development of microorganisms. Residues of antibiotics in amounts not exceeding 7 p.p m., may be present in raw foods to be consumed cooked, and in ice to be used for the preservation of fish products, after a special permit has been obtained in each case from the health authorities. Preference should be given to broad spectrum antibiotics, such as tetracyclines, etc., which can be destroyed by heat at a temperature of 100° C., and such antibiotics as the health authorities may authorize in the future.

Refrigeration Chambers

Article 35—The term *"Refrigeration Chamber"* means a closed room in which foods are preserved by means of artificial cold.

All food products stored in refrigeration chambers are presumed to be destined for human consumption. Any foods found unfit for human consumption shall be confiscated immediately, therefore.

All refrigeration chambers shall be disinfected at least once a year. Their inside temperature shall not under any circumstances exceed the temperature suitable for the various types of foods to be preserved. The chambers, as well as the utensils and equipment used in them, shall be maintained perfectly clean and tidy. Under no circumstances may food products be kept next to articles of another kind. The chambers shall be provided with good lighting to facilitate the control of the food products stored in them.

Refrigeration chambers shall be well ventilated, so that the air inside them may be renewed whenever necessary to keep it as pure as possible and at a hygrometric degree which may vary between 60 and 95 per centum.

Refrigeration chambers and machines may be put into use only after inspection and approval by the health authority and shall be subject to official control at all times. All refrigeration chambers shall have a thermometer recording maximum and minimum temperatures, and a hygrometer.

Article 36—As a general rule, meats (including domestic and wild fowl) shall, before storage in refrigeration chambers used also

for other animal products, be kept for some time in an antechamber, which shall likewise be relatively cold.

Meat cuts may be placed in the chamber only if they are in a perfect state of preservation. They shall be hung on a line of hooks so as to remain separate from each other, without touching the floor or walls of the chamber.

Fish may be admitted only if it is perfectly clean, well preserved and in order.

The cases used to pack fish, eggs, fruit and other food products shall always be perfectly clean. They shall be placed on shelves or boards spaced so as to permit the easy circulation of cold air and with enough space between them to permit easy passage and control.

Frozen meats, once defrosted, and refrigerated meats, domestic and wild fowl, and eggs, once taken out of the refrigeration chamber and exposed for some time to room temperature, are strictly prohibited from being returned to the refrigeration chamber, except when they were taken out to be transported or transferred to other refrigeration chambers.

Article 37—In general, artificial cold may be used to preserve perishable products of animal and vegetable origin, provided that it is employed in compliance with the requirements of this Code.

Article 38—Failure to comply with these requirements shall result in the temporary seizure or confiscation of the merchandise kept in cold storage until its fitness for consumption has been clearly established, without prejudice to the imposition of penalties for failure to comply with these requirements.

Article 39—Substances, products, etc. not destined for the purposes for which refrigeration chambers and antechambers are intended are strictly prohibited from being stored in the same.

Canned Foods in General

Article 40—The term *"Canned Food"* means any product of an animal or vegetable origin used as food which, having undergone adequate processing and being sold in hermetically sealed containers, retains its principal properties and remains suitable for consumption for some time.

Article 41—Canneries shall comply with the general rules and the following special requirements:

1. All departments in which food products are received, processed, and packaged shall have a waterproof floor, and walls waterproofed up to not less than 1.80 meters. They shall, whenever inspected, be found in a state of perfect repair, operation and cleanliness.

2. Containers are prohibited from being filled by submersion in the product which they are to contain. The reuse in foods of residues of brines, juices, syrups, oils, sauces, etc. obtained while canning products shall likewise be prohibited when they are not suitable for consumption.

3. All batches of canned foods shall be kept under observation for at least six days before being released for consumption.

4. After sterilizing canned foods, particularly canned vegetables, the cans after leaving the autoclave shall be cooled for not more than five hours in order to overcome the danger zone in which heat-resistant germs proliferate.

Article 42—Canned foods are hereby prohibited from being manufactured:

1. In establishments not licensed by the health authority or in which the pertinent rules of hygiene are not being observed.

2. With substances which are spoiled, damaged, infected, poorly preserved or lacking in nutritive qualities or which for some reason are unsuitable for consumption.

3. In accordance with processes which fail to meet the sanitary requirements or to guarantee the good preservation of the product.

4. By using substances or containers prohibited by this Code or by the health authority.

Article 43—As a general rule, canned foods shall meet the following requirements:

1. Their organoleptic and morphological characteristics shall not differ appreciably from the original characteristics of the same product when cooked (meats, vegetables, fruits).

2. Containers, labels and contents shall comply with the provisions of this Code. The labeling may be affixed only in the canneries, and manufacturers are prohibited from sending out labels to be affixed to containers outside their establishments. Cans which contain more than one product shall be labeled "Mixed Canned Foods," or "Mixed Jams," etc., and their components shall be mentioned individ-

ually in decreasing order of quantity. Exempted from this requirement are mixed preparations sold under the name of a special dish, such as stuffed cabbage, ragout, etc.

3. They shall not contain extraneous matter, prohibited ingredients, toxic metals or metalloids in amounts exceeding the tolerances fixed in Article 10 hereof, calculated on the solid product.

4. They shall be in a state of perfect preservation and shall not react to ammonium or sulphur compounds. Canned cured meat (corned beef, tongue, hash, etc.) may contain traces of hydrogen sulfide. As an exception, slight darkening will be tolerated in canned crustaceans, provided that it is due to the formation of ferrosoferric polysulfides.

5. The salt used (except in canned fish and shellfish) shall contain not more than 5 per cent of saltpeter (potassium or sodium nitrate) or more than 0.4 per cent of sodium nitrate.

6. They shall not contain any organic or mineral substance capable of reducing the commercial or nutritive value of the product or an excessive amount of condiments intended to cover up defects of the raw materials used in their preparation.

7. In general, it shall not be possible to require that the canning date be marked on products sterilized in hermetic containers; this may be required only in special cases, for certain dietetic products which contain substances sensitive to deterioration, always provided that the health authorities deem such a requirement advisable.

8. The term *"frosted"* may be applied to any products preserved by a cold treatment, regardless of the process used. However, products may only be sold as:

(a) *Refrigerated:* if they are refrigerated products none of whose parts has reached the freezing point.

(b) *Frozen:* if they are products whose temperature throughout has been reduced below freezing and which remain frozen until they are sold to the public.

(c) *Quick frozen or superfrozen:* raw products (vegetables, fruits and fruit derivatives, meat and meat derivatives, etc.) or precooked products (ready dinners) which meet all the requirements imposed by the application of the quick freezing technique in its various stages until they are sold to the public. The raw materials used shall be suitable for consumption. The time required to reduce the temperature of the products from 0° C. to −40° C. shall not exceed two hours, and

the time required to continue the process down to a preservation temperature of −18° C., or less, shall not exceed four hours. Only products processed in this fashion may be distributed and sold as quick frozen. The purchaser shall be advised that these products may not be kept at room temperature, like an ordinary canned food.

Article 44—The distribution, holding and sale of deteriorated canned foods is hereby prohibited. Any canned food, stored, exhibited or sold which has been prepared by a factory not officially licensed shall be seized forthwith.

Disinfestation of Foods

Article 45—The preventive or active disinfestation of cereals, vegetables, fresh and dried fruits is permitted, provided that the following requirements are complied with:

1. Except for the presence of insects or mites, the products must be in a state of good preservation.

2. The disinfestation shall take place in suitable installations, preferably first in a vacuum and then according to processes authorized by the health authority.

3. Immediately after disinfestation, the products shall undergo a physical or mechanical treatment which assures the elimination of any impurities of parasitic origin and of the disinfestant.

Article 46—The substances or physical processes used for the disinfestation shall not alter the purity, natural composition, or physico-chemical nature of the nutritive principles of the food treated. If poisonous substances are used to remove live insects they shall be easily removable simply by subsequent airing.

The following substances may be used as disinfestants: technically pure carbon sulfide, sulfur dioxide, carbon tetrachloride, ethyl oxide, methyl bromide, methyl formate, and such other substances as may be authorized by the health authority.

Hydrogen cyanide treatment shall be permitted only at plants which have special installations and specialized personnel available for such treatment, and only in particular cases.

The use of the following disinfestants is hereby prohibited: p-dichlorobenzene for flours; hydrocyanic acid and ethylene oxide for fresh fruit; carbon disulfide for fatty products, and gammexane for cereals. See Article 741.

Protective Agents

Article 47—The term "protective agents" means any preservatives, antiseptics, anti-fermentation agents, and antioxidants added to foods to prevent, retard, or arrest their alteration or decomposition.

Article 48—The following protective substances are in general considered as permitted:

Ethyl alcohol and brandies
Spices and spice essences
Glycerine
Smoke
Lecithins
Potassium or sodium nitrate
Common salt (Sodium Chloride)
Salt with condensed smoke

In addition, the following gases may be used to disinfest cereals, vegetables and fruit:

Carbon sulfide
Hydrocyanic acid
Methyl bromide
Chloropicrin
Ethyl formate
Carbon tetrachloride, and
Ethylene dichloride which may be mixed with carbon dioxide.

The health authority may authorize additional protective agents whenever it deems it advisable.

Article 49—The use of the following protective agents shall be considered as restricted and limited to the cases specified hereinafter; their use in amounts exceeding 5 per cent of the established limits shall not be permitted.

Food	Protective agent	Parts per million
1. Starches	Sulfur dioxide (SO_2)	100
2. Sugars (sucrose, dextrose)	Sulfur dioxide (SO_2)	70
Sugars hydromels	Sulfur dioxide (SO_2)	300
Glucose syrups	Sulfur dioxide (SO_2)	300
3. Caviar, fish pastes and canned shellfish	Hexamethylenetetramine	1,000
Caviar, fish pastes and canned shellfish	Benzoic acid and its salts	1,000
4. Beers	Sulfur dioxide (SO_2)	70
5. Canned vegetables	Sulfur dioxide (SO_2)	40
6. Condi ents in liquid and paste form (except mayonnaise)	Benzoic acid and its salts	2,000
7. Pickles	Benzoic acid and its salts	250
8. Coffee, guarana, mate and tea extracts	Methylic or propylic esters of p-oxybenzoic acid and their salts	100

	Food	Protective agent	Parts per million
9.	Dried fruit	Sulfur dioxide (SO_2)	1,500
	Fruit marmalades and jellies	Sulfur dioxide (SO_2)	40
	Fruit pulp for use in other preparations	Sulfur dioxide (SO_2)	350
	Fruit juices and liquid pectins	Sulfur dioxide (SO_2)	150
	Fruit juices and liquid pectins	Benzoic acid and its salts	1,200
	Concentrated fruit juices	Sulfur dioxide up to	600
	Concentrated fruit juices (except grape, apple, pear and citrus juice)	Formic acid	1,500
10.	Gelatins	Sulphur dioxide (SO_2)	1,000
11.	Fats, powdered milk, and dehydrated soups	Nordihydroguaiaretic acid (NDGA) and resins containing it *	100 to 500
	Fats, powdered milk, and dehydrated soups	Butyl hydroxyanisole (BHA) *	200
	Fats, powdered milk, and dehydrated soups	Esters of p-oxybenzoic acid *	200
	Fats, powdered milk, and dehydrated soups	Octyl and dodecyl gallate *	50 to 500
	Fats, powdered milk, and dehydrated soups	Propyl gallate *	100
12.	Mayonnaise and similar products	Benzoic acid and its salts	2,500
13.	Sausages	Benzoic acid and its salts	1,000
14.	Ciders	Carbon dioxide (CO_2)	200
15.	Wines	Carbon dioxide (CO_2)	450
16.	Artificial fillers for sausages	Formaldehyde up to	500

* As synergists, ascorbic, citric and phosphoric acids may be added in amounts of 5 to 10 mg. per 100 grams.

Article 50—The use of the following protective agents shall be prohibited, unless it has been specifically authorized by the present Code:

Alpha-bromopropionic acid and alpha-bromoisovaleric acid, derivatives thereof, and similar acids and their salts
Para-oxybenzoic acid and similar acids; their esters, salts and derivatives
Boric acid, its derivatives and salts
Bromoacetic acid and its derivatives
Cinnamic acid and its derivatives
Chloric acid and its derivatives and salts
Hydrofluoric acid and its derivatives and salts
Monochloracetic acid
Salicylic acid and its derivatives and salts
Iodoacetic acid and its derivatives

Oxygenated water and peroxides
Abrastol and naphthol derivatives
Formaldehyde
Hydroxyquinoline
Hexamethylenetetramine
Quinosol
Mercury salts
Thymol
Thiourea thio-acetamide

By way of exception and considering their origin, the natural presence of traces of the following substances shall be permitted:

Formaldehyde, in smoked products and caviar;
Boric acid, in certain cooking and table salts and in certain apples, pears, quince varieties, pomegranates, grapes, and by-products thereof;
Salicylic and benzoic acids in certain grapes, strawberries, plums, red currants and other fruits;
Formic acid in various fruits;
Fluorine in certain drinking waters and specific varieties of grapes and wines;
Bromide, in pineapple juice;
and such other substances as the health authorities may approve in the future.

CHAPTER V—LABELING

Article 71—The term "labeling" means any inscription, legend or marking which is printed upon, attached to, or engraved upon a product or its immediate commercial container which identifies the product in accordance with the laws in force and the provisions of this Code.

Article 72—Any food product which circulates in commerce or is held for sale shall bear a visible label in the national language which states:

1. The designation of the product and its nature, or the exact composition if the product is a mixture. For the purposes of this provision, the term "mixture" means any product that consists of elements or commercial articles of a varying composition, class or species, in which case the composition shall be declared in the labeling as follows: Mustard with curcuma and sugar; Torrone made of almonds, honey and sugar. On the other hand, if vegetable oils, wines, ciders, neutral alcohols, etc. are mixed or combined with each other, the resultant *mixture* is considered as a "cut" and in such cases, their composition need not be declared, in the same manner as generic names defined in this Code, unless the contrary is required particularly.

2. The measure, size, weight or net volume of each unit expressed in accordance with the decimal metric system. In the case of

preserved foods, the net weight shall include the weight of the liquid medium, when the same has become part of the product, such as oil, sauce, gravy, sugar syrup, and even brine if it can be used.

3. The name of the manufacturing establishment or the manufacturer or seller, and the place of manufacture. If the product has been imported, the place of origin of the merchandise and the name and address of the importer, packer, distributor, or seller. Moreover, it shall bear the clearly visible legend "Product of (name of country)."

4. All other indications required by the laws and regulations in force and by the present Code.

Article 73—The names of fruits, foods and other articles originating in a certain country shall be stated in its national language. In addition, translations may be given if this is considered practical, but such translations may not appear in a form or in letters more conspicuous than the markings written in the national language.

Expressions which may be confusing or misleading or expressions intended to suggest distinctions which do not exist are prohibited from being used on labels and in oral, radio or written advertising.

Article 74—To prevent deceptions or confusions, receptacles used for foods shall bear inscriptions stating clearly and visibly the exact name of the food, as defined in the present Code.

Article 75—Without prejudice to the right to use registered trademarks, the use of any false, exaggerated, or deceiving indication in any part of the labeling cannot be justified by referring to the opinion of a technician or specialist, or by explanations designed to clarify the use of the indication.

Article 76—Artificial products are not permitted to have in their labeling any symbols or designs representing raw materials of natural products.

Any artificial product not clearly marked as such for the information of purchasers will be considered a falsification.

Article 77—Labels of food products may not bear indications which refer to medicinal or therapeutic properties. Products which bear information of this kind or are exhibited for sale with a claim to curative properties shall be considered "medicinal specialties" and as such shall require the approval of the competent health authority.

Article 78—As a general rule, geographic names of a country, region or town may not be used to designate products manufactured

elsewhere when this may be deceiving. Exceptions to this rule are made for foreign geographic names which, through usage, have become generic for certain articles and which, for this reason, are no longer considered indications of origin, such as: French bread, Parmesan cheese, French Vermouth, Roquefort cheese, Indian sauce, English sauce, Portuguese sauce and other names that may be approved. Products (wines, cheeses and others) are prohibited from being designated by geographic names when they have not been prepared in the particular region or locality.

Article 79—Containers, the contents of which may deteriorate once the container is opened, shall have a warning marked on the principal or a secondary label to the effect that the product must be consumed immediately. [The End]

CHICK EMBRYO TEST FOR TOXICITY

Food and Drug Administration scientists have developed a new and faster method of determining the potential toxicity of drugs, food additives, pesticides and related chemicals through injection of the chemical directly into the yolks of fertile eggs before incubation, and determination of the effect on the chick embryo. Two reports were presented April 16 to the 47th annual meeting of the Federation of American Societies for Experimental Biology: one on the toxic effects of certain chemicals in combination, by Jean-Pierre Marliac and Mary K. Mutchler, and one on the toxicity of drugs by Jacqueline Verrett and Joseph McLaughlin, Jr., all of FDA's Division of Pharmacology. The reports presented to the Federation meeting covered some results of the experimental testing of 150 chemicals in over 30,000 eggs during three years. The toxic effects observed from injected chemicals vary from slight decrease in hatchability of the injected eggs to death of all embryos.

The new method is especially useful for determining possible teratogenic effects of a chemical, that is, its tendency to cause congenital deformities. Teratogenic effects observed in the chick embryo include a wide range of gross physical deformities such as shortened legs, shortened spines, parrot beaks and feather inhibition. Additional effects of a chemical may only be noted during the growth and development of the hatched chick. Certain combinations of chemicals produce a "synergistic" effect—that is, they are several times more toxic in combination than is either separately. This effect is demonstrated in the paper by Marliac and Mutchler, and the method promises to be useful in further studies of the possible "potentiation" effect of chemicals, such as pesticides, on each other.

A major advantage in the procedure is the speed with which results are obtained, and further, that if the results are completely negative for the developing chick embryo, this gives some confidence that the chemical will be safe for human use. The FDA scientists pointed out that the chick embryo method can be compared to a short circuiting of the protective mechanism of the placental barrier in an animal organism or even in a developing human embryo.

Legal Considerations in Experimental Design in Testing New Drugs on Humans

By MICHAEL F. MARKEL

This Paper Was Delivered at the Postgraduate Course on Animal and Clinical Pharmacologic Techniques in Drug Evaluation, February 4-15, 1963, Which Was Sponsored by the Section of Clinical Pharmacology, Department of Medicine, Hahnemann Medical College and Hospital of Philadelphia. Mr. Markel, a Former FDA Hearing Examiner, Is Now Chairman of the Division of Food, Drug and Cosmetic Law of the American Bar Association.

THE LEGAL CONSIDERATIONS in experimental design in this review of "animal and clinical pharmacologic techniques in drug evaluation," suggests a review of the legal requirements, or legal risks, if you will, implicit in any investigation undertaken to determine the safety and efficacy of new drugs by *human* experimentation and clinical testing.

To be sure, animal experimentation also involves certain legal risks. However, these are most likely to involve primarily contractual relationships between investigator and sponsor, and possibly tort claims arising from accidents occurring during the course of the investigation. A review of the agenda for these meetings suggests that such considerations are wholly incidental for present purposes and that a review of legal considerations in testing new drugs on humans is indicated. Therefore, the subject of this paper has been restricted accordingly.

Ordinarily any undertaking to determine legal requirements and prescribed penalties for any human conduct, directs initial inquiry to relevant statutory provisions and regulations lawfully issued pursuant to these. This is then followed by an examination of the court decisions which have construed this law, and in which judicial conclusions have been reached whether the prescribed standards of conduct have been met.

No Applicable Statutory Code

It may come as a surprise to some of you, however, to learn that no statutory code is in existence today anywhere which outlines a required procedure and course of conduct for those concerned with the evaluation of the safety and efficacy of drugs. The one exception to this general statement, to the extent that it is an exception, is the Drug Amendments of 1962 as this law will be implemented by administrative regulations governing "investigational drug research" along the lines indicated in the proposed regulations as published in the *Federal Register* for January 8, 1963. The specific requirements of these regulations will be noted and reviewed later against the background of the applicable common law principles to be summarized.

Note should also be taken as an exception to that general statement, of the code specifically adopted to serve as the basis for judging the conduct of the defendants in the so-called "Doctor's Trial," of the Nuremberg trials, officially designated as *United States v. Brandt* (Case 1). This trial resulted in convictions as well as acquittals. Death sentences were imposed on seven defendants, seven were acquitted, and sentences of confinement for varying periods were imposed on nine others. While this code does not have the force and effect of law in any jurisdiction, it was the law of that case. The convictions, as indicated, were based on findings of fact regarding the conduct of the defendants which failed to square with the principles of that code. Reference to that code is pertinent to this discussion because it was, no doubt, intended by those who drafted it, including United States representatives regarded as experts in this field, to incorporate the ethical standards and legal requirements as recognized by the profession and the courts of the Western Hemisphere.

However, even though no statutory code exists (except as noted) either here or, to the best of my knowledge, in any other jurisdiction, which spells out requirements for testing new drugs on humans, the courts have established basic principles which must be observed by those who would follow novel and untried procedures and use new and untried drugs on humans. The basis for these court decisions is the generally accepted, collective moral standard of the community as revealed by the code of professional ethics adopted by the profession of that community. In the absence of specific statutory requirements by which such conduct may be judged, courts must look to these as the basis for applying pertinent common law principles in the process of reaching a legal

conclusion regarding the propriety of the conduct subject to judicial review.

Indeed the source of all law is the collective conscience of the community as revealed by accepted codes of ethics. In our area of discussion, this is the code of ethics adopted and followed by the medical profession. The courts, if they would be just, must give due recognition to such codes.

"Common Law Principles"

In doing so, there is developed a set of principles through a series of decisions in specific cases in which the courts come to a conclusion with respect to the questioned conduct on the basis of the standard of conduct prescribed by the applicable code. These are commonly referred to as "common law principles."

Mr. Irving Ladimer, J. D., after review of various codes in his article [1] cited as a reference, states:

> Consequently, for any legal process, a reasonable consensus can be found containing the elements of a professional ethical code as a basis for considering liability or justification in fact situations involving research on human beings.

Legislative requirements usually follow later and are often inspired by incidences of flagrant disregard of these common law principles. For example, the so-called "Elixer Sulfanilamide" tragedy, responsible for the death of over 100 persons, was the one thing *extra* needed to induce the Congress to adopt legislation requiring that the safety of drugs be established before shipment in interstate commerce. The recent drug amendments and the greatly expanded administrative regulations proposed to be issued under that law, were the direct result of the thalidomide tragedy. However, subject to the specific requirement of this law and regulations, to be reviewed later, the area of legal review of our subject is the law as spelled out in applicable common law principles.

The fundamental legal premise which should serve as a beginning for this review is the basic concept in Anglo-Saxon jurisprudence, that the right of man to be free from tort upon his person is inviolable. This assures a right of freedom from *unjustified* assault upon his person to every human being. This then requires that when any person is subjected to medical treatment, the procedures adopted and the medication used must be justified and proper in the particular circumstances under which the treatment is given.

"Ordinary Care" Defined

Propriety of conduct of any individual under any given circumstance must meet the requirement that "ordinary care" be exercised in carrying out any authorized undertaking which may, or can, affect another person adversely. There are many definitions of this term. For our purposes the following statements of the rule by courts will suffice. Ordinary care has been said to be:

> . . . such a degree of care, skill and diligence as men of ordinary prudence, under similar circumstances, usually employ, and is to be determined with reference to all the attendant circumstances of the transaction.
>
> No man is held by law to a higher degree of skill than the fair average of his profession or trade, and the standard of due care is the conduct of the average prudent man.

General Practitioners and Specialists

In applying these basic principles to a physician engaged in general practice, the courts have said that what is required of him in the treatment of his patients is that he have and use his best judgment and such reasonable and ordinary degree of skill as is possessed and employed by similar practitioners under like circumstances in his community. It should be noted parenthetically that the term "community" includes a much larger area today than it did a century ago. It might have been a village at one time. It probably is the nation today.

As applied to specialists, *Corpus Juris Secundum* states the rule as follows:

> A physician holding himself out as having special knowledge and skill in the treatment of a particular organ, disease or type of injury is bound to bring to the discharge of his duty to a patient employing him as such specialist, not merely the average degree of skill possessed by general practitioners, but special degree of skill and knowledge possessed by physicians who devote special study and attention to the treatment of such organ, disease or injury, regard being had to the state of scientific knowledge at the time.

This, then, requires that when any person is subjected to medical treatment, the procedures adopted and the medication used must be justified and proper in the particular circumstances under which the treatment is given. In our area of discussion the "circumstances," or "propriety" of conduct, to be considered in reviewing applicable legal principles divide themselves into three general phases, (following animal experimentation usually regarded as phase one), namely: *medical experimentation; clinical investigation;* and *medical treatment by the general practitioner.*

Before reviewing the requirements in the circumstances of each of these phases, it should be stressed that no new drug should ever be administered to humans unless and until data regarding the safety of the drug are available from acceptable animal experiments. While the investigator or physician need not review the detailed reports of the animal experiment, he should, as a matter of due care, inform himself of the general nature and extent of the experiment; the identity and professional reputation of the investigators; the conclusion as to safety reached by them; and, above all, the evidence in the report, if any, regarding likely hazards which may be expected and for which the investigator testing the same drug on humans should look and be prepared to deal with, should the occasion require it.

The time limitation for this discussion does not permit a detailed review of the basic legal considerations pertinent to each of the three categories indicated. However, an outline of such legal considerations should suffice for purposes of alerting interested persons. Anyone interested in the details, including the arguments pro and con regarding some of the controversial points included in this summary, may continue this study by reading the annexed references in their entirety. These include excellent detailed discussions by outstanding authorities.

MEDICAL EXPERIMENT

A medical experiment may be regarded as an investigation or observation employing new procedures or administering new drugs to humans, not therefore tested on humans, by trained experts with a view of determining both its pharmacological activity in humans which is indicated or suggested by the data obtained from animal experiments and the safety of the test material to humans.

To be justified, any undertaking of a medical experiment should be based on information and data obtained from animal experimentation or otherwise, which hold out some promise that the results may reasonably be expected to contribute to the advancement of scientific knowledge and the general welfare. Loose experimentation only to satisfy the curiosity of an ambitious investigator is almost sure to subject such investigator to tort liability even though the person on whom the experiment is carried out may have consented to serve as the subject. The rationale here is that a person may not unreasonably consent to an assault on his body. Therefore, should injury

come to a person from an ill-considered experiment, his prior consent would not be a defense in a subsequent tort action. The need for exercising due care begins with the justification for experimentation on humans.

The therapeutic benefit to the subject being treated is incidental and is ordinarily not involved in medical experimentation on humans because, as a matter of good practice, such experimentation is invariably restricted to a relatively small group of volunteers enjoying normal health who, therefore, do not require therapeutic treatment.

Consultation with Qualified Experts

A medical experiment should be planned in consultation with several qualified experts and preferably with experts who are not expected to participate in the procedures of the experiment. Procedures finally adopted as a result of such consultations should be so designated that they will reasonably insure against undue hazards to the subject.

The volunteer subjects must have expressly consented to submit to the planned experiment. Such consent must be an *informed* consent; that is, the subject must fully understand the fact of experimentation, its general nature, and most important, the likely hazards which might be encountered.

However, even though a person consented to serve as a subject with full knowledge of the nature of the experiment, he may withdraw this consent at anytime during the course of the experiment. Therefore, the treatment of any specific subject must be stopped upon his indication of his unwillingness to continue. Should treatment continue thereafter, the investigator subjects himself to tort liability even though no injury may come to the subject from such continued treatment. The rationale here is the basic concept mentioned at the outset, namely, that the right of a human to be free from any unauthorized or unjustified assault on his person is inviolable.

The fact that such withdrawal by a subject might constitute a breach of contract made between him and the investigator will not serve as a defense in a tort action. The only rights the investigator has in those circumstances is to recover provable damages for breach of contract.

Side Reactions

The experimentation must be discontinued if, at anytime during the course of the experiment, unusual or unexpected side reactions

occur which cannot be readily appraised as to their likely hazards to the subject. Treatment may not be resumed until these have been explained and a conclusion has been reached that no untoward hazards are indicated by the occurrence.

There is no legal requirement that the results of a medical experiment be published even though the basic considerations in its undertaking were the contribution to scientific knowledge and general welfare. However, some believe that by reason of this legally recognized justification for medical experimentation on humans, a strong moral obligation exists to publish, whether the results were good or bad.

CLINICAL INVESTIGATION

The summary of legal considerations in planning and conducting a medical experiment on humans serves also as an outline for planning and conducting a clinical investigation. In general, like or similar considerations apply, subject to certain exceptions and deviations which should be noted.

While the principal object of a medical experiment is to promote scientific knowledge, the primary purpose of a clinical investigation is to determine the therapeutic benefit of the new drug to the patient being selected for treatment for his ailment for which the drug promises to have therapeutic value.

A clinical investigation should also be planned in conference with qualified experts. The extent of the investigation; that is, the size of the group to be treated should be determined on the basis of pharmacological and toxicological data available, not only from the animal experiments but also from a medical experiment on humans. Should a clinician undertake a clinical investigation without benefit of data derived from prior medical experimentation on humans, then due care would require that his group be kept small. If, on the other hand, promising data from medical experimentation on humans are available and particularly if these demonstrate fairly conclusively the absence of untoward hazards, then the clinical investigation may be extended to a relatively large group. In short, the extent of clinical investigation is a matter of judgment of qualified experts based on the pharmacological and toxicological data available to them.

The clinician, too, should have the consent of his patient to carry out the proposed clinical investigation. In his case, however, and especially where the doctor-patient relationship is also present, as it

often is, there *may* be circumstances under which consent cannot be obtained or where, in the clinician's judgment, the patient's interests are best served if he is not informed that something new is being tried. Such a satisfactory showing is a good defense to any charge of unauthorized assault.

Medical Experiments on Infants and Incompetents

While medical experiments on infants and incompetents are most unlikely, since it would be difficult to justify them, the clinician will have occasion to treat such persons. In these circumstances the patient in the one case is not legally capable of consenting and in the other not able to do so. The courts have held that when treatment of such patients is justified in the considered judgment of the clinician on the basis of expected benefits to these patients, then the *informed* consent of the parents in the one case and personal representatives in the other, will satisfy the legal requirement.

Controlled and Double Blind Investigation

Comparative observation and therapeutic treatment are regarded by many as the only solid foundation for experimental medicine. Often cure of a disease might be attributed to a treatment where recovery might well have occurred without medical treatment. Therefore, there may be circumstances where doing nothing will have to be mixed in with trying something new, in order to guard against false illusions of cure by the new treatment. Controlled, and sometimes double blind clinical investigations are indicated to eliminate psychogenic factors and bias. However, this, then, calls for a rather delicate decision as to which of the ailing patients are to be selected to continue without treatment and which are to be treated. In case of double blind testing, the investigator is also deprived of knowledge which might be regarded as essential for the exercise of due care in looking for, and dealing with, undesirable side effects or development of unexpected hazards.

It becomes obvious, therefore, that, at best, a decision to carry out a controlled or a double blind investigation is bound to involve some legal risks in the event harm comes to the patient which can be attributed to the procedure followed.

However, in general we must fall back to our definition of "due care." It is just as important that the patient receiving the placebo be not harmed from neglect as it is that the patient receiving the test drug be not harmed from treatment. The clinician's personal

judgment must be the basis for the decisions in such instances. In the event of harm that judgment is reviewable by applicable concepts of due care.

MEDICAL TREATMENT BY GENERAL PRACTITIONER

The general practitioner, too, must be guided by the foregoing outline of legal considerations as applicable to him.

The general practitioner, like the clinician, must be guided in the treatment of his patient solely by the needs of his patients. The patient's welfare should be the sole determining factor whether, in the considered judgment of his doctor, he should be subjected to a specific treatment.

In treating his patient the general practitioner, too, must exercise "reasonable care." In his case, this is that degree of care and diligence in the exercise of his skill and application of his learning reasonably required to achieve the expected benefit for his patient. He must use his best judgment in exercising his skill and apply his knowledge to that end.

The general practitioner is not held to the learning and skills of the specialist whose services are retained by reason of his superior knowledge. However, as a practical matter, a person holding a medical degree is not likely to be challenged on the ground of improper exercise of judgment or inadequate possession of skill. Lloyd Paul Stryker, in his book entitled *Courts and Doctors* says

> I have never seen it established that a doctor did not possess the requisite skill or that he did not "use his best judgment." I have never seen this done, probably for the reason that it is much easier to prove that a physician failed to employ reasonable care and diligence in that he did not follow the proper and approved practice. What his best judgment was and whether he used it, what his knowledge and skill actually were, would be difficult to establish by any proof.

"Proper and Approved Practice"

Accordingly, the legal consideration regarding the conduct of the private practitioner invites examination of what he may regard as "proper and approved practice" at his level of practice.

This very term excludes "medical experimentation" in the sense in which we have discussed this. The general practitioner may not indulge in "experimentation." Many malpractice cases in which the doctor has been held liable turn on the conclusion that the doctor indulged in experimentation which was neither authorized, nor called for, or which he was not qualified to perform. Of course, under the

present law there should be little occasion for encountering such a risk, because a drug will not, or at least should not, become available to the general practitioner until it has passed sufficient tests so that its use, as directed, can no longer be regarded as experimentation.

However, even after new medication, duly cleared, comes to him for use, he still owes his patient a duty to consider whether the patient's best interests will be served by administering such a cleared new drug. In exercising this judgment, all other well-established drugs which have been generally accepted in treating the same condition must be considered, because with respect to a given patient who has responded well to other available medication, a change to another and newer drug recommended for the same condition may well not be to that patient's best interest. The doctor should proceed from the "excellent" through the "amazing" on to the "fantastic" claimed therapeutic values of various drugs with great caution because a change from a medication which has proven effective to another offered for the same purpose could, in itself, constitute experimentation with certain patients. Such procedures are also undertaken at the physician's peril, depending on the circumstances, of course. As one court has said:

> If a physician sees fit to experiment with some other mode he should do so at his peril. In other words, we must be able, in the case of deleterious results, to satisfy the jury that he has reason for the faith that was in him and justify his experiment by some reasonable theory.

The general practitioner, too, should ordinarily obtain the patient's consent for the administration of a new drug. However, the exceptions noted in the review of the clinical investigation apply to the personal physician also. Indeed, in his case consent may often be implied. Where the continued and rather intimate doctor-patient relationship exists, consent is implied when normal conduct would not ordinarily call for special consent. In short, the general practitioner is much less vulnerable than either the medical investigator or the clinician for failure to obtain the patient's consent when deciding on a change in treatment, provided, always, that he restricts his medication to drugs which have been legally cleared for use in the treatment which he undertakes.

A Look at the 1962 Drug Amendments

This outline of legal considerations involved in testing new drugs on humans, though not complete in spite of its length, is, in my opinion, quite representative of the requirements and restraints of the

applicable common law principles. A brief look at the Drug Amendments of 1962 and the regulations proposed to be promulgated under the law is here indicated for our purposes, in order to determine what, if any, changes the statute makes in these, heretofore accepted, codes of ethics and common law principles.

It is my considered judgment that, subject to the mandatory requirement that certain records be kept and that full periodic reports be made to the Department, and perhaps other similar procedural requirements, the law merely codifies the common law principles as outlined.

A concise, yet adequate summary of the requirements of the new law is found in the "Summary of Drug Amendments of 1962" issued by the Department of Health, Education and Welfare in November, 1962. It reads:

> The new law lays a firm and explicit statutory basis for the already implied authority of the Department to impose conditions, related to public health protection, on exemption of new drugs and antibiotics for distribution for research or experimentation. In addition to the conferring of general authority to impose such conditions, the Secretary is specifically authorized to prevent the testing of new drugs (including antibiotics) on humans if specified safety conditions are not met. Regulations spelling out requirements to be met before such a drug may be tested for safety and effectiveness on human patients may, among other things, require:
>
> Submission of reports of preclinical tests, including animal tests, adequate to justify the proposed clinical testing.
>
> Obtaining signed agreements from investigators that work done will be under their personal supervision and drugs used will not be supplied to others.
>
> The law *directs* the Secretary to issue regulations conditioning the exemption of experimental drugs on the drug manufacturer's obtaining certification from the scientific investigators, stating that they will inform patients to whom the drug is to be administered, or their representatives, of the experimental status of the drug and obtain their consent except where the investigator deems this not feasible or, in his professional judgment, this is contrary to the best interests of the patient.
>
> Further, regulations are specifically authorized to require, as a condition of exemption of experimental drugs, the keeping of records and making of reports on the investigation that will enable the Secretary to evaluate the safety and effectiveness of the drug if later an application is made for approval of the drug for commercial distribution. (This authorization is not limited to drugs intended for humans.) This should make it possible for FDA scientists to familiarize themselves currently with the emerging scientific data on drugs before a new-drug application or an antibiotic application for approval for commercial distribution is made.

The regulations proposed to be issued under this law, as published in the *Federal Register* of January 8, 1963, spell out in considerable detail the manner in which the statutory requirements for

the use of the experimental drugs may be met. Subject to the detailed procedural requirements as spelled out, such regulations too, will not require anything fundamental not heretofore required by established applicable common law principles.

Exceptions to the Requirement

In making this statement I am not unmindful of the concern felt by some, as revealed by the Congressional debates, that inclusion of the exceptions to the requirement that the consent of the patient was essential to carrying out a new drug investigation, might serve to promote unwarranted experimentation by doctors. However, I believe these exceptions are also entirely consistent with the common law exceptions to the requirement that the patient's consent be obtained.

Should anyone go beyond the exceptions as recognized in the common law in reliance on these statutory exceptions and should injury result to the patient, the doctor would surely be held liable for having engaged in an unauthorized experimentation. Or putting it the other way, should the statute be construed as permitting experimentation without the patient's consent under conditions not recognized in common law as a valid condition for dispensing with obtaining consent, then the validity of the exceptions would be questionable because, in my opinion, the Congress cannot constitutionally take away from any person his invioable right to be free from assault on his person without his consent. In my opinion, the constitutionality of the exception can be sustained only by an interpretation which is consistent with the common law principles.

One can't help but take special note also in this connection of the number and the nature of the various comments and objections filed to the initial proposed regulation. According to the press release issued by the Department, over 300 written comments were received. Many have expressed concern lest the new law and these regulations prove contrary to the best interests of the public because they might discourage development of new and better drugs.

Last 25 Years Called the "Miracle Drug" Era

Such objections are reminiscent of the early days after the enactment of the so-called "new drug" section of the 1938 law which barred new drugs from interstate commerce until they had been established as safe for use on humans to the satisfaction of the government. I doubt that anyone can be found today who will claim that the

development of new and better drugs during the past quarter of a century has been impaired by that law. Indeed, industry sources have, in recent years, characterized this law as having been the most important influence in bringing about rational therapeutics. This period has been characterized as the "miracle drug" era.

One may predict with a reasonable degree of certainty that experience under this new law and regulations will parallel that of the last 25 years. Indeed, in my opinion, the fears expressed by those who believe that the new law and regulations are too restrictive, can be justified only by a confession of flagrant disregard of the professional code and applicable common law principles, for, as I have said, nothing is required which ought not to have been done in the past as a matter of ethical deportment and due regard to common law principles. However, the law will cramp the style of those who have been given to short cuts in disregard of these ethical and legal considerations.

In conclusion I may summarize by suggesting that the doctor, whether he be a medical investigator, a specially qualified clinician, or a general practitioner, who follows his professional code of ethics conscientiously has nothing to fear from the law, both statutory and common law.

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[The End]

WASHINGTON

ACTION AND NEWS

In the Food and Drug Administration

April Food Seizures Report.—Contaminated food seized during March totaled 389,587 pounds (194.8 tons). Approximately one-third of this total involved products in the danger-to-health category. These were wheat contaminated by seed wheat treated with a poisonous mercury agent, a nonpermitted color additive and pinto beans containing burrs. Insanitary warehouse conditions, spoilage or filth accounted for the remainder of the food seized.

Economic violations resulted in seizures of 12,514 pounds.

Drug and Device Seizures.—Twenty-three federal court actions were instituted against adulterated drugs and devices and misbranded products falsely promoted for the diagnosis and treatment of diseases or failing to be labeled as required. Included were dietary supplements, a veterinary drug, medicated feeds below their labeled strength, repacked physicians' samples, prescription and nonprescription drugs without mandatory labeling information or warning statements, defective prophylactics and devices failing to bear adequate directions for use.

Hazardous Substances.—Four actions were taken against a hazardous water repellent, and two brands of turpentine were seized. In each case the government charged failure to bear precautionary labeling required by the Federal Hazardous Substances Labeling Act.

Voluntary Actions by Industry.—The food industries in March voluntarily destroyed or denatured a total of 141,572 pounds of unfit foods to prevent their consumption. In addition, 42,144 pounds of short-weight dried beans and popcorn were voluntarily repacked and relabeled at an estimated cost of $1,200 to the manufacturer. Some of the largest voluntary food actions involved 40,000 pounds of rodent-contaminated flour denatured for use in animal feed, 12,450 pounds of fire-damaged margarine diverted to use in the manufacture of soap, and 21,000 pounds of filthy and moldy wheat destroyed.

Drugs originally valued at $73,600 retail selling price, were removed from the market voluntarily. Products included deficient vitamins, nonsterile intravenous solutions, antibiotics and veterinary drugs which had passed the expiration date, dietary supplements containing folic acid in excess of the permitted amount, a drug that was recalled because of instability and low potency, and fire-damaged drugs.

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