VOL. 30, No. 11 NOVEMBER 1975

Food Drug Cosmetic Law JOURNAL

A COMMERCE CLEARING HOUSE PUBLICATION
PUBLISHED IN ASSOCIATION WITH THE FOOD AND DRUG LAW INSTITUTE, INC.

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.

The FOOD DRUG COSMETIC LAW JOURNAL is published monthly by Commerce Clearing House, Inc. Subscription price: 1 year, $30; single copies, $3. Editorial and business offices, 4025 W. Peterson Ave., Chicago, Ill. 60646. Printed in United States of America.

November, 1975
Volume 30 • Number 11

Second-class postage paid at Chicago, Illinois and at additional mailing offices.

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TO THE READER

American Bar Association Meeting. The following papers were presented at the annual meeting of the Food, Drug and Cosmetic Law Committee of the Corporation, Banking and Business Law Section of the American Bar Association, which was held in Montreal, Canada on August 13, 1975.

"The Canadian Approach to Food and Drug Regulations" offers a description of the organizational structure of the Canadian regulatory system as well as an insight into the philosophy behind its enforcement procedures. The article, beginning on page 632, is written by *Dr. A. B. Morrison,* Assistant Deputy Minister of the Health Protection Branch in the Department of National Health and Welfare of Canada. Dr. Morrison also describes the regulation-making process in Canada and the relationship of the regulatory agencies with the legislative branch of government.

As a lawyer with more than 30 years of experience in the food, drug, cosmetic and device field, *Robert E. Curran* is in a position to comment knowledgeably on past developments and matters of current interest in this area. His article, "Canadian Regulation of Food, Drugs, Cosmetics and Devices—An Overview," includes comments on international uniformity, ingredient labeling, new drug applications, commercial advertising and medical device regulations. Mr. Curran is a member of the law firm of Soloway, Wright, Houston, Killeen and Greenberg. His article begins on page 644.

In his article dealing with matters of current concern regarding Canadian food regulation, *D. G. Chapman* outlines the parts of the Food and Drug Act specific to food and discusses some of the pertinent regulations promulgated under it. Mr. Chapman is Assistant Director-General of the Food Directorate of the Health Protection Branch in the Department of National Health and Welfare of Canada. Titled "Current Topics in Canadian Food Regulatory Affairs," the article begins on page 654.

James A. Robb, a member of the law firm of Strikeman, Elliott, Tamaki, Mercier & Robb, views the regulation of the food industry from the perspective of a lawyer whose practice includes that area. Beginning on page 659, the article explains that food legislation involves concurrent federal and provincial jurisdiction, and discusses the problems that arise from this. Mr. Robb's article is titled "Comments and Views from the Perspective of a Canadian Food Lawyer."

America's First Food and Drug Laws.—*Wallace F. Janssen* presents an interesting look at the first consumer protection laws of the United States in an article beginning on page 665. Mr. Janssen, the Food and Drug Administration historian, emphasizes the desire of the American colonists for safe food and drugs. The article, titled "America's First Food and Drug Laws," first appeared in the June 1975 issue of *FDA Consumer.*

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Food·Drug·Cosmetic Law
Journal

The Canadian Approach to Food and Drug Regulations

By A. B. MORRISON, Ph. D.

Dr. Morrison Is Assistant Deputy Minister of the Health Protection Branch in the Department of National Health and Welfare of Canada.

I AM HONORED and delighted to be invited to address this meeting—honored because of the high repute in which the profession of law is held, delighted because it gives me an opportunity to convey to you, as policy and lawmakers, some aspects of the Canadian approach to the regulation of food, drugs, cosmetics and devices.

In this presentation, I will deal with a number of topics briefly and in a general manner. I will outline our organizational structure, its relationship to the legislative arm of government and its jurisdiction over food, drugs, cosmetics and devices. In addition, I will discuss those parts of the Food and Drug Act and Regulations where I perceive there may be differences between Canadian and American legislation. Finally, I will attempt to explain in general terms our enforcement philosophy and briefly indicate the direction in which we are heading in our major regulatory thrusts.

Organization of the Health Protection Branch

I will begin with a few brief comments on organization. The Health Protection Branch (HPB) is concerned with the quality of Canada's food, drugs, cosmetics and medical devices, as well as with protecting consumers against environmental hazards including the occupational environment, radiation and harmful microorganisms. We thus carry most of the responsibilities of the Food and Drug Admin-

ease Center and the Environmental Protection Agency. We are mainly responsible for the administration of four pieces of federal legislation: the Food and Drug Act; the Narcotic Control Act; the Proprietary or Patent Medicine Act; and the Radiation Emitting Devices Act. To carry out these responsibilities, we operate a headquarters and research establishment in Ottawa, with major regional offices in Halifax, Montreal, Toronto, Winnipeg and Vancouver. The Branch is composed of six operating directorates including those responsible for food, drugs and environmental health. Our device safety program is located in the Environmental Health Directorate. We also have a large Field Operations unit which serves as our field arm, a Laboratory Centre for Disease Control and a non-medical use of drugs directorate.

Division of Responsibilities Within Government for Food, Drugs and Cosmetics

It is appropriate to explain the division of responsibilities for control over food, drugs and devices within the government of Canada. I have already indicated that the HPB is concerned with the quality of Canada's food, drugs, cosmetics and devices. In 1968, certain responsibilities of the Federal Health Department with respect to food and cosmetics were transferred to a newly formed department, the Department of Consumer and Corporate Affairs. This latter department is now concerned with economic fraud in food, including deceptive labelling, advertising and packaging as set out in the Food and Drug Act. It is also involved under the Consumer Packaging and Labelling Act with a large part of the labelling and packaging of cosmetics. However, the HPB retains jurisdiction over all other aspects of cosmetics, including health matters and the labelling of all cosmetics used in institutions (hospitals, nursing homes, factories, etc.). Later, in discussing legislative mandates, I will make passing reference to the relationship between the Consumer Packaging and Labelling Act and Regulations and the Food and Drug Act and Regulations.

The HPB retains responsibility for the setting of compositional standards for food. However, the Department of Consumer and Corporate Affairs enforces the food regulations dealing with compositional matter since it is considered an economic fraud if a food does not conform to its labelled claims.

Further, we have jurisdiction over matters relating to health hazards and safety of food, including nutritional aspects, inspection of food, food toxicology, including food additives, pesticides, natural toxicants, packaging materials, disinfectants and sanitizers in food processing plants, etc. As you can imagine, there is a high degree of interdepartmental co-operation between the Department of National Health and Welfare and the Department of Consumer and Corporate Affairs.

The HPB and the Department of Consumer and Corporate Affairs are not the only organizations in the federal government involved in assuring the wholesomeness and quality of the food supply. The Canada Department of Agriculture administers legislation concerning control of transmissible animal diseases and the regulation and inspection of meat and dairy products processed for interprovincial or export trade. The Department of the Environment administers similar legislation to assure the quality of marine products.

The HPB is accountable for all aspects of drugs, including advertising. Our jurisdiction extends over proprietary medicines, prescription products and over-the-counter preparations. We deal also with legal controls over narcotics, controlled and restricted drugs, to ensure they are not diverted from licit to illicit channels. On behalf of law enforcement agencies, including the Royal Canadian Mounted Police, provincial and municipal police forces, we analyze most drugs seized on the illicit market.

I trust this brief overview of our programs has not left too confused an image of who regulates what. Perhaps if I next turn to the legislative mandate for the regulation of food, drugs, cosmetics and devices, the matter will become clearer.

Legislation Governing Food, Drugs, Cosmetics and Devices

Gone are the days when the regulator and the regulated had a single piece of consumer legislation to govern with and be governed by. In this age of consumerism and burgeoning consumer legislation, not only has the amount of legislation increased but so also has the number of government agencies concerned with consumer affairs. I have already alluded to the latter. The same substance may be regulated in different aspects by different statutes. For example, disinfectants are classed as a drug in certain circumstances but are, at the same time, subject to the Pest Control Products Act which is enforced by Agriculture Canada. Indeed, if I may be permitted a

tongue-in-cheek comment, it looks like a lawyers' field day. It's not necessary (though it might be helpful) to be a "Philadelphia" lawyer.

Apart from the Income Tax Act, I cannot conceive of any legislation that has greater impact on the purse and health of Canadians than the Food and Drug Act and Regulations. The historians in my Branch tell me it is derived from the oldest legislation dealing with food and drugs in the western hemisphere. Its ancestor was born 100 years ago, almost by accident, as a result of a concern about alcohol. It is interesting to note that, a century ago, there was widespread concern in Canada about the social effects of alcoholism and broad public support for abolition of the sale of alcoholic beverages. In typical Canadian fashion, a committee of the House of Commons met to consider the problem raised by excess consumption of alcohol. (It has long been our practice to appoint a Royal Commission to investigate contentious issues before making judgments on them. Cynics would say that we hope the problem will go away if treated to a full measure of benign neglect.)

It concluded—and this is another example of the Canadian ability to reach sound decisions—that the problem was not one of *all* liquor, but only of *bad* liquor. As a result, a law to license compounders of alcoholic beverages and to prevent the adulteration of food, drink and drugs—the so-called Inland Revenue Act—was passed by Parliament and became operative on January 1, 1875. It was the great granddaddy of today's Food and Drug Act. I need hardly point out that it antedated comparable American legislation by over a quarter of a century.

I do not intend to go into the detailed statutory provisions of the Act and the Regulations but, since this is a comparative approach, permit me to highlight some of the statutory bases of our mandate.

Constitutional Aspects of the Food and Drug Act

Most importantly, the Food and Drug Act is criminal law. By virtue of Section 91, Subsection 27 of the British North America Act, criminal law is within federal jurisdiction. By way of explanation and comparison, the British North America Act purports to deal with legislative, executive and judicial power by dividing the totality of government between the central government and various provinces. Power is divided in terms of subject matter, leaving it to interpretation as to whether a legislative, executive or judicial power

is vested in the federal or a provincial government. Food, drugs, cosmetics and devices are nowhere mentioned in the division of subjects. This is not surprising, given the minor role of the state in health matters at the time of Confederation in 1867. Control over those substances has, however, been determined to be a matter of criminal law and therefore within federal jurisdiction. Several landmark decisions have upheld the federal primacy in this area and most legal authorities no longer seriously question it.

Hence, it is possible for us to legislate and regulate in these areas whether or not the subject matter is one which remains within a province or crosses provincial boundaries. In Canada, to date, we have chosen to deal with the safety aspects of food, drugs, cosmetics and devices in the same statute.

The Food and Drug Act is divided into a definition section and four parts. Part I treats each of the subjects so that individual consideration of special requirements and characteristics is possible. For example, advertising or sale of any food, drug, cosmetic or device as a preventative, cure or treatment for named diseases, disorders or abnormal physical states is prohibited.

Complex Device Technology

On the other hand, adulteration has applicability to food and drugs but not to cosmetics or devices. Similarly, there are prohibitions respecting the manufacture of food, drugs, and cosmetics under unsanitary conditions but no corresponding requirement with respect to devices. In light of today's complex device technology, it may be that we will have to look closely to determine if such a requirement is advisable for devices.

One of the most important interdictions contained in the Act prohibits the labelling, packaging, treating, processing, selling or advertising of food, drugs or devices in a manner that is false, misleading or deceptive or is likely to create an erroneous impression regarding its character, value, quantity, composition, merit or safety.

Part II makes provision for administration and enforcement. An inspector may at any reasonable time (considering our normal working hours, I cannot conceive that it would be other than business hours) enter any place where on reasonable grounds he believes any article to which the Act applies is manufactured, prepared, preserved, packaged or stored. He has authority to examine the article and to

take samples. In addition, he may examine anything he reasonably believes is connected therewith.

Among other things, an inspector can examine and copy books, documents or other records that he reasonably believes contain any information relevant to the enforcement of the Act or the Regulations.

An inspector can seize and detain, for such time as may be necessary, any article by means of or in relation to which he reasonably believes any provision of the Act or Regulations has been violated.

Reasonable Assistance

The person in charge of a place is required by law to give reasonable assistance and is prohibited from obstructing the inspector in the carrying out of his duties.

Once an article has been seized, it may be released by the inspector if he is satisfied that the law has been complied with.

Further, if the person who had possession of the article consents to its destruction, it is forfeited to the Crown (the federal government) and disposed of. The Act permits forfeiture upon conviction or upon application to a judge for an order to forfeiture where the owner does not consent.

The same part gives broad authority to make regulations to carry out provisions of the Act. For example, there is power:

(1) to declare any food or drug or class of food or drugs adulterated if any prescribed substance or class of substances is present or has been added, extracted or omitted;

(2) to regulate labelling, conditions of sale or the use of substances as ingredients to prevent any consumer from being misled as to quantity, character, value, composition or safety or to prevent injury to the health of the consumer and purchaser;

(3) to control importation;

(4) to establish standards of composition;

(5) to determine records a manufacturer must keep;

(6) to add to any of the Schedules (for example, prescription schedules);

(7) to define the expression "new drug."

Penalties are provided in Section 26 for a person who violates any of the provisions of the Act or Regulations.

Penalty Provisions

On summary conviction, the penalty for a first offense is limited to a fine not exceeding $500 or to imprisonment for a term not exceeding three months, or to both. For a subsequent offense, the penalty is limited to a fine not exceeding $1,000 or to imprisonment for a term not exceeding six months, or to both.

On conviction upon indictment, the penalty is limited to a fine not exceeding $5,000 or to imprisonment for a term not exceeding three years, or to both. It is of interest to note that the Inland Revenue Act of 1875 permitted a penalty of six months at hard labor for second offenders. It is clear that the road to penal reform is long and tortuous!

A special section exempts food, certain drugs, cosmetics and devices from the provisions of the Act if these substances are not manufactured for consumption in Canada and not sold for consumption in Canada.

Parts III and IV apply to what we call controlled and restricted drugs. These are drugs which are dealt with by our Bureau of Dangerous Drugs. The Bureau is, at least in part, analogous to your Drug Enforcement Agency—minus most of the muscle, since we do not do police-type enforcement work. We leave that dubious honor to the appropriate police agencies.

Consumer Fraud Aspects

While the Food and Drug Act, the Narcotic Control Act and the Proprietary or Patent Medicine Act are the only federal legislation governing the safety and effectiveness of drugs and devices in Canada, they certainly are not, as I have already said, the only federal law respecting food and cosmetics. I alluded earlier to the Consumer Packaging and Labelling Act. This legislation sets out a number of labelling requirements for food and cosmetics and assumes jurisdiction over the economic fraud aspects of these products. It overrides other similar legislation in this area. In the interest of simplicity, regulations which satisfy the requirements of the Consumer Packaging and Labelling Act have been incorporated in the Food Section of the Food and Drug Regulations. The same is not true for cosmetics. Except for health aspects of labelling of cosmetics and cosmetics for institutional use, these must comply with the Consumer Packaging and Labelling Regulations effective September 1, 1975.

There are other federal statutes imposing regulatory conditions on food, such as the Meat Inspection Act, the Agricultural Products Standards Act and the Fish Inspection Act. As I have already indicated, other federal departments (Agriculture, Environment) are concerned with the administration of these laws.

Of significance in the administration of food and drug law in Canada is the fact that, while the Food and Drug Act theoretically applies to all food, we traditionally have left the regulation of food in local retail outlets to provincial and municipal authorities.

The Regulation-Making Process in Canada

Having examined the main statutes concerning the regulation of food, drugs, cosmetics and devices, I will now turn to a consideration of the regulation-making process in Canada.

The impetus toward proposed changes, including new regulations and amendments to those already existing, may come from a great variety of interests. These include individuals within the government or the HPB, professional or trade organizations and consumers. In disagreement with Shaw, we do not believe that *all* great truths *always* begin as blasphemies. We recognize that the Branch does not have a monopoly on talent or integrity and that the regulatory process must of necessity and economy involve extensive discussion among the various groups—the regulators, the regulated, and the consumer representatives. Indeed, the assistance of the regulated is required to make certain that proposed regulatory changes are both theoretically sound and capable of practical application.

We are importers of a great many drugs, medical devices, cosmetics and food. Therefore, we keep a close eye on what other countries do about similar problems and often benefit through the adoption of sound principles or information used elsewhere. We do this in order not to impede the easy flow of necessary health products into Canada.

The *Canada Gazette,* like its cousin, the *Federal Register,* provides information on Orders-in-Council (regulations) passed by the Governor-in-Council. But unlike United States procedure, there is no regulatory requirement in Canada giving affected industries the legal right to comment on proposed regulations before enactment, that is, before they come into force. This deficiency was corrected nearly 30 years ago through the introduction of information letters, of which more than 400 have been published to date. They have been well

accepted by the trade and have contributed significantly to better relations with manufacturers and professional and consumer organizations. They provide a means of communicating to the industry necessary background information on the implication of proposed changes in regulations and administrative interpretation of regulations. They invite comments from industry on the proposed regulatory changes.

Comments from Industry

Informed comments from industry often result in changes to the proposed regulations to bring them into line with what is practically possible to achieve. This saves us the difficulty, as well as the embarrassment, of having to change them after they have been passed.

I wish to emphasize that we have no *legal* provisions for formal hearings. We believe that the communication we have with various interests is effective without a statutory requirement. In fact, we think it helps avoid the confrontation atmosphere which prevails in relationships between industry and regulatory agencies in other countries. We are firmly committed to the notion of full discussion with industry prior to regulatory changes. We try to avoid excessive formalism and legalism, however.

Once the proposed regulations have had thorough scrutiny in terms of content, they are submitted to the Department of Justice where modifications are made to bring them into conformity with accepted legal form and style. They are then presented to the Minister of National Health and Welfare for his approval and submission to the Governor-in-Council. I must stress that the final decision rests, as it should in our parliamentary system, with ministers and not with officials.

Explanation of Terms

Perhaps the terms "minister" and "Governor-in-Council" merit an explanation since they have an important bearing on regulations and regulatory action, as well as on policy and regulation-making function. Under the Canadian parliamentary system, the government in power is the political party having the greatest number of elected members. The person chosen by the party as leader is the Prime Minister. He (or perhaps, in the future, she) in turn selects as the Cabinet members from his (or her) party who have been elected to Parliament. The Cabinet is composed of the Prime Minister as Chairman, and ministers who are responsible for the administration of various departments of government. Under this system of government, an

order or a regulation of the Governor-in-Council is, in effect, an order made by a committee of the Cabinet.

You can see that the HPB, as a regulatory agency, is not isolated from the political process, though we believe we are much more isolated from partisan politics than are similar agencies elsewhere. The mechanism whereby we report to a politically elected representative who has ministerial responsibility before Parliament provides us with a continuing sensitivity to and awareness of the fact that the value judgments of society must be taken into account in reaching the final decisions about issues such as food and drug safety, acceptable risks and the role of the regulatory agency.

As officials, our task is to provide our Prime Minister with the best advice we possibly can. By "best," I mean technically best. He bears responsibility for policy and often has to defend his decisions on the floor of the House of Commons, before Parliamentary committees and, ultimately, before the people. We strive to achieve a proper balance between the responsibility of ministers and the responsiveness of public servants to their concerns.

Regulatory Policy

It is against this very general background that we formulate our enforcement philosophy and the administrative mechanisms to obtain compliance.

Since Canada is a significant importer of drugs, cosmetics, devices and food, we must consider carefully the impact of legislation affecting these commodities in other countries, particularly in the United States. In the area of drug legislation, we must be careful to ensure, for example, that it does not become so onerous as to make it prohibitive for a manufacturer to introduce a much-needed drug into Canada. Over the years, we have developed close liaison and friendship with regulatory agencies of other countries, particularly those of the United States, the United Kingdom, France, Switzerland and Sweden. We have frequent consultations, especially with the United States, on such matters as recalls of food, drugs, cosmetics and devices. In addition, there are regular bi-annual meetings of officials of the regulatory agencies of the United States, Canada and Britain to discuss matters of mutual concern. Also, we have concluded agreements with several national health agencies in other countries which export drugs to Canada. The object of these agreements is to exchange information on drug plant inspections to give us increased assurance that drugs imported into Canada have been produced in

conformity with our manufacturing facilities and control regulations. We believe that this co-operation will eliminate much needless duplication of effort. These agreements require that both countries have comparable legislation regarding quality control of medicines, that drug plant inspectors in both countries have appropriate scientific and practical experience and that administrative practices regarding reporting of technical details are mutually acceptable. Agreements for the exchange of this information have been concluded with the United States, the United Kingdom, Sweden, France and Switzerland. Negotiations are being conducted with a number of other nations whose standards are, we believe, appropriately high.

Flexible Enforcement Philosophy

We believe our enforcement philosophy must be flexible and respond in an adequate way to enable us to deal individually with unique and complex situations. An overly rigid bureaucracy is no answer to the immensely difficult issues we have to face each day. We prefer to work co-operatively with responsible manufacturers and to encourage voluntary compliance by industry. We try to avoid unnecessary confrontation and adversary proceedings insofar as possible. "Come, let us reason together," Isaiah said. That sums up what we try to do.

In order to foster voluntary compliance and avoid costly court procedures, officers of the Branch frequently meet with industry representatives to discuss alleged violations. Our Field Operations Directorate runs the gamut of compliance-type action—from private sessions with an offending company to instituting and completing court actions. For example, an informal technique called, for want of a better name, a formal hearing, is utilized in cases where our field staff is of the opinion that compliance may be gained without the institution of prosecution proceedings. Where appropriate, administrative decisions are reached in discussions between industry representatives and HPB officials which result in a greater assurance of safety of food and drugs for the public without resorting to prosecution.

This is not to say that court sanctions are not useful. I need not tell you that in any industry there are those who are too irresponsible, too venal or too obstinate to abide by appropriate regulatory standards. In the Canadian context, the resort in such cases to court actions is necessary to make regulations work. Thus, we do not hesitate to "go to the mat" with people who, for whatever reason, repeatedly fail to comply with the law. Although George Bernard

Shaw claimed that "silence is the most perfect expression of scorn," we usually do a little more than that.

Compliance Action

Whether the compliance action is a "voluntary" one or is imposed by a court, we consider it our duty to make sure regulations provide appropriate guidelines to ensure that industry accepts and lives up to its responsibilities and obligations to the public.

An example will illustrate the degree to which we believe that industry should shoulder its obligations. We have almost completed a set of device regulations under the Food and Drug Act. If approved by the Governor-in-Council, these will very shortly become law. The regulations will require manufacturers to live up to the standards claimed by them for particular devices. It will not be our policy to provide detailed performance standards, except in special circumstances. It is, we believe, industry's responsibility to determine the standards for most devices and then live up to them. For certain critical devices, such as nuclear-powered cardiac pacemakers, we will, of course, write detailed standards which all manufacturers will have to meet.

Before concluding, there is a regulatory matter which I believe to be unique to the Canadian situation and which has functioned admirably.

Under the authority of the Broadcasting Act, all radio and television commercials are subject to review and pre-clearance before use. Advertisements for food are reviewed by the Food Division of the Standards Branch, Department of Consumer and Corporate Affairs. Advertisements for drugs, cosmetics and devices are reviewed by the HPB. This pre-clearance system has prevented many of the advertising excesses encountered on television or radio in other countries.

To summarize, the Canadian approach to regulation of food, drugs, cosmetics and devices is to strive for sensible, scientifically sound regulations, administered wisely and flexibly. We have limited resources so we cannot be everywhere at all times to monitor the entire industry. Nor do we wish to do so. We have no desire to take on our shoulders the fundamental responsibility of manufacturers for their products. For better or worse, the regulator needs the cooperation of the industry, as well as that of the public, in order to make regulations effective. By the same token, we have access to court procedures to make regulations work if voluntary compliance fails. **[The End]**

Canadian Regulation of Food, Drugs, Cosmetics and Devices—An Overview

By ROBERT E. CURRAN, Q. C.

Mr. Curran Is a Member of the Law Firm of Soloway, Wright, Houston, Killeen and Greenberg.

FROM THE POINT OF VIEW of a lawyer practicing in the food, drug, cosmetic and device field, I would like to make a few comments.

Because I have been associated with the subject for more than 30 years, both in government service and in private practice, there are a number of comments I could make. I have tried to be selective, however, and to touch only on those points that might be of special interest to lawyers practicing in this particular area.

To give some perspective, it may be useful to discuss features of the Canadian system which may be different in the United States.

We do not have a Food and Drug Section of the Canadian Bar Association nor, for that matter, do we have a food and drug bar. There are relatively few lawyers in Canada who specialize in the subject, and this may be a question of cause and effect.

There are a number of reasons to explain the cause, the first being that the Food and Drug Act is criminal law and not based on commerce. There are certain other consumer protection acts, such as the Hazardous Products Act, the Narcotic Control Act and the Packaging and Labelling Act, which also are criminal law. The criminal law basis is the protection of the public health or the prevention of fraud. Injury to the public health has, under common law, been held to be a crime, and fraud is, of course, a criminal matter. Criminal law in Canada is a federal responsibility, and it follows that it has uniform application throughout the country.

Many years ago, our Food and Drug Administration (FDA)—rechristened HPB or Health Protection Branch—chose to rely on persuasion, education and cooperation, rather than criminal proceedings, to achieve the objectives of the Act. Criminal proceedings are usually a last resort when other efforts have failed or when the violation is so flagrant as to require a charge being laid.

Initiating Criminal Proceedings

The decision to lay a charge is one for HPB, as the system does not lend itself to a manufacturer initiating criminal proceedings against itself to secure jurisprudence.

There is therefore an almost total lack of jurisprudence respecting the Food and Drug Act in Canada. Whether this is a blessing or a curse is perhaps a matter of opinion. The jurisprudence which has been established has held the Food and Drug Act to be criminal law, and regulations under it are given the same force and effect as if contained in the Act. They must be within the authority of the Act and directly or ancillary to its purpose, namely, the protection of the public.

Dr. Morrison has explained our regulation-making procedure,[1] and it follows that a successful attack on a regulation would at best represent a short-lived or Pyrrhic victory. In all likelihood, the regulation in question would be amended. Therefore, any jurisprudence with respect to the successful challenge would be largely irrelevant.

If any further deterrent were needed to the establishment of a flourishing food and drug bar, most prosecutions are launched in a lower court and rarely go higher or result in jurisprudence. A magistrate's decision seldom echoes down the legal corridors of time.

Legal Issue

I do not suggest that an action could not be initiated in a higher court, but this has not been the practice. If a manufacturer chose to challenge HPB, either in relation to the Act or its regulations in, for example, the Federal Court, a legal issue would need to be raised. This would either be of a constitutional nature or a challenge to a regulation as being beyond the authority of the Governor-in-Council under the Act. With a very wide basis of authority, this would not be likely, and the constitutional position of the Act has been firmly established.

There is a further practical deterrent to a manufacturer commencing action or, for that matter, wishing to go to court. The Crown, whether plaintiff or defendant, would undoubtedly defend its position

[1] See article beginning on page 632.

on the ground of protecting the public health or preventing fraud. In either case, the publicity could be unpleasant for the manufacturer.

I mentioned cause and effect, and the above summarizes some of the causes. The effect has been a notable lack of interest, up to the present time, by the legal profession in Canada in recognizing food and drug law as a subject to warrant a specialized practice. Other fields are greener.

I think the time has come for Canadian lawyers to take more interest in this subject. More and more foods, drugs, etc. are attracting government interest. It may be fair to say that *caveat emptor* has been replaced by *caveat venditor*.

With the rise of consumerism and the growing public interest, government will become increasingly involved in the marketplace. The legal profession has a responsibility to be able to fairly present industry's point of view. An effective presentation involves more than a mere statement of industry's position. It requires some in-depth knowledge of the Food and Drug Act, as well as related statutes and their philosophy. This is an area where lawyers can function effectively. Generally speaking, a proper presentation of an industry position can best be made by a lawyer, without creating an adversary situation or being viewed as self-serving interest.

Information Letters

Actually, under our regulatory system, the officials desperately need industry input based on experience and knowledge. Through information letters about prospective regulations or policy changes, they now receive considerable industry input. Without this, there is a danger of sincere but idealistic efforts to regulate. We know that no regulation can be effective if it is not respected or enforceable. More interest by the legal profession could further improve the situation.

I might add that I am not critical of our system in the development of which I played some modest part. Frequently, when I argue on behalf of a client, assuming I am lucky enough to reach the right person and agency, I am often reminded that I assisted in developing the regulation or policy with which I am confronted. I must say that on such occasions, the officials are very courteous in reminding me of this, only asking whether I have changed the advice I gave in the first instance or whether I was then right.

I do not wish to give a "Pollyanna" impression that all is sweetness and light between industry and government. Issues do arise. However, with an honest effort by government to solicit industry

experience, most are resolved. Our regulations reflect not only the responsibility of government, but also of industry in striking a balance that recognizes the protection of the public health and the prevention of fraud.

I would like to say here, as I have said on other occasions, that I do not feel that industry and government necessarily enjoy conflicting views. Both seek a common objective: government, to protect the public; industry, to serve it. There can be no greater threat than the irresponsible or hit-and-run operator. He is a threat to government, to industry and to the public. Good controls which are reasonably enforced advantage everyone, and uniform ground rules are the basis of honesty and fair dealing.

International Uniformity

Against the above, I have a few comments to make arising from my experience. I recall that more than twenty-five years ago, when I was perhaps more naive and starry-eyed than I am today, I advocated to this very Section that it should interest itself in more international uniformity. I referred then to anomalies in standards and labelling which I felt did not advantage any country, nor add to public benefit. Drugs internationally sold under the same name might have differing standards, and foods legally salable in the United Kingdom might not be legally salable in North America. Some progress is being made in the drug field through the International Pharmacopoeia and, in the food field, through the Codex Alimentarius. They still have a long way to go; achieving detente would, I think, challenge even Dr. Henry Kissinger.

We follow closely developments by the FDA without necessarily echoing them. We are not unmindful of the over-the-counter (OTC) panel reviews, and I am sure we will suffer or benefit from the fallout. It is important to mention that we also endeavor to avoid some of the difficulties that are faced in the United States. As an example, we are carefully watching ingredient labelling for cosmetics. HPB has proposed a cosmetic notification which will give all necessary information on ingredients, and hopefully will obviate the controversial issue of ingredient listing.

A bilateral agreement was recently concluded by HPB with the FDA and one or two European countries, under which HPB will recognize local plant inspection for drugs being imported into Canada. When it gets off the launching pad, it should eliminate some of the

present difficulties which a Canadian drug importer faces, in assuring that the manufacturing facilities and controls for that drug are such as would be required in a Canadian operation.

Having spoken more or less positively of some achievements, I would now like to refer to an area in which, from my experience, there has not been as much progress as there should. I refer to new drugs. In 1949, Dr. C. A. Morrell, who was then head of HPB, and I visited Dr. Paul Dunbar, who was then Commissioner of the FDA. We wished to develop new drug procedures and to borrow from United States experience.

New Drug Regulations

Canada subsequently adopted new drug regulations modeled on those of the United States, and I cannot recall any difficulty in securing Canadian approval of a drug that had already been approved by the FDA.

The tranquillity of the drug industry was rudely disrupted in the early 1960's by Thalidomide. Following that tragedy, our Prime Minister insisted, as did President Kennedy, on a thorough review of new drug procedures.

Canada substantially adopted American revised procedures, and even today accepts for review a copy of a new drug application (NDA) as submitted to the FDA, including clinical evidence. At that point, however, the review given by the FDA to the NDA does not hasten Canadian approval in any way. Take the example of a drug which has first been approved in the United States and for which the manufacturer wishes to secure approval in Canada. When material that has been thoroughly reviewed by the FDA is presented to Canadian officials, I believe it should not be subjected to a duplicate review unless there are special circumstances or some reason to think that the original review was faulty. It could be that a second review would be helpful in some cases, but I do not know what they might be. Generally speaking, a second review in Canada is not likely to add to the safety or efficacy of a drug. I suggest that, rather than put the manufacturer to great trouble and expense, closer liaison with the FDA might obviate this.

NDAs are not only costly but also time consuming. The Canadian market for some drugs may be small and a manufacturer who has secured FDA approval may hesitate to have a drug cleared for our market, because of the expense in time and money. This is

especially so when the immediate financial return from the investment is limited. Canadians could therefore be deprived of the benefits of a new drug. I believe this has happened, and it should not be so. I do not suggest a rubber-stamp approval, but I think this is an area where cooperation between HPB and the FDA should be explored and developed. Such an agreement would be beneficial without any risk to the Canadian public.

Commercial Advertising

Having expressed a positive comment, I now refer to a different situation where I strongly support our system. This relates to our review of commercial advertising on radio and television for drugs, cosmetics, foods and devices.

Since the end of World War II, HPB has reviewed all such commercials before use. This has become a well-established procedure which has developed both facilities for rapid review and guidelines for advertisers and manufacturers.

The effect or impact of television commercials needs no emphasis, particularly with the advent of color. Our guidelines deal with truth and honesty which are frequently relative concepts in a sophisticated society. I do not often quarrel with the assessment of the officials, nor with their interpretation of a cunningly devised commercial which can easily give a different impression than the words convey. Often I feel that they try unnecessarily to protect an unsophisticated or even stupid consumer. Generally, however, it is difficult to take issue. In the area of a drug claim, I agree with their position that it must be supportable, not by testimonial but by scientific evidence.

A person viewing both United States and Canadian commercials will be conscious of some differences. For example, in Canada comparative advertising is sparingly permitted. In the case of drugs, it is not allowed at all.

Comparative Claims

The officials feel that a product should ride on its own merits, not on the coattails of denigrating other named products. To illustrate, a commercial in the United States for an anti-perspirant, which technically is a drug, showed five rival brands, with the advertiser claiming superiority. It is difficult to support such a claim when each contains almost the same active ingredients. Where is the superiority?

Another Canadian rule does not allow a negative statement to emphasize the absence of an ingredient. For example, many years ago a brand of baking powder claimed that it contained no alum. The implication clearly was that other baking powders did contain alum and that it was not a safe ingredient. It is simple to imagine the confusion in the public mind if a toothpaste made the claim that it contained no fluoride. Despite all the support for fluoride, this would immediately convey the impression, to some at least, that a non-fluoridated toothpaste was superior. I seriously raise the question as to whether the public is protected or confused by meaningless comparisons or negative statements.

A favorite in the analgesic field is "faster action." Medical evidence indicates that the time differential is infinitesimal. It is doubtful that the harassed housewife who claims instant relief does, in fact, derive any additional benefit from the so-called "faster action." The logical consequence of the play on "instant" might be a claim that the product goes to work as soon as the package is opened.

Having paid some tribute to our system, I would now like to say something of another drug area where I cannot do so.

Drug Notification System

Canada has instituted a drug notification system which I do not think is used in the United States. This was started in an effort to give HPB all necessary information about every drug on the Canadian market—who makes it, what it is for, what it does, what it contains. This is valuable information and has served a useful purpose.

Recently, however, a regulation was introduced requiring every drug label to bear a Drug Identification Number (DIN). This regulation necessitated the reprinting and, perhaps, the revision of every drug label used in Canada. It was an expensive procedure—government did not pay the cost; the costs were passed on to the consumer. I have yet to hear a satisfactory explanation of what DIN hopes to accomplish, over and above the notification. It provides that a seven or eight digit number be put on the label. This number is meaningless to the consumer, to the manufacturer and to the doctor. It may convey something to the pharmacist, but this again is doubtful. One wonders whether this is not a kind of "make-work" regulation without apparent benefit to anyone. I have tried repeatedly to get some explanation of DIN, but so far have not heard anything which would seem to justify the expense of the label change.

Before leaving the subject of labels, I think a word or two about the future would be timely. Our Packaging and Labelling Act and our Hazardous Products Act will require metric labelling. I need not emphasize the staggering cost, to say nothing of public confusion, resulting from the changeover. Is the ratio of benefit to cost warranted? (These Acts also require bilingual labelling which involves further consumer expense.)

Bilingual and Metric Labelling

Drugs and devices, however, are excluded from these two Acts so they do not yet require bilingual or metric labelling. As of the end of August, foods and cosmetics require such labelling. The Official Language Act of Quebec will shortly require French for all labels of products sold in Quebec.

Standardization of some containers is a further development that may be important. This is presently required for certain cosmetics under the Packaging and Labelling Act and could eventually be extended to certain classes of drugs.

The picture is untidy because the standardization will shortly be a reality for toothpaste and for certain other cosmetics. Many of these are also classed as drugs and technically are not subject to standardization. I express the hope that this situation will be remedied and that all products will be subject to uniform label requirements.

To resolve industry uncertainty, it would be useful if HPB gave some indication of the future. Meanwhile, manufacturers wishing to comply with foreseeable label requirements are in a quandary.

My comments about medical devices are few as the subject is only now being recognized. The present regulations are sparse, but the Department is rapidly attempting to overcome past neglect.

A special section has been established to recognize and control medical devices. New regulations are on the drawing board, or perhaps beyond it. The indications are that these regulations will be more comprehensive from a general point of view and will be supplemented by special regulations for a number of categories of devices. The latter will include hearing aids, portable oxygen units, cardiac pacemakers, contraceptive devices, etc.

The officials have solicited industry input and the regulations should truly reflect industry experience and, hopefully, at the same time, bear some relation to prospective regulations in the United

States. It would be useful in a growing field to have some practical cooperation, at least regarding labelling.

Performance Standards

Our device officials have indicated that performance standards will not be set. However, the manufacturer must be prepared to substantiate any performance claims made. It has been indicated that pre-clearance is not being considered. This, I predict, may be subject to the possibility that a manufacturer making a device for the first time will be required to demonstrate its ability and facilities to do so.

I have been actively associated with pacemaker regulations, and the companies for which I have acted have stressed the necessity for reducing the information required on the device to a realistic minimum. If the regulations require the implant and the leads to show in English and French the name and address of the manufacturer, the model, the serial number, polarity, among other items, research and development may be inhibited by the necessity to bring out a pacemaker of sufficient size to accommodate this information. This would be unfortunate.

The present pacemakers are roughly the size of an old-fashioned pocket watch. Future developments will likely produce one the size of a thumbnail. Reality and practicality must govern. I am sure there are other and better ways of giving the physician who is in charge of an undocumented patient all the information that he or she requires without impeding research and development.

Device Notification Formula

In concluding my remarks on devices, there is a proposal which I think merits careful review and additional thought. This is the device notification formula which HPB proposes. It will require a great deal of detailed information to be submitted respecting every device on the market. While there are some 75,000 drug notifications on file, it is estimated that devices may involve as many as 300,000. I need not elaborate on the cost to the manufacturer who may make or distribute many thousands of devices. Added to this is the ability of HPB to digest this information in a meaningful way. In my own bookcase are two catalogues of a client which show more than 30,000 items which it either manufactures or distributes.

A company would require extra staff to prepare the notifications and HPB would require extra staff to receive them. While it is im-

portant for government to be aware of what is on the market, who makes it, and what it is for, care should be taken that this does not impose a costly burden.

Priorities can be established by class, and the task undertaken in an orderly fashion. This will ultimately yield the information which is presently lacking, but without needless cost.

I hope I have kept reasonably within the terms of reference and that the comments I have made are received in the spirit in which they were intended. In my practice, I have always found a genuine desire on the part of our officials to be helpful, patient and understanding. They are also anxious that our regulations reflect both industry problems and government responsibility. **[The End]**

STATEMENT OF OWNERSHIP, MANAGEMENT AND CIRCULATION (Act of August 12, 1970: Section 3685, Title 39, United States Code)

1. Title of publication: Food Drug Cosmetic Law Journal. 2. Date of filing: October 1, 1975. 3. Frequency of issue: Monthly. 3A. Annual subscription price: $30.

4. Location of known office of publication: 4025 W. Peterson Ave., Chicago, Cook, Illinois 60646.

5. Location of the headquarters or general business offices of the publishers: Chicago, Ill. 60646.

6. Names and addresses of publisher, editor, and managing editor: publisher: Commerce Clearing House, Inc., Chicago, Ill. 60646; editor: Allen E. Schechter, Chicago, Ill. 60646; managing editor: George H. Harris, Chicago, Ill. 60646.

7. Owner: Commerce Clearing House, Inc., Chicago, Illinois 60646. Names and addresses of stockholders owning or holding 1 percent or more of total amount of stock: Bull & Co., Winston-Salem, N. C.; Carothers and Clark, Wilmington, Del.; Cede & Co., New York, New York; Cudd & Co., New York, New York; Eddy & Co., New York, New York; Meth & Co., Denver, Colo.; Pitt & Co., New York, New York; Reing & Co., New York, New York; The Corporation Trust Company (Delaware), New York, New York; C T Corporation System, New York, New York; The Millbrook Tribute Garden, Inc., Millbrook, New York; Justus L. Schlichting, Toms River, New Jersey; George T. Whalen, as Trustee under the will of Oakleigh Thorne, Millbrook, New York.

8. Known bondholders, mortgagees, and other security holders owning or holding 1 percent or more of total amount of bonds, mortgages or other securities: None.

9. For optional completion by publishers mailing at the regular rates: 39 U. S. C. 3626 provides in pertinent part: "No person who would have been entitled to mail matter under former section 4359 of this title shall mail such matter at the rates provided under this subsection unless he files annually with the Postal Service a written request for permission to mail matter at such rates." In accordance with the provisions of this statute, I hereby request permission to mail the publication named in Item 1 at the reduced postage rates presently authorized by 39 U. S. C. 3626. (Signed) Allen E. Schechter, editor.

10. For completion by nonprofit organizations authorized to mail at special rates: Not applicable.

11. Extent and nature of circulation:

11A. Total number copies printed (Net Press Run): Average number copies each issue during preceding 12 months: 1,471. Actual number of copies of single issue published nearest to filing date: 1,400. 11B. Paid circulation: 1. Sales through dealers and carriers, street vendors and counter sales: Average number copies each issue during preceding 12 months: None. Actual number of copies of single issue published nearest to filing date: None. 2. Mail subscriptions: Average number copies each issue during preceding 12 months: 1,058. Actual number of copies of single issue published nearest to filing date: 1,070. 11C. Total paid circulation: Average number copies each issue during preceding 12 months: 1,058. Actual number of copies of single issue published nearest to filing date: 1,070. 11D. Free distribution by mail, carrier or other means: Samples, complimentary, and other free copies: Average number copies each issue during preceding 12 months: 129. Actual number of copies of single issue published nearest to filing date: 125. 11E. Total distribution (Sum of C and D): Average number copies each issue during preceding 12 months: 1,187. Actual number of copies of single issue published nearest to filing date: 1,195. 11F. Copies not distributed: 1. Office use, left-over, unaccounted, spoiled after printing: Average number copies each issue during preceding 12 months: 284. Actual number of copies of single issue published nearest to filing date: 205. 2. Returns from news agents: Average number copies each issue during preceding 12 months: None. Actual number of copies of single issue published nearest to filing date: None. 11G. Total (Sum of E and F—should equal net press run shown in A): Average number copies each issue during preceding 12 months: 1,471. Actual number of copies of single issue published nearest to filing date: 1,400. I certify that the statements made by me above are correct and complete. (Signed) Allen E. Schechter.

Current Topics in Canadian Food Regulatory Affairs

By D. G. CHAPMAN

Mr. Chapman Is Assistant Director-General of the Food Directorate of the Health Protection Branch in the Department of National Health and Welfare of Canada.

WE ARE LIVING THROUGH VERY CHALLENGING TIMES regarding the quantity, quality, nutritional value and safety of our food supply. This challenge applies not only to the agricultural worker who produces the food and to the food technologist who develops new food products, but also to the regulatory agencies, including their legal advisors. The enforcement agency must write regulations which will, on one hand, ensure that safe and nutritious foods are made available to the consumer but which, at the same time, will not stifle the advances that are taking place in food technology and, hence, prevent consumers from obtaining the food products to which they are entitled.

The main thrusts of the Food and Drug Act, as it relates to foods, are that foods shall be safe and that they shall not be presented in a deceptive manner.

Section 4 of the Act, dealing with safety, reads as follows:

"No person shall sell an article of food that

(a) has in or upon it any poisonous or harmful substance;

(b) is unfit for human consumption;

(c) consists in whole or in part of any filthy, putrid, disgusting, rotten, decomposed or diseased animal or vegetable substance;

(d) is adulterated; or

(e) was manufactured, prepared, preserved, packaged or stored under unsanitary conditions."

The Section dealing with deception, Section 5, reads, in part, as follows:

"No person shall label, package, treat, process, sell or advertise any food in a manner that is false, misleading or deceptive or is likely to create an erroneous impression regarding its character, value, quantity, composition, merit or safety."

Another important Section of the Act is that which gives authority to the Governor-in-Council to make regulations for carrying the purposes and the provisions of the Act into effect.

We have taken full advantage of this Section and have written some 230 pages of regulations dealing with foods. These regulations deal with the various classes of foods including alcoholic beverages, dairy products, fats and oils, fruits and vegetables, grain and bakery products, meat products, sugars, fish products, poultry products, and foods for special dietary use, as well as with food additives and tolerances for pesticide residues.

After those brief introductory remarks, I now will offer a few comments on some current topics in food regulatory affairs.

Food Additives

The Health Protection Branch (HPB) continues to devote quite a number of man-years to the evaluation of chemicals for possible addition to or subtraction from the permitted list of food additives. In Canada, there is no generally recognized as safe (GRAS) list of food additives as there is in the United States. A chemical is either on the permitted list of food additives or it is not. Included in the list are the foods to which it may be added, together with the amount of the food additive which may be present. If the chemical is not on the permitted list, foods containing it are in violation of the Regulations.

It should be pointed out that neither flavoring preparations nor components of packaging materials are included in the legal definition of a food additive in the Canadian Food and Drug Regulations. In the case of these two classes of food additives, a short negative list has been developed. For example, we have listed those flavoring materials which are prohibited including coumarin, safrole and oil of calamus. We have found this practice to be a good alternative to the Food and Drug Administration policy of attempting to list all permitted flavoring materials and components of packaging materials.

Before a food additive is accepted for inclusion on the permitted list in the Regulations, it must meet certain criteria developed by officers of HPB. These criteria form the basis of our policy regarding the use of food additives and are as follows:

(1) The food additive must be safe for continuous use.

(2) Its use must not lead to deception.

(3) Its use must result in an advantage to the consumer by:

(a) improving or maintaining the nutritive value of the food;

(b) improving or maintaining the quality or acceptability of the food; or

(c) increasing or maintaining the quantity of food.

Since 1949, it has been found necessary to prohibit the use of 20 chemicals in foods. These banned chemicals are 10 synthetic food colors, 3 flavoring preparations, 3 cobalt salts used as foam stabilizing agents in beer, 2 preservatives, a bleaching agent for flour and, in 1969 and 1970, cyclamates, the artificial sweetener.

Cyclamates

Let me add an additional word about cyclamates. Concern regarding this artificial sweetener came to a head in late October of 1969. Canned fruits which contained cyclamates and which had already been packed were allowed to be sold for approximately one year after the original announcement. However, because of the adverse publicity given to the cyclamate-containing foods, sales fell off sharply and large inventories were still on hand when the prohibition became effective. As a result, a fruit canning company in western Canada took legal action against Her Majesty the Queen to recover these losses in the Federal Court of Canada.

I think it would be useful to quote one short paragraph in Justice Darrel V. Heald's ruling on this matter.

"Considering all the evidence adduced, I am satisfied that the officials of the Food and Drug Directorate acted prudently, expeditiously and reasonably in the public interest. To have acted otherwise, in the circumstances herein related, might well have exposed them to a charge of negligence or a breach of duty. Accordingly, I have no hesitation in rejecting the Plaintiff's allegations of impropriety in the actions of the Food and Drug Directorate. For the above reasons, the Plaintiff's action is dismissed with costs."

HPB recently received a request to reinstate cyclamates as permitted food additives for use in commercially prepared foods. Our evaluators are now carefully reviewing all new toxicological data on these compounds which have been developed in recent years. The results of this review, together with the earlier data available on cyclamates, will be taken into consideration in order to arrive at a decision regarding the future use of cyclamates.

Substitute Foods

I now wish to turn to the area of substitute or simulated foods. In 1971, HPB issued a statement to the effect that a food sold as a substitute for a traditional food should be nutritionally similar to the food which it was replacing.

It was not until early in 1975, however, that the first regulations dealing with substitute foods were finalized. As of February 12, 1975, products sold as meat extenders must contain a minimum of 16 percent high-quality protein, as well as specific levels of vitamins (thiamine, riboflavin, niacin, pyridoxine, pantothenic acid, folic acid, and vitamin B_{12}) and of the minerals (copper, iron, magnesium, potassium and zinc). These requirements will ensure that, when the extender is mixed with meat, the final product will be as nutritious as the all-meat product.

At the same time, the nutritional requirements for completely simulated meat products were established. Hence, Canadian consumers are assured that substitute meat products are as nutritious as the traditional all-meat products.

The *Canada Gazette* has published a new regulation dealing with the nutritional requirements for products simulating whole eggs. These products must contain a specific quantity and quality of protein, as well as calcium, iron, zinc, potassium, vitamin A, thiamine, riboflavin, niacin, pantothenic acid, vitamin B_6, vitamin B_{12}, folic acid, vitamin E and not more than three milligrams of cholesterol.

The regulations controlling the nutritional value of substitute meats and substitute eggs are just the beginning of the writing of regulations for a series of other substitute food products which have appeared or will be appearing on our grocery store shelves.

It should be pointed out that the regulations which we have written or will write controlling substitute foods are *not standards*. The writing of a standard, requiring a listing of all ingredients and food additives which may be used, tends to be too inflexible and may prevent improvements in the product which the food technologist may wish to make. Our preference is to write a regulation setting forth the major elements of the food in which the consumer is primarily interested. This allows the food processor the freedom to innovate with regard to the minor constituents and food additives.

Microbiological Aspects of Foods

The microbiological aspects of foods is certainly a topic of current interest. More man-days are lost as a result of illnesses caused by microorganisms in foods, and more foods are recalled because of problems associated with bacteria than for any other reason.

As a result, more and more of the food regulations now being developed will include a requirement regarding the microbiological

aspects. Earlier this year, the standard for cocoa was amended to require that the product be free of the bacteria salmonella. In addition, a new regulation was written requiring that frog legs also be free of salmonella.

HPB will shortly be proposing bacteriological requirements for the hamburg-type meat products. This results from an examination of many hundreds of samples of ground beef from all parts of Canada.

Mandatory Addition of Nutrients to Foods

Finally, I would like to make reference to our current interest in the mandatory addition of vitamins and minerals to foods. The results of the Nutrition Canada Survey showed that significant numbers of Canadians are consuming less than adequate quantities of vitamin D, vitamin A, vitamin C, iron and, in some instances, thiamine. These findings have led us to an examination of the role of food enrichment programs in the correction or prevention of nutrient deficiencies.

The Food and Drug Regulations currently permit the addition of specified vitamins and mineral nutrients to a number of foods. With the exception of the addition of iodine to salt, and vitamins and iron to instant or ready breakfasts, the addition of vitamins and mineral nutrients to foods is, at present, optional and left to the discretion of the individual manufacturer.

In light of the results of Nutrition Canada, we have concluded that enrichment of foods with the nutrients mentioned above should no longer be optional but must, in the interests of public health, be made mandatory.

It has therefore been proposed that the addition of a number of nutrients be made mandatory to certain food items. Examples of these proposals are as follows: vitamins A and D to a number of milk products and margarine; viamin C to certain fruit juices, tomato juice, fruit drinks and evaporated milk; and thiamine, riboflavin, niacin and iron to flour and alimentary pastes.

The mandatory addition of these nutrients to certain items in the food supply will permit Canadians to improve their nutritional status, if needed.

Conclusion

Food standards and regulations of the future will stress the nutritional and microbiological aspects of foods but will, at the same time, provide sufficient flexibility in order to take advantage of the advances being made in food technology and pass them on the consumer.

[The End]

Comments and Views from the Perspective of a Canadian Food Lawyer

By JAMES A. ROBB, Q. C.

Mr. Robb Is a Member of the Law Firm of Strikeman, Elliott, Tamaki, Mercier & Robb.

IT IS DOUBTFUL if a food and drug bar exists in Canada. When I was asked to recommend someone beyond Robert E. Curran, with whom I discussed the problem, I could think of no one.[1] As a result, I am presenting these comments. I make no pretense at being a specialist in this particular field. I am an administrative lawyer, if that title qualifies me. When once asked for a definition of administrative law, I suggested that it was anything that I happen to enjoy doing. I do enjoy food.

In these days of extended government involvement in every phase of business, the definition is truer than I realized at that time. This involvement and its extension is as true in the food industry as in others. Controls have existed since shortly after Canadian Confederation. The situation is further complicated in Canada by the federal system and the joint and occasionally conflicting jurisdictions to which government involvement in the food industry gives rise. In his 1953 book on the subject, Mr. Curran suggested that "the reference to the food law" and the "food and drug law" is "usually identified with the Food and Drug Act."[2] While undoubtedly this Act and its antecedents are basic to Canadian law on the subject, the scope of food law for a practitioner has broadened with the years, not only

[1] For article by Robert E. Curran, see page 644.

[2] Curran, Robert E., *Canadian Food and Drug Laws*, published by Commerce Clearing House, Inc. for the Food and Drug Law Institute, (1953) p. 27.

in jurisdiction but in scope. In addition to the federal law, the food industry must consider the applicable provincial and even municipal regulatory provisions concerned.

The Constitutional Problem

Under the British North America Act, which serves as our Constitution, agriculture is a concurrent jurisdiction where both provincial and federal laws are valid so long as the provincial act is not repugnant to the federal act. In fact, in many cases, the federal power to legislate in the food field has been upheld on the basis of the federal jurisdiction over criminal law, or trade and commerce. The provincial right to legislate in the field has been upheld on the grounds of the right to legislate on agriculture, on property and civil rights in a province and on the imposition of punishment (by fine and penalty or imprisonment) to enforce any laws within provincial jurisdiction.

The practical effects of this division of jurisdiction are that food standards are dictated by the federal government while market regulation and policy are controlled by provincial legislation. An exception is the export and import controls which have recently been used by federal authorities. Municipal regulations or city bylaws, at least in Quebec, often govern production and marketing of food intended for human consumption. In Ontario, this jurisdiction is more properly provincial.

Thus, the Food and Drug Act and Regulations thereunder are, in effect, quasi-criminal statutes giving rise to criminal prosecutions. The provincial acts, usually administered by a department of agriculture, are largely concerned with the marketing of agricultural products, the setting of standards for such marketing and the establishment of marketing procedures. Health standards are administered by a city department of health, concerned with the final stage in transmitting food products to the consumer.

Conflicting Jurisdiction

There are areas of conflicting jurisdiction. However, only in the case of specific marketing legislation have these areas been seriously challenged on a constitutional basis. Needless to say, other challenges have taken place in an effort to prevent application of a penal statute at one level or the other. In general, the courts have tended to regard this type of argument as technical and have given judgment supporting the imposition of the penalty.

In the marketing cases, after a series of judicial decisions generally giving precedence to provincial marketing powers, a compromise was reached permitting delegation of powers from provincial to federal marketing boards. This enables establishment of national marketing policies and standards. It is a *de facto* constitutional accommodation.[3]

Exercise of the Federal Jurisdiction

While the area of constitutional law is somewhat exotic and occasionally has a practical application when a client is in the situation of being pushed around by a non-constitutional body, it is far from the day-to-day implementation of and defense against the implementation of regulatory legislation. In fact, my main experience with federal food and drug legislation is in advising clients to plead guilty to charges laid. The area of negotiation with the department in the establishment of regulations has not been exploited by the legal profession in Canada. As a general rule, internal company specialists, often with direct relationship or experience with the food and drug directorates, are involved in the establishment or change of regulations.

In fact, when a matter has reached the stage of a prosecution, it is often difficult for a lawyer to give advice other than to plead guilty. The Act is, in fact, a prosecutor's act. Charges are in general terms, and distinct advantages are given departmental expertise in administration and enforcement. Thus, for example, Section 7 of the Food and Drug Act makes the general statement that "no person shall manufacture or prepare preserved packages or store any food under unsanitary conditions." Unsanitary conditions are defined in Section 2 as "conditions or circumstances as might contaminate a food, with dirt or filth or render the same injurious to health." Charges have been laid under this section in a case where salmonella was located on the roof of a sealed building in which food products were being prepared.

Further, a certificate of analysis by an inspector of the food and drug authority is proof in itself and, unless challenged, is binding upon a court. (Section 30.) For example, in the case of the salmonella present on the roof, there is no method to challenge the certificate. A

[3] *The King v. Eastern Terminal Elevator Co.* (1925) S. C. R. 434; *A.-G. B. C. v. A.-G. Canada (Natural Products Marketing)* (1937) A. C. 377; *P. E. I. Potato Marketing Board v. Willis* 2 S. C. R. 392; *A.-G. Nova Scotia v. A.-G. Canada* (1951) S. C. R. 31.

check by an independent expert might or might not find a similar indication either inside or outside the building. Defense becomes difficult and, aside from the fine, the public relations consequences of this type of charge are difficult, if not impossible, to overcome. A guilty plea is often the better part of valor.

Discretionary Charges

Fortunately, discretion and intelligence have generally characterized the administration of this Act. However, the danger of discretionary charges is only too well known. It has been tempting to rationalize some of the problems of various clients by reference to their relations with the inspector concerned rather than by any reference to government policy, law or regulation. How valid these rationalizations are depends on time and place, but the fact that they exist and have been offered as explanations indicates the danger.

The power of the ability to decide whether a charge would or would not be laid—the "Discretionary Justice" of the 1970 book by Kenneth Culp Davis—is quite apparent in regulation of the food industry. Too often charges are subject to negotiation, thereby leading to fears of abuse. Often, however, the negotiation and cooperation in solving the problem is the most effective way of dealing with a health hazard without causing undue damage to the corporation concerned. This solution does not appear in the legislation and can only appear in intelligent administration of the Act, unsatisfactory as that may be to a lawyer.

Provincial Jurisdiction

These comments are also applicable at a provincial level. We recently had the experience of trial of a sector of the food industry by public inquiry. Public inquiries have been increasingly used, particularly in Ontario, for dealing with subjects which are politically sensitive and which, for one reason or another, have fallen into the hands of groups flaunting the conventional legal approach. A similar inquiry on labor unions was held recently. The resulting legislation undoubtedly was more easily accepted as a result of the inquiry. The inquiry investigated the meat product industry and, without trying to destroy any faith in local restaurants, the use by that industry of carrion and diseased animals for human consumption. One individual, with a demeanor suggesting a questionable reputation, appeared at the inquiry. His answers led the prosecuting attorney to ask. "Do

you mean to say you deal in dead, diseased and maimed animals?" This person had the self-confidence to respond, "Of course not sir, I only deal in unlucky animals."

This inquiry did underline weaknesses in enforcement regulations at both the provincial and federal inspection levels. It also indicated the facility with which inspections could be forged. Legislation and tighter regulations are planned in this area. However, the problem is not so much legal as administrative due to the necessity of making legislation work and acting under it.

Much of the enforcement and even legislation, at least in urban areas, in this province and to a lesser extent in other provinces, has been delegated to municipal health authorities. Thus, the Montreal Urban Community has powers over "all stages of production and marketing of food intended for consumption."[4] Often these powers are exercised by reference to the regulations and standards established by other jurisdictions, federal and provincial. Reference to the Food and Drug Act occurs in the Montreal and Quebec Urban Community By-Laws. These standards are enforced by city health departments by seizure and penalties. The difficulty has not been the laws, despite some arguments on delegated legislation, but their enforcement.

Establishment of Marketing Bodies

Similarly, the provincial laws and regulations enforcing marketing practices on individual producers often result in attempts to avoid their application when it becomes profitable to do so. In more spectacular cases, the regulations have been challenged on constitutional grounds; in the less spectacular, by redefining the particular product concerned. The establishment of such marketing bodies over a period of time has led to both a legal and *de facto* adjustment to their existence and powers. The area is not as fruitful a source of litigation as it once was.

Of more importance has been the recent spate of labelling regulations. We are faced not only with increased requirements but with standards of bilingual content. The first labelling regulations requiring equal prominence for the French language were, in fact, under the Agricultural Marketing Act. These regulations are presently under challenge before the courts.

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[4] Montreal Urban Community Act, Article 186.

Since that time, both the federal and the provincial governments have enacted broader legislation requiring not only informative labelling and standardization of containers, but also requiring that such labelling be in both official languages. Both Acts have political undertones. The federal Act is a direct result of the federal policy of bilingualism and biculturalism. The provincial Act is a direct result of the provincial policy for protection of the French language. The Acts have practical significance in protecting the right to a knowledge of the labelling requirements on behalf of the consumer who does not know the other language. Regulations under both Acts are presently in the process of implementation.

Under the federal Act, one of the problems appears to be the definition of a "pre-packaged product." Thus, if a product exported to Canada is packaged in a form for sale to the consumer, bilingual labelling may be required. While, to the best of my knowledge, this has not led to any litigation as yet, questions arise as to when it is intended that a product should be repackaged.

French Language Labels

Under the Quebec Language Act, a problem of prominence for the French language will, in all probability, be the source of litigation. Already private prosecutions under the Agricultural Marketing Act have raised this problem. It is hoped that regulations in the process of development will eliminate the need for difficult and, in many cases, non-productive exercises of judgment. It is clear that at present a product must be labelled at least in French.

Under the provincial jurisdiction, a more regulatory approach is taken. In both jurisdictions, however, when a charge is laid, a fairly clear case has been prepared. In general, the role of the practicing lawyer is negotiation of the amount of the fine and the means of avoiding future fines. Again, the role of discretion, not law, is prominent.

I trust this brief summary provides a practitioner's overview of the status of food legislation in our country. Regrettably, in dealing with the administrators of such legislation, one finds that lawyers are not necessarily *persona grata*. Lawyers do have a tendency to clutter up the record and raise legal issues which perhaps interfere with the effective enforcement of the Act even though those issues may make the enforcement less arbitrary and, in the long run, contribute to better public understanding and confidence in the laws concerned.

[The End]

America's First Food and Drug Laws

By WALLACE F. JANSSEN

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WHEN WE CELEBRATE the 200th anniversary of Independence Day, on July 4, 1976, we will be thinking of the past, the present, and the future. We will have a unique opportunity to make an assessment of our accomplishments and institutions, viewed in a perspective of two centuries of tremendous change. This is already beginning to take place across the country, as bicentennial commissions and committees delve into local history, refurbish historic sites, prepare exhibits, and plan commemorative programs.

Taking a close look at the past, a new experience for many Americans, can have salutary effects. Every generation needs to learn anew how it got to where it is, and where it seems to be going.

When *FDA Consumer* was first published (as *FDA Papers*), each issue had in its masthead a small picture of Dr. Harvey W. Wiley, the crusading chemist and physician who led the fight for the first Federal Food and Drug Act, passed in 1906. But long before Wiley's day there were local food and drug laws, dating from colonial times.

Today, hardly anyone knows these laws existed, much less what they contained, or why. Yet, they were the forerunners of our present statutes, and dealt with some familiar problems.

In colonial days, and long afterward, consumers, to a large extent, were their own food and drug inspectors. They sniffed meat and fish to make sure it was fresh, and scrutinized flour and fruit for signs of worms. Practically all food was sold in bulk, there being few packaged, processed, or manufactured products on the market. Commercially prepared bread was a notable exception. Although much

bread was made at home, every town of any size had its bakers. And because bread was the "staff of life," especially for the poor, our first food laws were "assizes of bread."

Originating in 13th century England, the assizes were designed to standardize the weight of loaves in relation to the prevailing price of wheat and flour. Basically, they were price-fixing laws, regulating the profit of the middleman, the baker, while leaving the price of grain free to fluctuate with the market. But they had other purposes. Such a law was enacted in 1646 by the General Court of Massachusetts Bay Colony:

"It is ordered by this Court and Authority thereof; that henceforth every Baker shall have a distinct mark for his Bread, and keep the true assizes, as hereafter is expressed."

A table followed, showing what a penny loaf of three qualities of bread—"white," "wheat," and "household"—should weigh when wheat was selling at stated prices.

For enforcement, each town was required to have "one or two able persons" annually chosen and "sworn unto the faithful discharge of his or their office; who are hereby Authorized to enter into all houses, either with a Constable or without, where they shall suspect or be informed of any bread baked for sale, and to weigh the said bread as oft as they see cause, and seize all such as they find defective." The bread inspectors were also to check the weight of butter packed for sale and to "seize any found light after notice once given."

Penalty for Short Weight

The penalty for short weight, or failure of the maker to identify his bread or butter, was forfeiture of the product, with one-third going to the officer "for his pains, and the rest to the poor."

In 1652, the Massachusetts bread law was amended because of "much deceit used by some bakers and others, who when the clerk of the market cometh to weigh their bread, pretend they have none but for their own use, and yet afterward put their bread to sale, which upon trial hath been found too light." The Amendment required bakers to make all their bread in the legally required sizes.

Early bread laws in England, and later in the colonies, also prohibited adulteration with foreign ingredients such as ground beans or chalk. In 1720, the Massachusetts law was completely rewritten. New provisions banned the substitution of "any other grain" than the kind specified in the law, established a quality standard by out-

lawing any bread "found wanting either in the goodness of the stuff whereof the same shall be made, or in the due working or baking thereof," and required "that a proper allowance (in weight) be made for the drying of biscuit."

Responding to complaints of fraud over the sale in New York City of bread made of "unmerchantable flour," the General Assembly of New York in 1773, forbade bakers to sell bread unless made from flour that had passed an inspection required for exported flour. Any consumer could sue the baker before any justice of the peace and get punitive damages of four shillings (plus costs) for each violation. The only defense for the baker was to prove that his bread was made entirely from inspected flour.

Food Inspection Laws

It was the merchants and traders of the colonies who first appreciated the need for additional food inspection laws. They sponsored numerous laws standardizing weights and measures, fixing the sizes of casks and barrels used to store and ship foods domestically and overseas, and providing for inspection and official certification that the products were properly packed. To a great extent these laws explain themselves, as well as giving us a picture of colonial industry and its marketing problems.

Shipping their salted fish, beef, pork, flour, ship's biscuit, and similar products overseas, American merchants risked spoilage and contamination by insects, rodents, and seawater. Making good time, it took a month to six weeks to sail from New York to Liverpool. Tight casks, barrels, and hogsheads were needed, as well as proper packing and salting of perishable commodities. Even if the ships arrived safely, there was always the question of whether importers might take advantage by claiming the goods to be spoiled or of poor quality not worth the going price. The preamble to one of Pennsylvania's "Duke of York" laws hints at the situation:

"Whereas, It is the interest of all governments to exercise truth and uprightness in all their Dealings & Commerce, which many persons for (base) ends do so often violate: Wherefore that the Commodities generally exported to foreign markets may be Good in respect to their Quality and, Compleat in respect to their Quantity, and to prevent differences about measures, Be it enacted . . . ."

The law goes on to establish standards for packing, sealing, and measures.

Massachusetts may have been the first of the colonies to routinely inspect food exports. In 1641, the Massachusetts General Court

passed a law regulating the sizes of casks, and requiring each town to select a gager or packer to check containers of fish, beef, and pork. It was this official's duty to check for size and to see that beef and pork were packed so "that the best be not left out," that fish were packed "all of one kind," and that "all cask be packed full and sound, and well seasoned (salted)." He was to put his seal on casks he packed and to be paid "four shillings per tun" (a tun is a kind of cask) by the owner. He was to be paid "one shilling per tun" for inspecting and approving casks packed by others.

Laws of the Colonies

The laws of the colonies reflected the importance of their major industries. Massachusetts had extensive laws related to fish and fishing; in Virginia and Maryland the most detailed laws were concerned with tobacco.

As early as 1668, Massachusetts appointed fish inspectors because its trade had been damaged "by bad making of Fish." In the same year a closed season was ordered against fishing for codfish, hake, haddock, pollack, and mackerel during their spawning season.

Also in 1668, Massachusetts passed a "food additive" law. It banned the use of "Turtoodas Salt, which leaves spots upon fish, by reason of shells and trash in it."

Various laws were enacted to protect and promote trade. In 1740, the New York General Assembly, concerned about damage to the reputation of local products by the practice of repacking inferior beef and pork from other places in barrels carrying the brand of the City of New York passed a law providing that repacked meat could carry the New York brand only if it were "in Fact Sound, Firm, & Really Good." Otherwise, the barrels would have to show the meat's place of origin. Some 45 years later, Massachusetts, seeing an opportunity to develop an export business in tobacco, passed an inspection and packing law similar to Maryland's. This statute regulated butter and other products as well as tobacco, and it called on the "Provers of Butter" to take samples with "an hollow iron searcher," exactly as an FDA inspector would today.

The Treaty of Paris that formally ended this Nation's fight for independence was less than two years old when one of the most significant food laws in our history was enacted. This was the "Act against selling unwholesome Provisions," passed on March 8, 1785, by the General Court of Massachusetts, to protect consumers against

adulterated food. The Act, which established criminal penalties for violations, is generally considered the first comprehensive food adulteration law passed in the United States.

Absence of Drug Statutes

In contrast to the rather numerous food laws of the colonies, there was a striking absence of statutes dealing with drugs, although such laws had existed in Europe from medieval times. This is not to say that the colonial people were unconcerned about drugs and what was done with them. In 1630, the Massachusetts Court of Assistants sentenced Nicholas Knopp to be

"fyned 5 pounds for takeing upon him to cure the scurvey by a water of noe worth nor value, which hee solde att a very deare rate, to be imprisoned till hee pay his fine or give securitye for it, or els be whipped & shall be lyable to any mans action of whom he hath receaved money for the said water."

No statute is cited in the record of this, perhaps America's first drug misbranding case. The offense was fraud, which was punishable under common law. Nor do we know the content of Knopp's "water," which may have been no less effective than some of the accepted remedies for scurvy, though lemon juice and fruits and vegetables were already known to have protective powers.

Scurvy was just one of the many diseases that ravaged the colonists. Smallpox produced more casualties than all the bullets fired in the Revolution, notwithstanding the development of workable quarantine systems as early as 1720, and compulsory inoculation of American troops in 1776.

Epidemics of yellow fever, malaria, typhoid fever, scarlet fever, diphtheria, and measles struck repeatedly. Other diseases—dysentery, pneumonia and consumption—were endemic and killed as many people, but were less frightening, being taken for granted.

Having no lack of diseases, our colonial forebears also had no lack of drugs to treat them. But with very few exceptions these were ineffective. Why then, were there no laws to protect the drug purchaser or user?

There was no question about the desires of the people. Then, as now, they wanted safe and effective treatment—an objective clearly stated in "An Act Respecting Chirurgions, Midwives and Physicians," passed in Massachusetts in 1649, and in New York in 1684. With no provision for enforcement, it was more a code of ethics than a statute. The patient was to be protected by the practitioner's adherence to

"known, approved rules of art," with no departures from accepted practice without consultation of qualified persons, and patient consent.

Yet, these restraints were not intended to "discourage any from all lawful use of their skill, but rather to encourage and direct them in the right use thereof." The parallel between this philosophy and that of modern law is striking.

The drugs of the times ranged from the innocuous to the preposterous. One of the most popular notions was that the worse a medicine tasted, the more likely it was to be effective. Dung and urine from various animals were common medical ingredients in the 17th century. If a root, seed, or leaf resembled a human organ, it was considered especially likely to be effective for conditions affecting that organ.

Patent Medicines

Patent medicines imported from England were equally ineffective. Only a bare handful of the drugs in use had medical merit—opium for pain, Peruvian bark for fevers, willow bark, which contains salicylates, being notable examples.

That some patients recovered after receiving a treatment was generally regarded as proof that it worked. Thus, coincidence created one medical fad after another. Medical men, no less than laymen, were vulnerable to what we would consider quackery. Most of what they did, in fact, would be quackery today.

The record of the last illness of George Washington is revealing of the state of medical practice at the end of the 18th century: he was given a mixture of molasses, vinegar, and butter, which he could not swallow; he was made to eat sal volatile (a menthol salve); he was bled a pint; his throat was wrapped in flannel soaked in sal volatile; his feet were bathed in warm water; a blister (poultice) of Spanish flies (cantharides) was applied to his throat; he was bled another pint, made to gargle with sage tea and vinegar, and then bled again.

As the General worsened, he was bled a full quart, and given a laxative of calomel and an emetic of tartar. One young physician suggested a new and revolutionary surgical idea, today's tracheotomy operation, the opening of the windpipe below the point of mucous obstruction so that Washington might breathe. He was overruled by older and wiser heads, and instead, plasters of wheat bran were applied to the feet. Shortly afterward, Washington died.

Today, Washington's illness probably would be diagnosed as a streptococcal infection, and treated successfully with antibiotics.

In this maze of blunderbuss medication, superstition, ancient traditions, and uncontrolled empiricism, it is not so surprising that drug laws were virtually non-existent. Views and theories concerning medication were so widely varied that no consensus could be achieved. Systematic study of individual drugs was exceptional. Meanwhile, the pharmacopoeias, like those published in Edinborough and London, insofar as they were known in America, seemed sufficient as a means of regulation.

Rational Therapeutics

Yet, there was slow progress toward rational therapeutics.

The treatment of scurvy, known empirically before Nicholas Knopp peddled his "water" in 1630, became scientifically established in 1747, when John Lind, a Scottish naval surgeon, proved by experiments that citrus fruit cured and also prevented the disease. But it was not until 1794 that the British navy made lime juice a part of the daily ration. (The Dutch had required their ships to carry sauerkraut for scurvy prevention beginning in 1593).

More rapid was the introduction of digitalis to strengthen and regulate the heartbeat. Dr. William Withering's "Account of the Foxglove," published in England in 1785, has been characterized as the first large-scale study of any drug applying sound principles of scientific investigation. Within six months, the distinguished American physician and patriot, Dr. Hall Jackson, of New Hampshire, was writing to Withering for seeds of the digitalis plant, and in 1787 he was sending seeds to other American physicians and scientists.

The epic public health development in colonial America, however, was inoculation for smallpox.

Days of public prayer and fasting proclaimed by the legislatures had been the first official actions against the recurrent epidemics. By 1720, Boston had quarantine regulations which may have reduced the number of outbreaks, but did not prevent them. In 1721, the famous Reverend Dr. Cotton Mather read of the inoculation procedure brought to England from Turkey by Lady Mary Wortley Montagu. Failing to interest the medical community of Boston in a trial of the method (they scorned it), Mather persuaded a personal friend, the distinguished physician Dr. Zabdiel Boylston, to try it. Boylston inoculated his only son, aged 13, and two Negro servants, with complete success. In the

ensuing year Boylston inoculated 247 persons, of whom only 6 died, probably because of prior infection.

Violent opposition to the practice arose almost immediately. It was contended that inoculation spread, rather than controlled, the infection. The Mather and Boylston homes were bombed, and Boylston was assaulted on the street. Other inoculators were similarly attacked, but persisted in their efforts.

Benjamin Franklin, who had lost a son to smallpox, became a strong advocate of inoculation. Other prominent supporters included George Washington and Thomas Jefferson.

Opposition to Inoculation

Opposition to inoculation continued over the next half-century (and still does among some groups) despite the demonstration of its effectiveness in one epidemic after another.

By July 1776, however, the practice was generally accepted by the public throughout the colonies. Second only to the Declaration of Independence in the news of the day at Boston, was the mass inoculation of troops and civilians which the legislature had ordered on July 3. Hannah Winthrop, writing to her friend Mercy Warren, said, "the reigning subject is the Small Pox . . . Men, Women and Children eagerly crowding to innoculate is I think as modish as running away from the troops of a barbarous George was the last year."

And James Warren, writing to John Adams on July 17, 1776, said,

". . . this Town is now become a great Hospital for Innoculation . . . this is the reigning subject of conversation and even Politics might have been suspended for a time if your Declaration of Independence . . . had not reached us. The Declaration came on Saturday & diffused a general joy. Every one of us feels more Important than ever; we now congratulate each other as Freemen. It has really raised our Spirits to a tone Beneficial to mitigate the Malignancy of the Small Pox & what is of more consequence seems to animate and inspire every one to support & defend the Independence he feels."

In the saga of smallpox immunization lies perhaps another clue to the lack of drug laws in colonial America. Various public and private interests had brought food laws into being, but the sense of urgency which finally made inoculation a war measure was generally absent in the area of drugs.

Not until 1848 was the first federal drug law to be enacted—the Import Drug Act, passed because anti-malarial medication for the U. S. troops in Mexico was found to be grossly adulterated and lacking in potency. But that is another story. **[The End]**

FOOD DRUG COSMETIC
LAW JOURNAL

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