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# Food Drug Cosmetic Law JOURNAL

The Single Convention for Narcotic Drugs . . . . . ROBERT W. GREGG

The Cranberry Scare and Cabinet Immunity . . . . . EDWARD L. SMITH

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

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# REPORTS

## TO THE READER

**Robert Lee Swain Pharmacy Seminar.**—Before we tell you about the authors who have contributed articles for this issue, it seems fitting that we should tell you about the recent establishment of a seminar cosponsored by the University of Maryland School of Pharmacy and the Maryland Pharmaceutical Association in honor of Robert Lee Swain.

The Annual Dr. Robert L. Swain Pharmacy Seminar has been established by the Maryland Pharmaceutical Association with a twofold purpose in mind.

It first purposes to recognize the many years of service Dr. Swain has devoted to the profession of pharmacy. He has distinguished himself as a Maryland health official, as secretary of the Maryland Board of Pharmacy and as editor of the *Maryland Pharmacist*. He has served on the American Foundation for Pharmaceutical Education, the American Council on Pharmaceutical Education and the Committee on the Pharmaceutical Survey. Also, Dr. Swain is a past president of the Maryland Pharmaceutical Association, the American Pharmaceutical Association and the National Association of Boards of Pharmacy. For many years, he was chairman of the trustees of the United States Pharmacopeia. He is presently editor-in-chief of *Drug Topics and Drug Trade News*.

Secondly, the Maryland Pharmaceutical Association is striving to bring to pharmacists and the allied drug industry, information of interest to all segments of the profession and the industry. Changing conditions and practices demand we meet in open forum to obtain information and discuss pharmacy problems with experts. The Dr. Swain Seminar will provide such an opportunity annually.

**International Law.**—Mr. Robert W. Gregg's article begins at page 187. This article marks a development of great importance in international law discussing as it does the single narcotics convention. This convention was the subject of an earlier article in the November, 1958 issue of the FOOD DRUG COSMETIC LAW JOURNAL, written by Commissioner Anslinger.

With the help of two grants from the Wake Forest College Graduate Council and the Shell Foundation, *Robert W. Gregg*, a professor at Wake Forest College, spent several weeks at United Nations headquarters last summer studying the documents of the Commission on Narcotic Drugs.

His article briefly surveys the existing state of international treaty law in respect to narcotics, analyzes the defects in the former control system, and outlines the efforts which were made by the commission.

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Journal

# The Single Convention for Narcotic Drugs

By ROBERT W. GREGG

This article is based on the author's research on international regulatory problems with the assistance of grants from the Shell Foundation and the Wake Forest College Graduate Council.

THE UNITED NATIONS has been the source of a considerable amount of news and several headlines in the early months of 1961. A riot marred the deliberations of the Security Council, the General Assembly reconvened to take a new look at the fast-moving Congo crisis, the Soviets stepped up their attack on the Secretary-General, and the United States parted company with its allies over the difficult question of African nationalism. During these same trying weeks, the United Nations was also the scene of an important event which commanded no headlines and few inches of news space. That event was duly and unobtrusively recorded each day in the *New York Times* box, "The Proceedings in the U. N.," as the "Conference for the Adoption of a Single Convention on Narcotic Drugs." Convened on January 24, this conference labored for two months to hammer out a treaty to serve as the basis for the international control of narcotics. On February 15, while demonstrators clashed with guards in the Security Council chamber, delegates from some 70 states, meeting in a conference room in the same building, debated a technical point concerning changes in the scope of international control over narcotic drugs. Three weeks later, as President Nkrumah of Ghana addressed the General Assembly in an atmosphere chilled by the cold war, an *ad hoc* committee of the drug conference discussed provisions pertaining to the functions and composition of international drug control

organs. The contrasts at United Nations headquarters were pronounced in February and March.

The quiet, less spectacular work of the conference was concluded on March 25. By a vote of 46 in favor, none against, and eight abstentions, the conference adopted The Single Convention on Narcotic Drugs.[1] This little publicized treaty represents the culmination of many years of endeavor under the aegis of the United Nations. At the time the conference convened, an extensive body of drug treaty law was already in existence, but it had been developed over a period of nearly 50 years and was to be found in some nine conventions and protocols. Because they were drafted at different times under different sets of circumstances and ratified by different combinations of states in each case, the several international agreements amounted to a patchwork of obligations and commitments which was not wholly satisfactory. Considerable progress had been made in curtailing the abuses of narcotic drugs, but those abuses had not been eradicated. It was against this background of persistent but unfulfilled international effort that the narcotics conference opened.

The conference conceived its functions to be two in number. As a minimum effort it was to endeavor to codify the complex nexus of treaty law already in existence. However, an equally important reason for convening the conference was to further develop and expand international narcotics control. Early in its drafting history the new treaty was labeled, for obvious reasons, the Single Convention; but those who were concerned with narcotics problems hoped that it would prove to be *greater* than the sum of the parts it replaced.

Although the Single Convention on Narcotic Drugs is the product of compromise and is not as ambitious a document as it was in its draft form when the United Nations conference began it is nonetheless a substantial new document and a prospectively important contribution to the field of international regulation. It represents a clarification and extension of international law on a frontier where cooperation is possible and where progress, though difficult to achieve, is clearly and demonstrably for the benefit of all nations, regardless of ideology or political commitment.

The narcotic drug problem, reduced to its essentials, is this: to establish regulatory control which will eliminate all abuses of narcotic drugs while guaranteeing an adequate supply of those drugs for

[1] The convention is contained in UN Doc. E/CONF.34/22, hereafter cited as the Single Convention.

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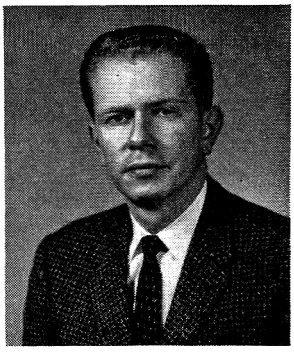

medical and scientific purposes. In the beginning, control efforts were almost exclusively national, but it soom became apparent that the problem would have to be treated on a universal basis. The nation which does not exercise control over drugs, or whose control system is inadequate or ineffectual, represents an invitation to illicit trafficking, which is detrimental to all nations. Conscious of this fact, the world community moved to internationalize controls.

The international regulatory campaign, inaugurated in 1909 at Shanghai, gathered momentum slowly. As a result of lack of knowledge and experience, nations undertook the task of regulation in this uncharted area of international cooperation with considerable caution. Following the exploratory Shanghai meeting, which was concerned primarily with opium smoking in the Far East, the first large-scale drug conference was held at The Hague in 1912. The convention [2] concluded there enunciated a number of principles which still serve as the basis for international narcotics control, but it was lacking in teeth and failed to establish even a rudimentary international control center. At the conclusion of World War I, the peace treaties were used as a vehicle for bringing The Hague convention into force and an even more significant step was taken whereby the League of Nations was assigned responsibility for the supervision of international regulation of narcotic drugs.

Some of the most important of the features of international regulation now in effect were developed under the aegis of the League of Nations and its Opium Advisory Committee. Two conferences, one in 1925 and the other in 1931, resulted in conventions which significantly strengthened international law, regulation and coopera-

[2] League of Nations, *Treaty Series* (LNTS), Vol. 8, pp. 187 ff.

tion in the drug area. The Geneva Convention of 1925 [3] established the Permanent Central Opium Board (PCOB) and sought to regulate narcotic drugs by bringing trade in such drugs under a more comprehensive and stringent control regime. Predicated on the assumption that it would be much more difficult to misuse narcotics if each act of importation and exportation were subject to government approval, the Geneva Convention made exports contingent upon certification by the government of an importing company that the drugs in question are needed for medical or scientific purposes in that country. The PCOB has served to focus attention on the availability of drugs and the flow of international trade by acting as a clearing house for statistics which governments are required to submit annually in respect to production, manufacture, consumption, and stocks, and quarterly in respect to imports and exports.

It was impossible for states long to ignore the fact that the careful channeling of the international drug trade was not adequate and that illicit traffic will exist as long as an excessive amount of drugs is available. The Opium Advisory Committee of the League addressed itself to the problem of eliminating the excess. The result was a convention adopted at Geneva in 1931,[4] usually referred to as the Limitation Convention, which undertook to reduce the available supply of manufactured drugs to a level consistent with world needs for medical and scientific purposes. The need for narcotic drugs has been determined from estimates submitted annually by nations to a Drug Supervisory Body (DSB), created by the convention. A careful comparison of the statistics made available to the PCOB each year and the estimates furnished to the DSB has enabled the PCOB to determine whether a nation has exceeded its estimated need. In effect, then, the Permanent Central Opium Board has kept a balance sheet of the world's narcotic drug supplies and requirements.

Taken together, the 1925 and 1931 conventions constituted a significant effort to regulate an important industry on an international scale; but they did not solve the drug problem. Illicit traffic continued to flow, albeit with more difficulty. One loophole was the ineffectiveness of sanctions in deterring the traffickers. For a variety of reasons, many governments failed to provide for punishments severe enough to discourage the lucrative illicit traffic in narcotic drugs. Further-

[3] LNTS, Vol. 81, pp. 317 ff. For text as amended by protocol signed at Lake Success, N. Y., December 11, 1946, see UN Doc. E/NT/2.

[4] LNTS, Vol. 139, pp. 301 ff. For text as amended by 1946 protocol, see UN Doc. E/NT/3.

more, international cooperation in dealing with the trafficker had not been particularly successful. In 1936, another international convention was approved at Geneva[5] which was concerned almost exclusively with this facet of the problem. Unfortunately, it has been the least satisfactory of the narcotics conventions in force, having been ratified by only a few states.

These conventions, adopted at Geneva in 1925, 1931 and 1936, were a major part of the legacy bequeathed to the United Nations by the League of Nations. The Opium Advisory Committee had a fruitful life span and the PCOB and the DSB quickly established themselves as useful and highly competent organs in the protracted campaign to regulate narcotic drugs. When the United Nations assumed control after World War II, and the Commission on Narcotic Drugs assumed the responsibilities of the Opium Advisory Committee, two problems seemed to require immediate attention: synthetic drugs and the production of drug raw materials.

Since the conclusion of the Limitation Convention in 1931, many new drugs had been developed, especially synthetic drugs, which were not subject to the earlier controls. In 1948, a protocol was signed at Paris[6] which made synthetic drugs subject to the existing control system and also made provision for bringing additional addiction-producing drugs under the control of the 1931 convention with the assistance of the World Health Organization.

The second and even older problem with which the Commission on Narcotic Drugs was confronted was the matter of regulating the production of narcotic raw materials, such as opium. International control had never been imposed at the beginning of the drug-making process, that is, at the planting and harvesting stage. The Opium Advisory Committee was working on this problem when the Second World War erupted, and the commission quite naturally turned its attention to this matter at an early date. Failing in its efforts to establish an international opium monopoly, the commission elaborated a production control system based upon the limitation of permissible stocks of opium. Furthermore, production of opium for export was restricted to seven nations. This oblique attempt to regulate production was embodied in a protocol adopted at New York in 1953.[7] This instrument was regarded by most of its signers as a temporary measure,

[5] LNTS, Vol. 198, pp. 229 ff. For text as amended by 1946 protocol, see UN Doc. E/NT/5.

[6] UN Doc. E/NT/7.

[7] UN Doc. E/NT/8.

to serve the function of production control until the anticipated Single Convention became a reality. However, the 1953 protocol has never come into force.

To this roster of narcotics instruments should be added the Protocol of 1946,[8] which effected the transition from the League of Nations to the United Nations in the drug field, and two earlier agreements of more limited scope and application, adopted at Geneva in 1925 and at Bangkok in 1931,[9] which sought gradually to suppress opium smoking. Thus, no fewer than nine multilateral treaties purporting to regulate narcotics and imposing a wide range of obligations upon parties had been concluded prior to 1961. These nine treaties have constituted a major effort at cooperation on a near universal scale in an area which does not lend itself easily to regulation.

The theme of this long campaign has always been cooperation, not coercion. The foundation stones of control and regulation are today, as they have always been, national laws and national administrative practices. A principal function of the several international conventions has been to raise the standards of national regulation and to extend the network of control through all nations; indeed, the adoption of the Single Convention comes at a time when many nations are intensifying their efforts to eliminate abuses of narcotics. Iran and Afghanistan, for example, have recently undertaken to outlaw opium production; this is a major step, particularly for Iran, which has been a principal opium producer for export.

The United States has only recently enacted into law one of the most important pieces of drug legislation adopted by this country since it first took an active interest in the problem half a century ago. This measure, the Narcotics Manufacturing Act of 1960,[10] represents a major stride in the continuing effort of the United States, as manufacturer, exporter, and target of the lucrative illicit traffic, to supply leadership in the world-wide drug control campaign. A brief commentary on this important domestic legislation may serve to suggest the interrelationship of national and international effort in the narcotics field.

The principal purpose of the act has been succinctly stated: "to give full effect to treaty obligations of the United States to limit exclusively to medical and scientific purposes the manufacture of nar-

[8] UN Doc. E/NT/6.

[9] LNTS, Vol. 51, pp. 337 ff., and Vol. 177, pp. 373 ff., respectively. For texts as amended by 1946 protocol, see UN Doc. E/NT/1 and E/NT/4, respectively.

[10] 74 Stat. 55, 21 USC Sec. 501 (1960).

cotic drugs and to require that such manufacture be restricted to persons and premises that have been licensed for the purpose." [11]

Previously the United States had discharged its obligation under the 1931 convention, that is, the obligation to limit to medical and scientific uses its manufacture of narcotics, by the indirect method of restricting the importation of natural drug raw materials. Today, however, the United States, *inter alia*, manufactures many of its drugs synthetically, a fact which led to the conclusion of the Paris Protocol of 1948. Responding to this changed situation, Congress has now spelled out detailed licensing requirements and formulated manufacturing quotas. The manufacture and distribution of drugs, especially synthetic drugs, are subject to specific quantitative limitations for the first time. Furthermore, procedures are enunciated in the Narcotics Manufacturing Act for (a) notifying the United Nations that a new drug has addiction-producing properties, and (b) receiving a finding or decision from the WHO or the Commission on Narcotic Drugs that a drug is addiction-producing. In this way, the flexibility of control which the 1948 protocol hoped to achieve is incorporated into the new act. Finally, the controls over drug exports from the United States have been modified to require that exports be authorized only if the receiving country is a party to the convention under which the particular drug is controlled.

The passage of this law and the promulgation of the necessary rules and regulations by the commissioner of narcotics gives the United States a very comprehensive and detailed drug control system. In fact, there exists today in the world an elaborate structure of national laws and multilateral treaties, not totally encompassing the problem but constituting a major bulwark against the abuse of narcotic drugs. If the trafficker has not been eliminated, his task has been made infinitely more difficult; if addiction still exists, it is at least not as easy to sustain.

The fact that the drug control campaign had not achieved all of its objectives prompted the decision to convene the plenipotentiary conference in 1961. What have been the deficiencies in the international drug control system? Why did it become necessary to codify existing international treaty law and, if possible, extend it? [12]

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[11] S. Rept. 1077, 86th Cong., 2d Sess. (1960), p. 1.

[12] For analysis of the shortcomings of the present system, see Herbert L. May, "The Single Convention on Narcotic Drugs: Comments and Possibilities," 7 *Bulletin Narcotics* 1 (1955); Bertil A. Renborg, "International Control of Narcotics," 22 *Law & Contemporary Problems* 86 (1957).

In the first place, the control regimes have been too complicated because of the number of conventions in the field. Supposedly these conventions formed an interlocking system of control; yet they have not all been ratified by the same states.[13] The result has been so many legal relationships between states and between states and the international drug organs that the control system has not been able to function at maximum effectiveness.

The international organs themselves have constituted an unnecessarily complex control machinery. In an effort to combat abuses of narcotic drugs, the commission was established under the Economic and Social Council, the Permanent Central Opium Board and the Drug Supervisory Body were created by treaties, and the World Health Organization was given responsibilities in the drug field under three treaties. Each of these bodies has had distinct but related functions; however, they have derived their authority from different agreements, have had their own secretariats, and have confronted nations with the necessity of discharging responsibilities to a number of different organizations.

The provisions of the several conventions have also formed a complex maze of obligations. Inasmuch as the problem is so many-sided, it would be unrealistic to expect a simple control system. But surely the system could be simpler than it has been; nine treaties have frequently added up to inconsistency, duplication, and even obsolescence. This has posed problems for any nation conscientious enough to wish to make a maximum contribution to narcotics control, and especially for the large numbers of states with limited administrative experience and means for financing a sophisticated, efficient domestic control system.

A further defect has been that the techniques of control have been comparatively inflexible, a dangerous flaw in dealing with a problem which can be confined only if the control system is sufficiently fluid to take into account new and perhaps unforeseen developments. A danger exists that technological progress and advances in pharmacology may have the unwanted subsidiary effect of facilitating trafficking and addiction. The control bodies have been handicapped by excessively detailed treaty clauses which have rendered the international experts less effective and less able to use their good judgment to thwart the traffic. There has been a need for greater

[13] For status of ratifications as of March 15, 1960, see UN Doc. E/CN.7/378/Add.3 (1960).

discretionary authority at the international level, in order that action may be taken promptly along the constantly shifting front of the narcotics problem. It is no longer adequate to respond to each new phase of the narcotics struggle with an international conference and a new convention : that is a slow and costly process.

Finally, the control system has been characterized by loopholes which could be tightened, but not closed, by making all nations parties to the same comprehensive treaty, consolidating international bodies devoted to the problem, or granting to those bodies greater discretion. In other words, some of the problems cannot be solved merely by tinkering with the existing patterns of obligation and regulation. For example, one of the most critical deficiencies in this field has been that raw materials have not been sufficiently controlled by previous conventions. In this and in other areas, a need has existed for instituting major new programs of control.

The Single Convention was proposed as a highly desirable, perhaps even an imperative step in overcoming the defects of an excessive number of treaties, an overly complex administrative machinery, the inflexibility of the control system and the inadequate scope of treaty law. The need for taking this step had existed for a long time ; it had become increasingly urgent.

The Commission on Narcotic Drugs first considered the question of the Single Convention in 1948 ; ten years later work was concluded on the preparatory draft which became the working paper for the plenipotentiary conference.[14]

At the commission's third session, the United States introduced a resolution which called for a unified convention, incorporating the provisions of treaties already in force and closing gaps in the existing control system, especially by providing for a limitation of the production of drug raw materials. The importance of this proposal was appreciated by all member states, and the commission requested the Economic and Social Council to authorize the Secretary-General to prepare a draft convention. ECOSOC responded favorably and the Single Convention became a matter of high priority for the Commission.

Aware that it might be some time before the sweeping change of the Single Convention could be effected, the commission first turned its attention to consideration of an interim agreement limit-

[14] For third draft, see UN Doc. E/CN.7/AC.3/9 (1958), hereafter cited as Draft Single Convention. For earlier drafts, see UN Doc. E/CN.7/AC.3/3 (1951); UN Doc. E/CN.7/AC.3/7 (1956).

ing opium production. However, the Secretariat's first draft of the Single Convention was before the fifth session of the commission and that body began a detailed study of it at the seventh session in 1952. Six years and two drafts later, the commission completed consideration of all outstanding questions and felt that it might at last submit the results of its labors to an international conference.

Those were not easy years of gestation. Many alternative texts had to be eliminated and numerous ambiguities weeded out before the tedious task of preparation could be considered finished. The commission had tended to accept, early in its deliberations, the thesis that unification of existing treaties should be more than a mere compilation and consolidation of existing texts, and that weaknesses and complexities ought to be removed. However in practice it was difficult for the members of the Commission to agree on an acceptable text which would correct those weaknesses and resolve those complexities. Consequently, conflicts over a number of controversial clauses occupied the Commission through many meetings, and were finally "resolved" only tentatively, the dissenting states reserving the right to carry their objections to the plenary conference.

When the conference finally convened, the delegates had the benefit of a patiently prepared working draft, extensive comments on the draft by a large number of states and international organizations,[15] and the very considerable resources and assistance of the Division of Narcotic Drugs of the United Nations' Secretariat. The conference was well attended. There had been some question about the scope of invitations, which were finally extended to all states members of the United Nations, the specialized agencies, and the International Atomic Energy Association. This formula had the advantage of near-universality, but excluded several Communist regimes while permitting such nonmembers as Switzerland, the Federal Republic of Germany, and the Republic of Korea to attend. Nevertheless, all of the major powers except Communist China attended, as did the important drug manufacturing states, the principal opium, coca bush, and cannabis producing states, and most of those states which have been centers of illicit traffic. In all, 73 states plus the PCOB, DSB, WHO, ILO, ICAO, and INTERPOL had accredited representatives at the conference. As a result, the convention which was adopted can be said to reflect a universal consensus. That con-

[15] See UN Doc. E/CONF.34/1 (1960). All other E/CONF.34 documents cited were issued in 1961.

sensus was achieved only after many long weeks, numerous compromises, and the deletion of a number of controversial provisions.

What is to be the new pattern of national obligation and international control under the Single Convention? It is, in its essence, the old pattern of earlier conventions, streamlined to some extent and somewhat more ambitious in its sweep. It reflects a continued stress upon the principle of indirect, that is, national control. Most of the controversial features of the Draft Single Convention which did *not* survive the conference failed because they deviated from the principle of indirect control. Leland Goodrich, writing prior to the conference but with the commentaries of states upon the Draft Single Convention at his disposal, observed that "there is no evidence that in dealing with this problem of admitted international concern, and largely technical in character, states are willing to yield their responsibilities in legislative and administrative fields to international organs." [16] The conference sustained that impression. As several delegates to the conference remarked, the centralization of drug controls has progressed about as far as can reasonably be expected at the present time; to insist upon more direct controls flies in the face of the demonstrated sensitivity of states to encroachment upon sovereign prerogatives.

The new convention, therefore, follows the pattern of the 1925, 1931, 1948, and other earlier conventions. It incorporates most of their features and includes few major innovations. Before noting its principal provisions, it might be well to observe that the most conspicuous feature of the new convention should ultimately be its singularity. In time, as it comes into force and existing treaties are phased out, this instrument will constitute the single codified statement of international law in the narcotics field.

The scope of the Single Convention is defined in clauses providing for different control regimes for different drugs and preparations, depending on their properties. Furthermore, provision is made for altering the scope of control by adding drugs to any of the several regimes or transferring drugs from one regime to another. This element of flexibility has been carried over from the 1948 Protocol, but the procedure has been modified. The WHO will continue to play

[16] Leland M. Goodrich, "New Trends in Narcotics Control," *International Conciliation*, No. 530, November, 1960, p. 193. This monograph, published on the eve of the conference, is an excellent study of the third draft prepared by the commission.

a role in adapting the scope of international control to changing developments in scientific and medical knowledge; however, its role will not be decisive. Power to decide whether a new drug should be subject to control, and if so to what regime, is granted to the Commission. It is the intention of the new treaty that the WHO shall be consulted by the commission, but the decision-making responsibility rests with the administrative organ, representative of governments, not with the technical body. In addition to this change, the conference also accepted a procedure for the review of a contested Commission decision by an *ad hoc* panel of three experts competent to deal with narcotic problems.[17]

One of the central features of the Single Convention is a simplified international control machinery. The complexity of the existing machinery had been one of the most frequently cited shortcomings of drug treaty law. Responding favorably to one of the key proposals in the Draft Single Convention, the conference consolidated the PCOB and the DSB and designated the new organ the International Narcotics Control Board. Functioning in both an administrative and a quasi-judicial capacity, the new board will still be distinct from the policy-making organ in the field, the Commission on Narcotic Drugs. This simplification of the administrative machinery will make one organ responsible for administering the estimates system *and* the system of statistical returns. In addition, the board will have broad powers to adopt measures to insure implementation of the convention's provisions by all states. This consolidation of functions has interesting implications. Heretofore, one international body has participated in determining maximum permissible holdings of drugs by nations; a second body has used these maxima as a guide in overseeing the discharge of treaty obligations by nations and invoking sanctions in the event that nations were delinquent or were tending to become centers of illicit traffic. Now a single organ will perform these distinctive tasks.

There was little objection to transferring many provisions, based primarily upon the widely accepted 1925 and 1931 conventions, to the new treaty. However, the clause authorizing the board to establish estimates for nonparties that do not submit them stirred up some of the conference's sharpest debate. The Soviet bloc members insisted

[17] For scope of convention and changes therein, see Single Convention, Art. 2 and 3.

that several states—the People's Republic of Outer Mongolia was frequently cited as an example—may be denied an opportunity to become parties to the Single Convention and that the board should therefore have no authority to establish estimates for them.[18] In spite of such protests, the version of the convention which was finally approved retains the time-honored authority of the board in respect to third parties, thus strengthening the control regime by universalizing the estimates system.

The board, it should be noted, is to consist of 11 members, elected for three-year terms as follows: three out of five nominated by WHO, and eight from a list nominated by United Nations members and parties to the Single Convention who are not members. It is hoped that this formula will result in a board of "technical competence, impartiality, and disinterestedness," although it was apparent during the conference that many nations tended to regard the board as a body which should reflect the principle of geographical distribution, at best an irrelevant criterion.[19]

One of the most controversial sections of the Draft Single Convention pertained to the board's grant of powers for enforcing the provisions of the convention. In the final analysis, the conference dropped several of the more divisive proposals and settled for a package of enforcement measures which are at once mild and based on the precedent of earlier treaties, especially the 1925 convention and the still-born 1953 protocol. Among those measures which may be adopted by the board are requests for information and for explanations, public declarations that a party has violated its obligations, and recommendations that embargos on imports and exports be imposed. Within this range of sanctions, the board has considerable discretionary authority.[20] The controversy within the conference over third parties extended to the question of the board's enforcement powers as well as to its authority to establish estimates. In an acrimonious debate on March 9, the Soviet bloc delegates pressed the view that international law is violated when nonparties are made the prospective objects of board actions to which they have never given their consent. A rare roll call vote was demanded on this political twist to an essentially technical question, and the custom of

[18] See UN Doc. E/CONF.34/SR.28, pp. 16-20.

[19] For provisions regarding international control organs, and especially the board and its composition and functions, see Single Convention, Art. 5-16.

[20] See Single Convention, Art. 14.

requiring cooperation from nonparties to treaties in the drug field was continued by a comfortable margin.[21]

A sizeable number of articles in the Single Convention deal with the responsibilities of states. Inasmuch as the drug control system is essentially decentralized, these are among the most vital articles in the convention and its success will be determined largely by how completely and efficiently these duties are assumed and discharged. Once again, the major portion of the catalog of state obligations has been drawn from the earlier conventions. Thus, states are required to supply a variety of information to the Secretary-General (annual reports, texts of laws and regulations concerning narcotics, details on the illicit traffic); detailed statistical data to the board (*re* production, consumption, manufacture, imports, exports, confiscations and stocks); and estimates to the board (*re* quantities of drugs to be produced, consumed, used in manufacture and held as stocks).[22] In addition, the Single Convention reiterates the provisions of the 1931 convention requiring that the manufacture and importation of drugs be limited to maximum levels computed on the basis of estimated requirements for a variety of purposes.[23]

States are also required to establish licensing systems and to control trade by means of a system of export and import authorizations. The pattern of these obligations in respect to trade and distribution is basically that prescribed by the 1925 convention. In one particular, however, the new treaty is updated to take into account the development of state ownership and operation of manufacturing and trade enterprises. Thus, the obligation to license these activities has been supplemented by recognition of an alternative method of control—the establishment of a state enterprise or system of state enterprises for the purpose of more effective control and surveillance of the drug industry. Although the conference declined to go so far in regulating domestic distribution as to require that prescriptions be written in the form of counterfoil books or that all printed and written material relative to drugs indicate their international nonproprietary name, recommendations to these effects are contained in the convention.[24]

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[21] See especially UN Doc. E/CONF. 34/SR.30.

[22] See Single Convention, Art. 17-20.

[23] See Single Convention Art. 21.

[24] See Single Convention, Art. 30 and 31.

An interesting new provision has been incorporated into the Single Convention, exempting narcotic drugs carried in first aid kits aboard trains, ships and aircraft from the normal operation of the international control regime, and especially from the relatively slow functioning of the export and import authorization system. The convention still requires the exercise of suitable caution in the use of these drugs to prevent them from being diverted into illicit traffic; but the need for expediting the clearance of small amounts of drugs for use in emergencies was impressed upon the conference with no great difficulty.[25]

Heretofore, the system of international control has been predicated upon the principle that the manufacture, export, import, distribution of, trade in, use and possession of narcotic drugs should be limited to medical and scientific needs. This principle is perpetuated, of course, in the Single Convention, but the scope of the principle has been expanded: the *production* of drugs is now to be limited exclusively to medical and scientific purposes, too. In effect, this means that narcotic raw materials such as opium, coca leaves and cannabis are to be subject to more stringent controls, and some of the most important clauses in the convention are those detailing obligations of states in respect to these raw materials and the agricultural processes by which they are produced.[26]

How effectively the production gap in international control has been closed by the measures in the Single Convention remains to be seen. But there now appears to be a very strong likelihood that the cultivation and harvesting stages of the drug process will be controlled by treaty for the first time, following innumerable frustrations in the long history of the drug control campaign. Such an extension of control was undertaken in respect to opium by the 1953 protocol, but that instrument never came into effect, many nations deliberately deferring action on it in the expectation that the Single Convention would include provisions in the area of production. Those expectations have now been realized.

Parties which permit the cultivation of the poppy for the production of opium are required to establish and maintain national opium agencies. These agencies are to designate areas in which the opium poppy may be cultivated, license cultivators, receive *all*

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[25] See Single Convention, Art. 32.
[26] See Single Convention, Art. 22-28.

crops harvested, and exercise an exclusive right of importing, exporting, wholesale trading and maintaining stocks of opium. If a party believes that the diversion of drugs into illicit channels can best be prevented by prohibiting cultivation, the party is directed to use its best endeavors to prohibit such cultivation. It will be noted that the controls on production are largely indirect; that is to say there are no provisions for the assignment of quotas or ceilings on production. One of the most important of the controls imposed on the production of opium, however, is a stipulation that only certain categories of states may produce opium for export. The basic criterion is whether the state was an opium exporter as of January 1, 1961; if a state did not produce opium for export at that time, however, it might still be authorized to do so if it notified the board of its intention to export up to five tons annually or received permission from ECOSOC to export more than five tons annually. Parties to the convention agree to import opium only from states which maintain adequate production control standards.[27]

Controls are imposed on the production of both the coca bush and cannabis, too. The relevant provisions employ an economy of words and simply require that states which permit the cultivation of these plants should apply to them the same system of controls as is required for opium in the convention.[28] In its draft form, the Single Convention subjected poppy straw to the same regime as opium; however, in the version adopted by the conference, a separate article is devoted to straw, applying to it a limited regime of control similar to that in the 1953 protocol. The function of these provisions is to prevent the production of opium from poppies cultivated for other purposes, to regulate the manufacture of narcotic substances from poppy straw, and to subject imports and exports of straw to a licensing system.[29]

The measures which the Single Convention enumerates for dealing with illicit traffickers are generally mild and carefully phrased to avoid conflict with different legal systems. Parties undertake to adopt such measures as will ensure that several specified offenses will be punishable on a scale commensurate with the seriousness of the offense. A section on extradition is included, which would make

[27] See Single Convention, Art. 23 and 24.

[28] See Single Convention, Art. 26 and 27, and Art. 28, respectively, for the coca bush and for cannabis.

[29] See Single Convention, Art. 25.

certain of the punishable offenses extradition crimes. However, it is made quite clear that all of these requirements are subject to constitutional limitations and domestic law.[30]

*Treatment of Addicts.* One other obligation is imposed upon states, and that has to do with the treatment of drug addicts. Parties are to give special attention to providing facilities for treatment and rehabilitation of addicts; furthermore, if drug addiction is a serious problem in a country, and economic resources are sufficient for the task, it is recommended that addicts be treated on a compulsory basis in closed institutions.[31] This is a new subject in drug treaty law. In all probability it will have little effect except in those countries which have adequate resources to undertake the costly task of institutional care and rehabilitation. However, its inclusion suggests that all facets of the drug problem are within the purview of the collective control effort, and that all approaches to the problem will be explored.

Although the convention specifies that narcotic drugs shall be used only for medical and scientific purposes, it was necessary to include transitional provisions which permit nonmedical or quasi-medical use of several narcotic substances for limited periods of time. For example, the quasi-medical use of opium shall be permitted for 15 years after the convention comes into force; the habit of chewing the coca leaf shall be permitted for 25 years after the convention comes into force; and cannabis may be used in indigenous medicines for a limited period not to exceed 25 years. These terms are spelled out in an article authorizing transitional reservations.[32] In other words, the spirit of the convention is that medical and scientific uses *only* shall be authorized; the letter of the convention permits temporary exceptions by reservation.

Thirty days following the fortieth ratification or accession to the Single Convention, it will enter into force. The number of required ratifications is large enough to guarantee that entry into force is contingent upon widespread approval; but it is not so large as to place the convention at the mercy of scattered national indifference or constitutional inertia.

The Single Convention is almost as interesting for what it omits as for what it includes. After concluding the preparation of its draft for the conference, the Commission on Narcotic Drugs in 1958

[30] See Single Convention, Art. 35-37.
[31] See Single Convention, Art. 38.
[32] See Single Convention, Art. 49.

candidly called attention to several provisions about which there had been serious disagreement within the commission.[33] In virtually every case, the conference resolved the disagreement by deleting the provision or changing a mandatory requirement to a mere recommendation. As a consequence, the treaty is considerably less ambitious in its final form than it was when it was submitted to the conference. Although many clauses were dropped or significantly modified by the conference, seven are of more than passing interest because they reveal a strong sentiment within the commission that the time is ripe for several new approaches to the drug problem. Obviously, the time is not ripe, but it is worth observing that each of these measures was adopted by the commission and included in its Draft Single Convention.

The original draft provided for the mandatory prohibition of drugs which were deemed particularly dangerous and of questionable therapeutic importance. Heroin is the standard example of this category of drugs. Although a majority on the commission felt that absolute prohibition was imperative if the incidence of drug addiction of therapeutic origin was to be reduced, opposition to this new principle was vigorous in both commission and conference. The United Kingdom, Canada, and several European states were particularly insistent in their opposition to a principle which they believed could impede medical progress. The matter, they argued, should be one for national but not international decision. This view prevailed.[34]

In its final draft, the commission had urged that the board be empowered to undertake a local inquiry, ostensibly to "elucidate the drug situation in a country or territory," and to impose a mandatory embargo as its most severe sanction. In making these recommendations, the commission was following the pattern of the 1953 protocol. But the failure of the 1953 protocol has been attributed in part to these very provisions, which were unacceptable to many states, especially those in the Soviet bloc and Yugoslavia; they have taken the view that both local inquiry and a mandatory embargo are violations of national sovereignty. Furthermore, the PCOB itself, which had never even used its authority to recommend an embargo, questioned the

[33] Economic and Social Council, *Official Records* (ECOSOC, OR): 26th Sess., Suppl. No. 9 (Doc. E/3133) (1958), pp. 50-54.

[34] For criticism of this provision, see UN Doc. E/CONF.34/1, pp. 33-41; UN Doc. E/CONF.34/SR. 5, 6, 14, and 15; UN Doc. E/CONF.34/C.2/SR.1-3.

wisdom of over-stressing the judicial nature of the board's responsibilities. Both provisions were quietly dropped from the convention.[35]

Governments have been required to furnish estimates of drug requirements since the 1931 convention came into effect; it was proposed to the conference that estimates also be required of the areas to be cultivated for the harvest of drug raw materials as well as of approximate quantities of drugs to be produced in those areas. There was a considerable lack of agreement as to the utility of such estimates, which many states felt were too unpredictable to be of much use. It was also argued that an obligation to furnish such difficult estimates would unduly burden governments of states raising the drug plants. A combination of these arguments persuaded the conference to abandon a compulsory requirement that such estimates be furnished, along with one calling for parties to furnish statistics as to areas under cultivation for drug production.[36]

One of the controversial features of the Draft Single Convention was the control regime for poppy straw. Traditionally, morphine has been extracted from the coagulated juice of the opium poppy; but in recent years, large amounts have been extracted from poppy straw, that is, the dried poppy capsule and upper part of the poppy stem. The 1953 protocol undertook to regulate the manufacture of narcotic substances from straw, but did not provide production controls. Not satisfied that these measures were adequate, the commission proposed a more stringent regulation comparable to that for opium. This decision was taken by a narrow seven to six vote; the dissenters, mostly European states, carried their vigorous objections to the conference, arguing that straw is only a by-product of poppy cultivation, that it is impracticable to use it for the illicit manufacture of morphine, that it has not figured in illicit traffic and that it would be extremely difficult to control at the farm level. In the face of so many criticisms, adamantly voiced, the conference retreated to the more limited approach adopted in 1953.[37]

Although the conference finally decided to limit the states which might be authorized to produce drug raw materials for export, it

[35] For criticism of this provision, see UN Doc. E/CONF.34/1, pp. 83-89; UN Doc. E/CONF.34/SR.19; UN Doc. E/CONF.34/C.10/SR.1-3. See, also, May, work cited at footnote 12, pp. 10-11.

[36] For criticism of this provision, see UN Doc. E/CONF.34/1, pp. 94, 97-98; UN Doc. E/CONF.34/SR.17 and 18; UN Doc. E/CONF.34/C.9/SR.2.

[37] For criticism of this provision, see UN Doc. E/CONF.34/1, pp. 103-110; UN Doc. E/CONF.34/SR.9 and 10; UN Doc. E/CONF.34/C.5/SR.1-4.

avoided inclusion in the convention of a closed list of such producers, identified by name. This had been done in the 1953 protocol and in the Draft Single Convention. According to the proposed formula, Afghanistan, Bulgaria, Greece, India, Iran, Turkey, the Union of Soviet Socialist Republics and Yugoslavia would have been authorized to produce opium for export, and Bolivia, Indonesia and Peru, coca leaves. Many states were highly critical of this abandonment of the free trade principle, particularly inasmuch as it tended to freeze trade in drug raw materials into the economic pattern of the 1950's. Decisions of Iran and Afghanistan to outlaw opium production called attention to the fact that a closed list of exporters could conceivably lead to serious drug shortages. The United Kingdom summed up the opposition to the closed list when it observed that it would be "most undesirable to create the risk of a monopoly of supply of opium by precluding countries well equipped and able to impose satisfactory controls from contributing to the production required to meet the world demand for opium for legitimate medical and scientific purposes." [38]

Another feature of the ill-fated 1953 protocol was ultimately vetoed by the conference when the provisions for limiting stocks were deleted. Prior to the conference, the Soviet Union had argued that "it is inappropriate to include in the Convention a provision impairing the right of a state freely to build up stocks of narcotic raw materials and narcotic medicaments and to maintain such stocks at the level it deems desirable." [39] Uncertain in any event as to the utility of maximum stock levels, the conference acceded to the Soviet view.

Finally, delegates modified several obligations which the draft had imposed upon states in their conduct of trade and distribution. Numerous states, including the United States, would not accept mandatory obligations to use counterfoil books in the writing of prescriptions or to require that all written material pertaining to drugs carry the recognized international nonproprietary name. These requirements, excessively complicating for many states, were altered to recommendations by the conference.[40]

Each of these departures from existing regimes of control was controversial and opposed by states whose continuing participation in

[38] UN Doc. E/CONF.34/1, p. 116. See, also, pp. 112-118, 124 and 125; UN Doc. E/CONF.34/C.5/SR.1, 5 and 6.

[39] UN Doc. E/CN.7/AC.3/8 (1957), p. 111. See, also, UN Doc. E/CONF. 34/1, pp. 119-120.

[40] For criticism of this provision, see UN Doc. E/CONF.34/1, pp. 133-139; UN Doc. E/CONF.34/SR.8 and 16; UN Doc. E/CONF.34/C.4/SR.1 and 2.

the drug control campaign was regarded as vitally important. In the course of the conference, it became apparent that delegates had little practical choice but to overrule the recommendation of the commission in each case. Although some of these schemes might have tightened the control system, it was widely conceded at the conference that not a great deal of substantive value was lost when these clauses were stricken from the convention.

An effort of considerable magnitude has just been concluded in New York, and it is too early to draw up more than a tentative balance sheet on the conference. Inconclusive as any evaluation may be, however, it seems desirable to review the results of the conference and hazard a prediction as to the fate of the convention which has been adopted.

Encouragement may be drawn from several facts:

(1) In spite of the fact that these are very parlous times, a successful international conference has been held; this suggests that international cooperation can be achieved in spite of the intensification of the cold war, and that the United Nations and its agencies can play an instrumental role in bringing about progress in areas where there is some mutuality of need and interest. It may beg the question to call the conference a success; however, in the sense that it brought together 70 odd states and produced a treaty which they could approve overwhelmingly, it was a success.

(2) The conference afforded an opportunity for a plenary review of the status of several outstanding problems in the field of drug control. It may have helped to dispel some persistent illusions which have been reflected in the commission's agenda for several years and which made the Draft Single Convention a somewhat unrealistic document. In particular, the concept of indirect control, with principal responsibility resting on states, has been reaffirmed, and the limits of centralized authority and mandatory obligations have been demonstrated.

(3) Consolidation of a number of treaties has been approved, and the new treaty should have the advantage of comparative simplicity and clarity. If nothing else had been accomplished, many nations believe that this result justifies the conference.

(4) The control of the production of drug raw materials has been established. Profiting by the lessons learned from the failure of the 1953 protocol, the conference did not take a large step in this area; but the measures which were adopted seem much more likely to enter into force than the more ambitious measures promoted in the 1950's.

On the other side of the ledger there are some reasons for concern about the conference and the convention which it adopted:

(1) If, for any reason, many states or a few key states fail to ratify the Single Convention, its value will be considerably depreciated. If the convention does not, in fact, become the *single* instrument in the field, it will simply be one more of many narcotics treaties, adhered to by some, perhaps even by many states, but only complicating an already confused regulatory picture.

(2) Political considerations made it impossible for the Chinese Communist government, *inter alia*, to attend the conference, and will make it difficult for that regime to become a party to the new treaty. The conference majority preferred not to try to solve the China question by opening the convention to any state (Peking will have to be invited to become a party by ECOSOC). However, the exclusion of mainland China may not help the cause of narcotics regulation; although opium production in China is illegal, that country was for many years one of the world's largest producers and there has been considerable evidence before the commission that a huge amount of opium is still produced in China and that it finds its way into illicit traffic on a vast scale.[41]

(3) There are, in addition, a number of weaknesses in the convention. They may be the product of necessity, but in view of the high hopes of so many for a more vigorous treaty, the end product may seem disappointing in its restraint and in what it reveals of the unwillingness of sovereign states to sacrifice real or imagined advantages in order to stop the drug traffic and drug addiction.

A spirit of compromise pervaded the conference, and the Single Convention shows it. Almost without exception, the compromising was done by those who preferred a more stringent treaty. However, most states found themselves in favor of more onerous requirements in some areas and of more lenient provisions in others, with the result that virtually all states had to yield at some point in order to achieve an acceptable convention. Consequently, although the Single Convention may not be an ideal instrument, it is a practical instrument which is the product of a broad consensus. It has an excellent chance of wide acceptance and entry into force at an early date. **[The End]**

[41] For discussion of opium production in China, see UN Doc. E/CN.7/211 (1950); UN Doc. E/CN.7/232/Add.2 (1952); UN Doc. E/CN.7/SR. 181 and 182 (1952); ECOSOC, OR: 30th Sess., Suppl. No. 9 (1960), paragraphs 93-121.

# The Cranberry Scare and Cabinet Immunity

By EDWARD L. SMITH

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A SINGLE PUBLIC WARNING by the Secretary of Health, Education, and Welfare caused millions of dollars in damages in 1959 to the nation's cranberry growers.[1]

Less than three weeks before Thanksgiving Day, Secretary Arthur S. Flemming warned housewives that part of the cranberry crop was contaminated with aminotriazole, a weed killer that has induced cancer in rats.[2]

As it turned out, most of the crop was "clean,"[3] but the announcement had a devastating effect on the cranberry business. In many homes the custom of serving cranberries with Thanksgiving turkey gave way to serving applesauce or cherries on the side instead. The industry reported that its retail sales dropped 67 per cent from Thanksgiving sales in previous years.[4]

[1] Statement by National Cranberry Institute in Boston, Massachusetts, December 21, 1959, *New York Times,* December 22, 1959, p. 35, col. 1.

[2] Statement by Arthur S. Flemming, Secretary of Health, Education, and Welfare, at a news conference, Washington, D. C., November 9, 1959, 2 CCH FOOD DRUG COSMETIC LAW REPORTS ¶ 7532 (1959).

[3] Secretary Flemming reported that 33,600,000 pounds of cranberries tested were free of contamination, and only 325,800 pounds were contaminated, *Hearings before the House Committee on Interstate and Foreign Commerce,* H. R. 7624, 86th Cong., 2d Sess., p. 68 (1960).

[4] Statement by Ambrose E. Stevens, executive vice president, National Cranberry Institute, in Washington, D. C., quoted in Associated Press dispatch, December 9, 1959.

The cranberry warning set off protests from several quarters, among them the cranberry growers,[5] the *New York Times*,[6] and even the American Medical Association.[7] Eventually the Eisenhower administration came to the rescue, announcing that it would pay $10 million for losses suffered by growers of unsold—and uncontaminated—cranberries.[8]

This voluntary government indemnity was the only compensation the innocent cranberry growers could have collected for their damages. They had no recourse through any legal action.

Persons who are damaged by an administrative act have two possible sources of compensation: (1) the officer whose act caused the injury, and (2) the government, on whose behalf the act was done.[9]

In the case of the cranberry warning, the government was immune, by specific exemption of the Federal Tort Claims Act. This immunity under the act covers acts done in executing a statute or regulation, even if invalid, or for acts within any federal agency's or employee's "discretionary function or duty . . . whether or not the discretion involved be abused."[10]

The cranberry growers had no recourse by legal action against Secretary Flemming, either. The Secretary was clearly authorized by statute to issue the public warning in a situation in which he believed there was "imminent danger" to the public.[11] In addition, a cabinet officer is immune from any tort liability as long as he acts within his "duties and functions"—even if he intentionally injures an innocent party out of spite or malice.[12]

Such immunity leaves the door open to possible abuse of power by the Secretary—in this instance the power to "regulate by press release." This raises a question: Is it better to risk abuse of such power than to limit it through the threat of possible liability to the Secretary?

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[5] Statement by Ambrose E. Stevens, in Washington, D. C., November 9, 1959, *New York Times*, November 10, 1959, p. 34, col. 1.

[6] *New York Times*, November 14, 1959, p. 20, col. 2.

[7] *American Medical Association Journal*, January 2, 1960, p. 62.

[8] *New York Times*, March 31, 1960, p. 1, col. 8.

[9] Schwartz, *An Introduction to American Administrative Law*, p. 208 (1958).

[10] 28 USC Sec. 2680(a) (1952).

[11] 52 Stat. 1058 (1938), 21 USC Sec. 375(b) (1958).

[12] *Spalding v. Vilas*, 161 U. S. 483 (1896).

The Secretary's authority to issue press releases comes from specific authority in the Federal Food, Drug, and Cosmetic Act,[13] and from accepted practice.[14]

The FDCA provides that the Secretary "may . . . cause to be disseminated information regarding food, drugs, devices or cosmetics in situations involving, in the opinion of the Secretary, imminent danger or gross deception of the consumer." [15]

A Senate report during consideration of the FDCA bill explained that the Act would give the Secretary "specific authority" to disseminate information,[16] an implication that he already had the authority by accepted usage.

In addition, the single court ruling on the publicity provision of the FDCA noted that "the only purpose of this statute is to place within the express scope of the duties of the Secretary something that was one of his implied functions." [17]

There was no way the cranberry producers could have prevented the Secretary from issuing the public cranberry warning, or any other press release, under this authority. It would not have mattered how defamatory his statement was or how flimsy his reasons for issuing it.

As a general rule, defamation will not be enjoined.[18] The court in *Hoxsey Cancer Clinic v. Folsom*, dealing with a public release by the Secretary of Health, Education, and Welfare, noted that "equity does not enjoin a libel or slander." It ruled that the remedy—if any—was an action for damages.[19] In *Hoxsey* the proprietor of a cancer clinic sought to stop the Secretary from issuing public notices that warned that the clinic's treatment for cancer was "worthless." The proprietor argued that there had been no notice or hearing prior to distribution of the circulars.

But the court refused to issue an injunction. It held that the Secretary can issue public warnings without notice or hearing, and that this will not violate the Constitutional right of due process. The

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[13] See footnote 11.

[14] "The practice of cabinet officers to issue public statements in respect to the activity of their departments is too well-known to require comment. Indeed, such announcements serve a useful if not essential role in the functioning of the democratic processes of government." *Glass v. Ickes*, 117 F. 2d 273 (CA of DC, 1940).

[15] See footnote 11.

[16] Quoted in Dunn, *Federal Food, Drug, and Cosmetic Act*, p. 265 (1938).

[17] *Hoxsey Cancer Clinic v. Folsom*, CCH FOOD DRUG COSMETIC LAW REPORTS ¶ 7417, 155 F. Supp. 376 (DC D of C, 1957).

[18] Prosser, *Torts* 573 (2d Ed., 1955).

[19] *Hoxsey Cancer Clinic v. Folsom*, cited at footnote 17, at p. 378.

court reasoned that issuing a public warning differs from issuing an order or directive, or from adjudicating rights:

"What [the Secretary and the chief of his Food and Drug Administration] are doing is disseminating information and warning the public against the use of certain medicines and of a certain treatment for internal cancer. This is no basis for requiring a hearing before information can be disseminated." [20]

The *Hoxsey* court made the correct decision,[21] but its reasoning was faulty. A public warning can have just as severe an impact as an order or directive. Certainly, the effect of the cranberry warning on the cranberry business was just as severe as a directive or order would have been to seize all cranberries on the market.[22]

Nevertheless, there is a sound basis for permitting the Secretary to issue public warnings of "imminent danger" without first holding a hearing or giving notice.

The purpose of warnings of "imminent danger" is the same as the purpose of seizure or destruction of property in emergency by public health officers—the protection of the public health. And destruction of property in emergencies without prior hearing has been upheld by the Supreme Court:

"[A] hearing before seizure and condemnation and destruction of food which is unwholesome and unfit for use is not necessary . . . [I]t is proper to provide that food which is unfit for human consumption should be summarily seized and destroyed to prevent the danger which would arise from eating it." [23]

Congress has, in fact, given the Secretary power to seize misbranded goods under a more lenient test than that of "imminent danger"; the FDCA provides that he may seize misbranded goods without hearing if he has "probable cause to believe . . . that the misbranded article is dangerous to health or that the labeling of the misbranded article is fraudulent or would be in a material respect misleading to the injury or damage of the purchaser or consumer." [24]

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[20] See case cited at footnote 17, at p. 378.

[21] See Christopher, *Constitutional Questions in Food and Drug Laws*, p. 32 (1960).

[22] See Grossman and Hart, "Food, Drug and Cosmetic Law," in *1959 Annual Survey of American Law*, p. 222-223 (1960). It should be noted in this connection that the cranberry warning was followed up by a program by the government and the industry to seize and test cranberries for contamination. See footnote 3.

[23] *North American Cold Storage Company v. Chicago*, 211 U. S. 306 (1908).

[24] 52 Stat. 1044 (1938), 21 USC 304(a) (1958).

This broad provision was upheld by the Supreme Court on the ground that "we cannot say that due process requires [a hearing] at this stage." [25]

Judging from Congress's reaction to the cranberry warning, it clearly intended Secretary Flemming to act as he did. On the floor of Congress, members made only scattered references to the incident, and only a few articles, letters, editorials and other comments—pro and con—were inserted in the *Congressional Record*.[26]

Secretary Flemming testified about the cranberry warning and its effects before two House committees. In both instances, Congressmen questioned him respectfully and sought information; none made any effort to vilify him or to question his authority to issue the warning.[27]

The Secretary submitted to both committees a full report of the events that led to the warning, and defended his authority and his obligation to make the warning.

His most detailed defense was to questions submitted to him by Representative Fred Marshall of Minnesota, a member of the House Committee on Appropriations. The Secretary explained the purpose of the public warning:

"[T]here is much precedent for protection of the public health by the Government, including use of public warnings where necessary. Indeed, the Government has no right to withhold from its citizens information about situations or products which may endanger the public health. Certainly it is the public policy as set down in the Federal Food, Drug, and Cosmetic Act that consumers are to be protected from harmful (and, since 1958, even inadequately tested) contaminants of food . . . .

"The Food and Drug Administration has on many occasions gone to the news media with public warnings about products on the market which have been found to constitute a danger to health . . . . Usually

[25] *Ewing v. Mytinger & Casselberry, Inc.*, CCH FOOD DRUG COSMETIC LAW REPORTS ¶ 7156, 70 S. Ct. 870, 339 U. S. 594 (1950).

[26] 106 *Congressional Record* A147 (Daily Edition January 11, 1960), A341-343 (Daily Edition, January 13, 1960), A622 (Daily Edition, January 25, 1960), 1670 (Daily Edition, February 2, 1960), 2076 and A1014-1015 (Daily Edition, February 8, 1960).

[27] *Hearings before the Subcommittee on Departments of Labor and Health, Education and Welfare and Related Agencies of the House Committee on Appropriations*, 86th Cong., 2d Sess. 165-190, 777 (1960); *Hearings before the House Committee on Interstate and Foreign Commerce*, 86th Cong., 2d Sess., H. R. 7624, 63-69 (1960).

only a single firm or product, or at most a few firms, is involved. The economic impact of such a warning on the firms or products involved is necessarily severe. The cranberry episode differs only in that here almost an entire industry was affected . . . ." [28]

In testimony before the House Committee on Interstate and Foreign Commerce, the Secretary justified the injury of innocent cranberry growers:

"[T]here is one thing that a responsible government cannot do. It cannot fail to place at the top of its list of priorities the health of all of the people even though by so doing it may be or may appear to be acting against the economic interests of a segment of our society." [29] More specifically, he argued that "the innocent consumer should not be made the victim . . . in order to protect the innocent producer." [30]

He also defended issuing the warning at the height of the cranberry marketing season. The Secretary said it had been issued as soon as contaminated cranberries had been discovered:

"The timing of the announcement was governed by the factual situation completely beyond our control. It is obvious that the public could not be protected from contaminated cranberries if action were deferred until the cranberries had already been consumed." [31]

Congress, then, gave no indication that it considered the cranberry warning an act beyond the powers it had delegated to the Secretary. In fact, seven months after the warning was issued, Congress re-affirmed the Secretary's power to issue such public warnings. It passed the Federal Hazardous Substances Act.

This act contains a publicity provision practically identical to the publicity provision in the FDCA; the Hazardous Substances Act authorizes the Secretary to disseminate information about hazardous substances "involving, in the opinion of the Secretary, imminent danger to health." [32] The provision went through Congress as originally drafted, apparently without discussion.[33]

Thus, the Secretary is free to issue public warnings, but he also is immune against dangers for damages for injuries caused by the warnings. The Supreme Court ruled in 1896, in the landmark case of

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[28] *Hearings before Subcommittee of the House Committee on Appropriations,* cited at footnote 27, at pp. 168-171.

[29] *Hearings before House Committee on Interstate and Foreign Commerce,* cited at footnote 27, at pp. 168-171.

[30] See footnote 29.

[31] See footnote 29.

[32] 74 Stat. 379 (1960).

[33] S. Rept. 1158, 86th Cong., 2d Sess. 9, 13 (1960); H. Rept. 1861, 86th Cong., 2d Sess. 12 (1960).

*Spalding v. Vilas*, that cabinet officers are not liable for defamation in their "official communications . . . in the discharge of duties imposed upon them by law." [34] Otherwise, the Court said, effective administration would be seriously crippled by fear of liability.

*Spalding* held that this immunity applied regardless of the officer's motive, because "personal motives cannot be imputed to duly-authorized conduct." [35]

Prior to *Spalding*, executive officers were held immune from tort liability for acts of discretion only if the acts were made in good faith. Acts made maliciously were not protected,[36] but an exception had been made that judges were immune to civil liability for errors in their judicial actions, regardless of motive,[37] and *Spalding* was based on this exception.[38]

*Spalding* involved not a public release but a circular sent to postmasters by the Postmaster General. He was sued for libel because of the contents of the circular; the Supreme Court held that in issuing the circular he was clearly within his discretionary authority.

*Spalding* involved a departmental communication, but it was extended by the federal courts to cover public statements by cabinet officers.[39] It was the basis of a long line of federal decisions which extended the cover of immunity to federal officials far below cabinet rank.[40]

Despite the large number of decisions based on *Spalding*, it was more than 60 years before the Supreme Court itself passed again on the rule of the case. Then, in 1959, only a few months before the cranberry warning was issued, the court upheld the entire line of cases that extended immunity, in the companion cases of *Barr v. Matteo* [41] and *Howard v. Lyons*.[42]

*Barr* involved a press release by an acting director of the Office of Rent Stabilization; *Howard* involved a press release by the commander of the Naval Shipyard in Boston. In both cases the United

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[34] Work cited at footnote 33, at p. 498.

[35] See footnote 34.

[36] "[I]t is not enough to show he committed an error in judgment, but it must have been a malicious and willful error." *Wilkes v. Dinsman*, 48 U. S. 266 (1849); *Kendall v. Stokes*, 44 U. S. 87 (1845); *White v. Nicholls*, 44 U. S. 266 (1845).

[37] *Bradley v. Fisher*, 80 U. S. 335 (1872).

[38] See case cited at footnote 37 at pp. 493, 498.

[39] See case cited at footnote 14; *Mellon v. Brewer*, 18 F. 2d 168 (CA of DC, 1927); *Standard Nut Margarine Company v. Mellon*, 72 F. 2d 557 (CA of DC, 1934).

[40] Cases are collected in Handler and Klein, "Defense of Privilege in Defamation Suits Against Government Executive Officials," 74 *Harvard Law Review* 44 (1960).

[41] 360 U. S. 564.

[42] 360 U. S. 593.

States Court of Appeals had held the officials liable for statements they had made in the releases.[43]

The Supreme Court, however, held that they were immune to actions for libel, on the ground that government officials have immunity from any tort liability that results from "action taken in the exercise of their official responsibilities"—even if the action is malicious.[44]

Some judges have gone along only reluctantly with this rule of immunity, fearing this liberal extension of immunity to officials below cabinet rank. One judge argued that the rule may have "unwittingly created a privilege so extensive as to be almost unlimited and altogether subversive of the fundamental principle that no man in this country is so high that he is above the law." [45] There is no question that the rule is presently valid. Certainly, there has been even less objection to immunity for cabinet officers.

The Secretary clearly cannot be held liable for the effects of his public warnings, provided they are within his "duties and functions." And even if his acts exceed these "duties and functions" he will receive the benefit of the doubt in borderline cases. The Supreme Court indicated as much in *Spalding*:

"[W]e recognize a distinction between action taken by the head of a department in reference to matters which are manifestly or palpably beyond his authority, and actions having more or less connection with the general matters committed by law to his control or supervision." [46]

Judge Learned Hand set the limits of immunity protection this way: "What is meant by saying that the officer must be acting within his power cannot be more than that the occasion must be such as would have justified the act, if he had been using his power for any of the purposes on whose account it was vested in him." [47]

Simply because the Secretary has this broad, absolute privilege does not mean he will abuse it, however. There are other safeguards.

He is, after all, a cabinet officer appointed by the President. Although considerations other than caliber are important in choosing

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[43] *Barr v. Matteo*, 244 F. 2d 767 (CA of DC, 1957); *Lyons v. Howard*, 250 F. 2d 912 (CA-1, 1958).

[44] *Barr v. Matteo*, cited at footnote 43.

[45] Concurring opinion of Chief Justice Groner, *Glass v. Ickes*, cited at footnote 14. See, also, dissent of Brennan, J., in *Barr v. Matteo*, cited at footnote 43, that "even if *Spalding v. Vilas* . . . allows a cabinet officer the defense of an absolute privilege in defamation suits I see no warrant for extending its doctrine to the extent done."

[46] *Spalding v. Vilas*, cited at footnote 12, at p. 498.

[47] *Gregoire v. Biddle*, 177 F. 2d 579 CA-2, 1949).

cabinet officers, in recent years the choice has been based increasingly on ability and qualifications—the officers' "special knowledge and experience over the matters with which their departments deal." [48]

In addition, the Secretary is a politician, and politicians are sensitive to the pressures of interest groups and other politicians.[49] There are also the seldom-invoked limitations of "last resort"—the power of removal by the President,[50] and impeachment.[51]

Secretary Flemming's cranberry warning seems particularly noteworthy since he must have anticipated that it would trigger a storm of criticism—criticism that could only hurt him politically. As the *Wall Street Journal* commented:

"There is a saying going around Washington these days: If Secretary Flemming of the Department of Health, Education, and Welfare had any political ambitions, his goose is cooked in cranberry sauce." [52]

The *Spalding* rule has been criticized by some who would go back to the "good faith" test of immunity, rather than follow the "across-the-board" immunity of *Spalding*.[53] But the danger to the public is less that the Secretary will abuse this privilege than the danger that he will become overly cautious about issuing public warnings, because of consequences that would harm him politically.[54]

The solution is for the government to compensate those innocent parties who are injured by the effect of public warnings or by other discretionary acts of executive officers. Responsible officials seeking to protect the public should not be hobbled. "When the public gets the benefit of a program, the public should pay for the torts that may be expected in carrying out the program." [55] **[The End]**

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[48] Young, Ogg and Ray's, *Introduction to American Government*, p. 333 (11th Ed., 1956). See, also, Fenno, *The President's Cabinet*, p. 53 (1959).

[49] See Truman, *The Governmental Process*, p. 405 (1951).

[50] *Myers v. U. S.*, 272 U. S. 52 (1926).

[51] U. S. Constitution, Art. II, Sec. 4.

[52] *Wall Street Journal*, November 17, 1959, p. 18, col. 1.

[53] See Handler and Klein, cited at footnote 40, at pp. 64-69, for proposal of a "due-care" privilege that would apply when the official had a reasonable belief that the statement was true and publication justified. See, also, discussion of *Barr v. Matteo* in Schwartz, "Administrative Law," *1959 Annual Survey of American* Law, pp. 108-110 (1960).

[54] Truman, work cited at footnote 49, at pp. 409-410 that "a department head or a chief executive may find in standing aloof from some policy conflicts a higher expediency than in committing his full resources to achieving a dominant position."

[55] Davis, 3 *Administrative Law* Sec. 26.07 (1958).

# Food and Drug Administration Problems from the Laboratory Viewpoint

By JOHN L. HARVEY

This Paper Was Delivered Before the Armed Forces Institute of Pathology, Military Environmental Pathology Division, Washington, D. C., in March, 1961. John L. Harvey Is Deputy Commissioner, Food and Drug Administration, United States Department of Health, Education, and Welfare.

THE FACTS ARE CLEAR that there is more than one drug manufacturer in this country who specializes in making replicas of well-known and well-advertised drugs. Without the development and advertising costs, these companies are able to undersell the genuine article. They have been able to find a ready market for their counterfeit article. This problem has many facets—social, economic, ethical and law enforcement. From the regulatory standpoint our position is that many of these counterfeit drugs, which are not manufactured under the strict controls which are imposed on the genuine article, are potentially dangerous and illegal. A description of our activities in this program would in itself be a fascinating story but would not be apropos to our subject. The part of this story that is pertinent is how we determine which drugs are counterfeit; how we identify the manufacturers of the nongenuine article. Obviously, we are not afforded full cooperation in getting the complete facts, as the manufacturer is quite deliberately trying to duplicate another article in size, shape and composition.

The method used is a "ballistic" method not unlike, in some respects, the identification of a particular gun having fired a recovered bullet. It includes a systematic comparison of unknown tablets and capsules with authentic samples from known manufacturing sources along with a program for keeping such a collection up-to-date. The

criteria for identification may be better understood after a brief description of drug tablet manufacture.

After compounding and mixing, drug tablets are formed by tablet presses which operate at pressures up to three tons per square inch between two punches in a die. The simplest type of tablet press is the single-place machine which has only one pair of punches. The granulation is fed into the die and compressed as the upper and lower punches come together. Any deviation of the punch faces from a smooth flat surface is shown in reverse on the surfaces of the tablets. Most manufacturers who produce tablets in large volume use rotary presses having 16 pairs or more of punches, each pair operating like a single-place machine.

Many different types of punches are used in tablet manufacture. Their outline may be round, oval, rectangular, triangular, heart-shaped, etc. The faces of the punches may be flat, concave or convex; they may be unscored, single-scored, double-scored or monogrammed; the edges may produce a flat-bevel, round bevel or no bevel at all. Each of these types includes variations, such as the degree of curvature of the concave or convex faces, bevel angle, groove or score angle, width and depth of groove, etc. To complicate the matter further, upper and lower punches may be combined in various ways.

The first step in tablet identification is the examination of the tablets for these "gross punch marks," usually without magnification. This examination includes the measurement of tablet diameter and thickness, tablet weight, the determination of tablet shape, color, type of score marks, bevels and surface (flat, concave or convex), presence of monograms, or other identifying characteristics.

The second step is the examination of the tablets under a low-power microscope (10 X) to detect minute punch marks on the surfaces. Punches, even when new, show various characteristic microscopic marks that can be used to differentiate them. As the punches are used they develop other characteristic shapes, marks or imperfections that are impressed into the tablets and positively identify a tablet with a given manufacturer's punch, just as fingerprints identify a human being.

Rough handling of the punches may cause characteristic scratches, pits and ridges on the punches, which are matched in reverse on the tablets. Sometimes the upper and lower punches hit together with no granulation between them; this damages the punches, usually by flattening the score marks of the upper punches and correspondingly

denting or scoring the lower punches. This may happen to only one of the punches of the set or to all of them. The extent and character of these imperfections depend on what types of punches are used, how much of the punch surfaces hit together, whether the punches rotate before hitting again, or other factors.

If the punches fit loosely into the die, some of the granulation is squeezed into the gap between the punch and die as the material is compresseed, and a ridge forms at the tablet edges. Sometimes punches are not highly polished when they are made or when they are reworked, and the marks of the grinding wheel or file are left on the punches and show up on the tablets as straight or variously curved striations.

By mounting a tablet so that a silhouette of the tablet is projected or by mounting the tablet under a microscope with the groove vertical, the width and depth of the groove or score mark and the groove angle can be measured.

The punch marks detected and measured on the tablets in question can then be compared with punch marks of tablets of known manufacture.

The final step in tablet identification is determination of the ingredients and study of their microscopic habit by the optical-crystallographic method. Each crystalline compound has its own set of peculiar and specific optical properties that serve to identify and differentiate it from all other compounds. These properties, which include refractive indices, extinction angle, sign of elongation, topic sign and axial angle, may be determined for each crystalline substance present by mounting a portion of the crushed tablet in a liquid of suitable refractive index and examing it under a polarizing microscope with polarized light. The results of this microscopic analysis are then compared with the results of a similar microscopic analysis of tablets of known manufacture, and to the manufacturer's formula.

By making these comparisons of gross and microscopic punch marks, and identity and microscopic habits of ingredients of the tablets in question with those of tablets of known manufacture the manufacturer of tablets of unknown origin can be determined.

Capsule identification proceeds in somewhat the same way. It is more difficult than tablet identification, however, because there are fewer external characteristics than can be used, and capsules usually contain fewer ingredients. The capsule size, shape, color and weight

are determined, and any characteristic markings are observed. Some manufacturers use special shapes; others have monograms molded into the capsule; still others print a name or monogram on their capsules. In the case of time-disintegration capsules, the external characteristics of the pellets are determined, such as glossiness, colors, size, shape, mottling of color pattern, and lumpiness of surface. All of these characteristics, as well as microscopic habit and identity of ingredients, are utilized in the identification of drug capsules.

We have been unusually successful in determining by these methods, the manufacturing source of many drug products. Some particular lots have resisted identification for a while, but eventually a telltale mark or ingredient will furnish the clue we need.

Let us turn now to a more tasty subject—fresh frozen foods. This industry, although a normal practice by the Eskimos, has only been in existence as a commercial entity some 30 years.

The freezing preservation of foods—first begun with fish and later extended to vegetables, berries, fruits, and other foods—has created whole new industries engaged in the manufacture, warehousing, distribution, and retail sale of products that approach fresh foods in taste, nutritional quality and eye appeal. Although these foods require cooking by the consumer similar to that required for fresh foods, they offer great convenience to the housewife as they are readily stored, offer a minimum of waste and preparation, and permit the use of seasonable products at "out of season" times of the year.

One of the most interesting developments in the frozen food industry—and perhaps an expected outgrowth considering the eager acceptance of such convenience foods—has been the emergence of frozen precooked foods requiring the consumer to do little more than heat and serve complete meals from packages stored in a freezer. The production of frozen precooked foods has substituted the manufacturing plant for the kitchen of the consumer and in so doing has shifted the quality control of the food from the housewife to the manufacturer. She must accept on faith that such products are prepared from clean, sound and wholesome raw materials and that the food is mixed, compounded, prepared and packaged under sanitary conditions at least comparable to those prevailing in her own kitchen. It is the responsibility of the Food and Drug Administration to insure that this expectation of the consumer is fulfilled.

The laboratory problems which needed solving in order to carry out this responsibility were to develop bacteriological methods and

criteria in order to (if possible) objectively judge from the examination of a sample of a frozen food whether such reasonable standards of sanitation had been met during the manufacturing process. Some of the variables will be readily apparent—the bacteriological flora of the raw materials as well as the kind of ingredients used; the cleanliness of the tables, dishes and utensils used in the preparation; the personal hygiene of the employees; the times and temperatures involved from both a bacteriacidal and an incubating aspect; and storage and distributing practices that sometimes involve significant temperature changes.

Based on our own experience plus the experiences of other interested state and local enforcement agencies, the following selection of determinations was made which it was felt might be the most helpful.

(1) The aerobic plate count: This will fluctuate with production processes and sanitation control and may be considered a rough index of general sanitation.

(2) The MPN (most probable number) of coliform organisms. This group is considered to be more directly associated with plant and employee sanitation than is the aerobic plate count. The coliform group is widely used as a criterion of the potability of water; however, caution must be exercised in extending considerations applicable to water supplies directly to foods until their true significance in foods has been established. Coliform bacteria are readily destroyed by heat such as the cooking processes utilized in preparing many of the ingredients used in frozen precooked foods. Hence, their presence may mean inadequate cooking, recontamination after cooking, and, occasionally, the addition of uncooked materials such as natural cheese, egg products, flour, etc., to the cooked product.

(3) The MPN (most probable number) of fecal *Escherichia coli:* As a natural inhabitant of the intestines of man and warm-blooded animals, *E. coli* is generally regarded as a more specific indication of fecal pollution than other members of the coliform group. Although *E. coli* may also be found as a contaminant in some material ingredients of frozen foods, its isolation from precooked foods in association with observed instanitary production practices is regarded as significant.

(4) Coagulase-positive staphylococci: One of the criteria of potential enterotoxigenicity of staphylococci is the coagulation of plasma by the organism. The isolation of appreciable numbers of coagulase-positive strains of staphylococci from a food product is a matter of

concern since the product may be, or could readily become, a hazard to the public health. Since the elaboration of enterotoxin by staphylococci depends upon favorable temperature conditions and the toxin is heat-stable when formed, it is clear that the sanitary practices and temperature-time relationships involved in food production must be carefully evaluated.

We then tested our selection by applying them to some 3,000 samples collected from 63 frozen food plants from March, 1958 to June, 1959. Teams of an experienced inspector and a bacteriologist made comprehensive inspections, observing and recording the variables mentioned plus much other relevant data. They also collected samples of raw materials, line samples of products "in-process" and samples of finished materials. The listed tests were then applied.

We found no firm relationship between plant conditions and the bacteriological flora of the final product. Generally, it appears from these data that while the aerobic plate count varies with production processes it does serve as a rough guide to plant sanitation. Plate counts and coliform content are related to equipment cleanliness and to time and temperature of holding periods. *E. coli* findings are related to personnel contamination which may be accentuated by holding the product for excessive periods without adequate refrigeration. In products containing raw natural cheeses or uncooked eggs, coliforms, including *E. coli*, will occur frequently. The finding of coagulase positive staphylococci is usually related to employee contamination of the product during an operation requiring a great deal of handling. The deboning of poultry and dicing of the meat are examples of operations often leading to staphylococci contamination. Products containing a natural cheese often show a low incidence of coagulase positive staphylococci.

We can further conclude that until much more data is accumulated, laboratory examination of frozen food products is essential but tht final evaluation from a regulatory standpoint will still depend on factory inspection observations and the subjective approach.

One of the most perplexing scientific problems now confronting the Food and Drug Administration deals with what is called the "chick edema factor."

The problem was first of theoretical interest only. It was reported to us about five years ago that cooking fat from roadside "hamburger joints" where it was kept at relatively high temperature for long periods, was toxic to laboratory rats. Our knowledge of commercial deep fat frying operations in food factories did not indicate compa-

rable conditions to roadside restaurants. The information, therefore, added to our knowledge of toxic fats but no regulatory significance was recognized. Because the literature disclosed some suspicion that heated fats might be carcinogenic, and because of general scientific interest, our scientists did conduct some studies. They heated cottonseed oil for some 300 hours in the presence of air, and saponified the tarry residue. The liberated fatty acids were esterified and molecularly distilled into a monomeric fraction, a dimeric fraction and a residue called "higher polymers." Animal feeding tests showed the residue innocuous and the dimeric fraction highly toxic. The monomeric fraction, which was present in the greatest amount, was further separated into an "urea adduct" and an "urea filtrate" fraction by taking advantage of the property of urea to form complexes with normal straight chain fatty acids and esters, precipitating them from an alcoholic solution saturated with urea. The urea adducting material was found innocuous; the filtrate toxic.

We had reached this stage of consideration of the heated fat problem in 1957, when a spectacular event diverted our interests. Flocks of chickens in the midwest started developing alarming mortality due to what was called "chick edema." Characteristic symptoms of the disease are the presence of excessive fluid in the pericardial sac, in the abdominal cavity, and occasionally subcutaneously. Mortality begins in approximately the third week. At the time we began investigating, it was estimated that a million chickens had been affected and it was already established that fat incorporated in the feed was responsible.

The incorporation of fat into chicken feed is a relatively new development in the feed business and was introduced on the basis of studies which demonstrated its advantages in terms of weight gains per unit of cost. The studies, however, did not contemplate the fat source that was finally developed to be the source here! Fatty acids are used in very large quantities in industrial operations in the manufacture of lubricants, rubber, asphalt, roofing, chemicals and foods. Relatively low grade fats are catalytically split into fatty acids and glycerol at high temperatures and pressures, and the glycerol is recovered. The fatty acids are distilled under vacuum and the first distillate is used directly as the highest grade of mixed fatty acids, or it may be separated by a crystallization process into stearic and oleic acids. The residue from this distillation is resplit and redistilled and the second distillate yields a lower grade of fatty acid. The second residue is

usually good only for highways or tires but occasionally it is again recycled to obtain a third distillate and residue. The supplier of the fat component of the chicken feed we were investigating had in fact gone through the third cycle and had found an outlet for a large quantity of the products from this third operation. The fatty acid splitter and the feed formulator, neither of whom thought it necessary to test the addition of this product to chicken feed, both recently pleaded guilty to a violation of the Federal Food, Drug, and Cosmetic Act and were fined $1,000 each.

As soon as the causative agent was identified we recognized that we were dealing with a special case of the toxicity of overheated fats. We were able to obtain a sample of the implicated feed and the fat residue component. The residue component was found to contain 88 per cent free fatty acids and about 11 per cent unsaponifiable residue. The acids were treated with urea and feeding tests were made on the three fractions. The urea adduct was found innocuous: the urea filtrate toxic to rats but not to chickens. The unsaponifiable fraction produced pronounced edema symptoms—we had roughly separated the "chick edema factor."

By alumma column chromatography we have made further progress. By applying this technique to quantities of the unsaponifiable material we obtained three distinct fractions. The first was characterized as mixed hydrocarbons and was eluted with petroleum ether alone. When the elution reached a constant minimum with petroleum ether the solvent was made more polar with 25 per cent ethyl ether and a second fraction was eluted which was characterized as ketonic. The third and final fraction was eluted with ethyl ether and consisted of the steroids and oxidized materials. The toxic factor was now found in the ketonic fraction.

Although the original fat residue was now exhausted, a fresh supply was obtained from an unexpected source. We learned that a monkey study being performed at Harvard University utilizing a synthetic fat, triolein, had to be abandoned because the animals died and 40 pounds of the synthetic fat remained. We found the triolein contained the "chick edema factor." We started again. Concentrating on the ketonic fraction of the unsaponifiable material, and by repeated and delicate chromatographic treatment, our chemists obtained 2.64 mgs. of white crystals of unknown composition but definitely the "chick edema factor." This material fed at 1 ppm in the diet killed chickens in 21 days; at 0.1 ppm very definite edema was present at autopsy

after 21 days. Almost coincidental with our isolation, Merck & Company also announced isolation of the factor. Although not absolutely identical, it is evident that each had independently been successful in a difficult task. Merck & Company additionally reported that their product contained chlorine, an ingredient not expected. Our product also contained chlorine.

So we are now trying to determine more of the secrets of the "chick edema factor." Are chlorinated hydrocarbons used as pesticides responsible? Is the bleaching of tallow by active chlorine materials involved? Do we have a situation similar to the outbreak of hyperkeritosis of several years ago involving chlorinated napthalenes which entered animal feeds through lubricating grease? Only further research will tell.

In the meantime, and to emphasize the problem, another outbreak of chick edema occurred in Georgia in October of last year. Fat is again implicated but this time it is rendered fat, not distilled fatty acids. This may change some of our tentative conclusions that the distillation process was the source of the toxic factor. Maybe we are back to the dark brown fat in Joe's Diner again.

Now I would like to combine several major problems dealing with the development of precise analytical methods into one item for discussion with you. The Food, Drug, and Cosmetic Act has a number of different parts which carry the responsibility of either the development of suitable analytical methods, or the checking of proposed methods. Inherent in our work as always is the responsibility of striving to improve existing methods in accuracy, precision, or that important commodity, time.

A firm seeking to market a "new drug," under the basic provision of the Food, Drug, and Cosmetic Act that requires adequate showing of safety for intended use must include an adequate assay method for a determination of the active component. A manufacturer who petitions for a tolerance deemed safe of a pesticide to be applied to an agricultural crop must also submit a method for its determination. So also must a manufacturer of a "food additive" submit a practical analytical method in order to obtain a regulation allowing the addition of the substance to the food supply. One might suspect then that our task is mainly clerical—copying the methods and having them readily available when a sample for examination presents itself. But, as this audience knows, methods are just not amenable to such casual treatment. They must be tested and retested, subjected to trial

by different people at different laboratories in order to develop the "kinks" and singularities that are a part of the evolution of a dependable method. Hence, our Washington and field laboratories are busy with that method testing for which no end is in sight. Also, of course, we have the problem of pesticides or food additives being used without prior approval, in which case there is many times no method to test but rather one to develop.

However, we are encouraged not at the magnitude of the task ahead which is challenging but not encouraging; but with the fact that we note a slowing down in how far we are falling behind. Through the combined efforts of all—industry as well as government, methods are being developed. Technical improvements are being made and with new tools we are doing things in the laboratory that were only dreamed of a few years ago. Spectrophotometry, refinements in column, paper and gas chromatography, and application of bio-assay methods to pesticides have all contributed to the development of needed methods. The latest tool which initially seems to have a real future in this and other food and drug work is the microcoulometric gas chromatographic apparatus. So, even if we never catch up, we hope never to fall too far behind.

We have two brand new problems—the final dimensions of which, like the universe, are not clear—but we know they are large. One is the methods testing and development work which will fall to us with full effectiveness of the color additive amendments of 1960 passed by the Congress last July. These amendments require the listing of nearly all color components of foods, drugs and cosmetics at levels demonstrated to be safe. This will call for the development of quantitative methods for color additives in a great variety of combinations and will involve in some instances real, complex problems. Again, as in food additives, methods will have to be furnished, but again, testing will be necessary and we must also be prepared to detect color additives for which appropriate regulations have not been obtained.

The other new problem is the Federal Hazardous Substances Labeling Act, also passed last July. This statute replaces the 1927 Caustic Poison Act which required warning labeling on 12 specific products. Although nearly adequate 30 years ago, this statute has long needed replacement for anywhere near adequate consumer protection. The Federal Hazardous Substances Labeling Act requires warning labeling on containers suitable or intended for household use whenever the contents might cause substantial illness or injury be-

cause they are toxic, flammable, corrosive, irritant, strongly sensitizing, or if it generates pressure through heat, decomposition or by other means. Chemical, physical and bio-assay testing will need to be developed in order to regulate the estimated 300,000 products that fall under this statute. We have every expectation that our efforts along with a great deal of voluntary efforts by the regulated industry, will have a real effect on the 600,000 injuries each year due to household hazardous substances of which 500 are said to result in death.

**[The End]**

## STANDARD OF IDENTITY FOR FROZEN RAW BREADED SHRIMP

The Food and Drug Administration recently published an industry proposal to adopt a definition and standard of identity for frozen raw breaded shrimp.

The National Fisheries Institute, Inc., Washington, D. C., and the National Shrimp Breaders Association, Inc., Chicago, jointly filed the proposal which FDA published in the *Federal Register*. All interested persons are invited to file their views and comments with the Hearing Clerk, Department of Health, Education, and Welfare, Room 5440, 330 Independence Avenue, S. W., Washington 25, D. C., by May 30, 1961.

The Federal Food, Drug, and Cosmetic Act requires that any standard adopted must be one that will promote honesty and fair dealing in the interest of the consumer.

The industry proposal would require that frozen raw breaded shrimp (prawns) contain not less than 50 per cent by weight of shrimp material, as determined by a specified method. The term "shrimp material" would mean the headed, peeled and deveined tail portion of a shrimp, with or without tail fin and the immediately adjacent shell segment. The shrimp material could be in either of the following optional forms: fantail or butterfly (deveined and split); round or round fantail (deveined but not split); butterfly, tail off (deveined and split, tail fin and shell segments removed); round, tail off (deveined but not split, tail and shell segments removed); and tidbits (parts of tail portions, but free of tail fin and shell segments).

The proposal also specifies the optional ingredients which could be used in preparation of batter and breading for coating of the shrimp material.

The name of the frozen breaded shrimp product prepared from each of the optional forms of shrimp material specified is listed in the proposal.

The proposal would also require the label to bear the name of the optional form of the food and a listing of the optional ingredients used in the preparation of the batter and breading. If a spice is used to impart a color, the label would have to declare it as both a spice and a coloring.

# The Federal Trade Commission and Food, Drug and Cosmetic Advertising

By SAMUEL L. WILLIAMS

**The Author, Chief Project Attorney of the Federal Trade Commission's Bureau of Investigation, Delivered This Talk Before the Maryland Pharmaceutical Association, Baltimore, at a Seminar Honoring Dr. Robert L. Swain on March 23, 1961.**

AT THE ONSET, let me thank this association and particularly its secretary, Mr. Joseph Cohen, for extending me an invitation to discuss a portion of the work of the Federal Trade Commission. I am here in the capacity of an employee and any opinion or conclusion I may express represents my own personal views and does not necessarily reflect the official view, opinion or policy of the Commission.

The Commission was established by Congress in 1914 as an independent regulatory agency of the federal government. It is a quasi-judicial body consisting of five commissioners appointed by the President and confirmed by the Senate for a period of seven years. No more than three commissioners may be members of the same political party. Since 1950, the President, by law, has designated a chairman from among the commissioners. As you doubtless know, this is a time of change and the President has just announced the appointment of a new chairman and two additional new commissioners. For the fiscal year 1961, Congress appropriated approximately $7.5 million to the Commission. As of the present time it employs about 800 persons, including some 300 attorneys. Its headquarters office is in Washington, but nearly 200 of its employees are located in ten field offices throughout the country.

The Federal Trade Commission Act, which established the Commission, declared illegal "unfair methods of competition in commerce" and directed the Commission to prevent such unfair methods of competition. The statute states that whenever the Commission has reason to believe that a person, partnership or corporation has been or is using any unfair method of competition or an unfair or deceptive act in commerce, it may issue a complaint stating its charges where it appears that such a proceeding would be in the public interest.

Congress has left to the Commission and the courts the power to define on a case-by-case basis what may be unfair methods of competition, or unfair or deceptive acts or practices. Under the statutes it administers, the Commission may prevent the use of false or misleading advertising concerning almost any product. Representations which may be prohibited include false and deceptive statements as to materials, ingredients, quality, purity, source, attributes or propriety, nature of manufacture, and former price. These have also included misrepresentation of therapeutic and corrective properties of medicinal preparations and devices and cosmetics, and the false misrepresentation expressly or by failure to disclose their potential harmfulness that such preparations may be safely used. The making of false and disparaging statements respecting a competitor's products and business —in some cases under the guise of appearing to be a disinterested and specially informed source or through purported scientific but, in fact, misleading demonstrations or tests—have been the subject of many proceedings. Other examples of practices prohibited are the passing off of goods for those of competitors through the appropriation, duplication or simulation of such competitors' trade names, labels and counter display catalogs.

The Commission was organized in March, 1915, and before the end of the year advertising clubs were urging it to take steps to suppress untrue advertising as an unfair method of competition. The first two cease and desist orders issued by the Commission prohibited the use of false and misleading advertising. Its first order prohibited deceptive advertising of a drug, and was issued in 1918. The first order reviewed by the courts involved a false and misleading advertising of food. The Supreme Court approved a cease and desist order involving deceptive advertising as early as 1922. It has been estimated that as early as 1925 orders involving false and misleading advertising constituted some 75 per cent of the total issued by the Commission annually.

During its early history, the Commission established literally hundreds of new landmarks in the field of unfair competition for industry guidance and consumer protection. However, 17 years passed before it found that it was without authority to prohibit advertising which misled the public even though there was no showing of competitive injury to truthful advertisers.

The Commission's enforcement efforts were seriously curtailed by the Supreme Court in the famous case of *FTC v. Raladam Company*, decided in 1931 (CCH TRADE REGULATION REPORTS (Supp. Vol. VI) ¶ 6307, 283 U. S. 643 (1931)). In this case, the Court held that the Commission could not prohibit false and misleading advertising of an obesity cure where there was no showing of substantial competition present or potential and no evidence that a competitor had been injured or threatened with substantial injury by false advertising. Seven years later, Congress passed the Wheeler-Lea amendment to the Federal Trade Commission Act. In 1938, it added the following words to Section 5 of the Federal Trade Commission Act "and unfair or deceptive acts or practices in commerce." The primary purpose of this amendment was to counteract the *Raladam* decision, but the Wheeler-Lea amendment was not limited to this purpose. To these amendments was also added Section 12 of the Federal Trade Commission Act declaring certain advertisements of foods, drugs, devices and cosmetics, unfair or deceptive acts or practices in commerce within the meaning of Section 5. Thus, the Commission was armed with additional weapons against the false advertising of these products. Under these provisions, the Commission may now proceed openly and directly against false and misleading advertising to protect the public against deception rather than attempt to accomplish this as an indirect instance of competitive protection. While the prohibition of Section 5 extends to all commodities including foods, drugs and cosmetics, the Wheeler-Lea amendment did not stop there. Section 12 of that amendment provides specifically that dissemination of false and misleading advertising for any such products constitutes an unfair or deceptive act or practice in violation of Section 5 if either the product or the advertisement itself moves in commerce.

An additional step was taken by adding Section 15. This section defines a false advertisement relating to foods, drugs, cosmetics and devices as an advertisement other than labeling which is misleading in a material respect. In determining whether advertising is false, the

Commission is directed to consider not only direct falsehood but, also, failure to reveal material facts respecting consequence resulting from the use of the product. It is under the authority of this provision that the Commission has required the inclusion of appropriate warning statements for potentially harmful products.

It was under Section 15 that the Commission considered the effect of an advertisement for a dietary supplement containing iron in the case of *Alberty v. FTC* (1950-1951 TRADE CASES ¶ 62,583, 182 F. 2d 36 (CA of D C)). The product involved was represented as being of value in the treatment of a number of vague symptoms, such as lassitude and fatigue. It was clearly shown that the product involved was of value in the treatment of these symptoms only in the case of iron deficiency and that the Commission could require that any advertising claims be so restricted. However, the Commission went a step further in its order to cease and desist and required the disclosure that the symptoms in question were in fact due less frequently to iron deficiency than to other causes. Upon appeal to the circuit court, the Commission's counsel argued that the order would do no more than require the disclosure of material fact within the intent of Section 15. The Court held that this portion of the order was invalid and stated in part:

"The Commission must find either of two things before it can require the affirmative clause complained of: (1) that failure to make such statement is misleading because of the consequences from the use of the product, or (2) that failure to make such statement is misleading because of the things claimed in the advertisement. There is no such finding here." (*Alberty*, cited above, at p. 39.)

Recent decisions of the Commission and the courts in the case of *Keele Hair and Scalp Specialists, Inc. v. FTC*, 1960 TRADE CASES ¶ 69,615, 275 F. 2d 18 (CA-5), and *Ward Laboratories, Inc. v. FTC*, 1960 TRADE CASES ¶ 69,690, 276 F. 2d 952 (CA-2), both decided in 1960, have clarified the Commission's power to require affirmative disclosure. These cases involve the advertising of treatments represented to be of value in the prevention and cure of baldness. The United States Courts of Appeals for both the Second and Fifth Circuits have affirmed orders of the Commission which limited claims for hair growth to cases other than male pattern baldness, and required the respondents' advertisements to clearly and conspicuously reveal the fact that the majority of cases of thinning hair and baldness are the beginning and more fully developing states of male pattern baldness and that the respondents' preparation will not in cases of this nature check thinning hair, prevent or over-

come baldness, cause new hair to grow, or cause hair to become thicker. The Court of Appeals for the Fifth Circuit in the *Keele* case stated:

"There is nothing in the *Alberty* case that prevents enforcement of a cease and desist order requiring affirmative disclosure. The *Alberty* case simply held that the Commission must make certain findings before compelling affirmative disclosure. The Commission made the required findings and on the basis of these findings issued its order requiring that the petitioners disclose affirmatively that Keele preparations would not be effective against male pattern baldness. Failure to disclose that approximately 95 percent of the cases of baldness fall within the male pattern type is plainly misleading, when the petitioners claim they treat virtually all cases of baldness." (Cited above, at p. 21.)

A review of the Commission's actions since the passage of the Wheeler-Lea Act 22 years ago leads to the conclusion that there has been a great improvement in the quality of food, drug and cosmetic advertising. By and large, extravagant and false claims for cure-alls have been curbed. It is now clear that many of the worthless and dangerous drugs and devices have been removed from the channels of trade. For this reason, I believe it is safe to assume that the quality of drugs sold over-the-counter to the public has greatly improved as a result of the passage of the 1938 acts. Examples from the Federal Trade Commission's administration of the Wheeler-Lea Act clearly illustrate considerable improvement in the advertising of products coming within the purview of this act.

The Commission has been intensely active in proceeding against falsely advertised treatments for arthritis, rheumatism and related difficulties. Numbers of these proceedings have involved products, containing aspirin or some other ordinary analgesic drug, which were being sold at highly inflated prices by means of advertising which promised a cure or long lasting relief from arthritis, rheumatism and other similar ailments, or otherwise grossly exaggerated the limited palliative effect of the preparation on the minor symptoms of these conditions. Action has been taken with respect to similar misrepresentations made for liniments, ointments and other nostrums sold for external application in cases of rheumatism and arthritis.

Dietary supplements, a variety of drugs and a number of types of devices advertised as providing simple, easy and rapid means of

reducing excess body weight, have been the subject of close attention by the Commission and it is presently engaged in numerous efforts to curb misrepresentation in this broad area. Action has recently been taken involving advertising used to promote the sale of "medical" books which hold out to the general public regimens allegedly effective in the prevention, treatment and cure of a variety of serious diseases. On July 19, 1960, the Commission issued an order against Witkower Press, Inc., (Dkt. No. 6533) which advertised a book represented as teaching a successful system for the treatment of arthritis. The principal remedy advocated in this book was the consumption of a mixture of cod-liver oil and orange juice. The Commission's authority does not extend to the regulation of the contents of such a book, but it does cover the advertising practices used to promote its sale, that is, the advertising representations concerning the contents of the book.

The Federal Trade Commission polices only the advertising of foods, cosmetics and drug products and devices. The labeling and development or production of such products and devices are matters within the jurisdiction of the Food and Drug Administration to which I shall refer later.

In speaking of the Commission's actions in the area of quality control, it should be clearly understood that my statements are limited to those claims dealing with effective quality control made in advertisements. Most of the Commission's cases involving false and misleading advertising have been directed to statements concerning the quality or effectiveness of the products advertised. However, the activities or procedures of a firm producing pharmaceuticals may also be misrepresented. Any advertiser is fully responsible for representations of this character. This maxim is illustrated by advertisements which state or imply without foundation that the firm doing the advertising is exercising adequate control over the production of its products. Specific terms may be employed such as "a system of quality control," "rigid quality control" or a number of other similar representations, but I believe that the uniform and common understanding of such statements is that a careful check on the quality of the manufactured product is being maintained. It is the duty of the Commission to insure that statements of this character accurately reflect the nature and extent of the manufacturer's control. This is particularly important in the manufacture of pharmaceuticals.

The Commission's position in such a matter is that any advertising claim relating to quality control is a representation within the usual meaning of the terms as understood in the pharmaceutical industry, namely, that the firm doing the advertising continuously employs an adequate control system.

It is apparent that any examination of the truthfulness of a claim of adequate quality control depends upon a definition of the phrase "adequate quality control."

No definition of quality control has been adopted or considered by the Commission. However, a member of the Commission's Division of Scientific Opinions, Mr. Thomas H. Riggs, has devised a definition which may be helpful to you in this respect. It is as follows:

"An *adequate control system* observes the regular and continuous use of all reasonable methods, procedures and operations that are necessary, and sufficient to insure the uniformity of pharmaceutical products as to safety and efficacy, including the use of those which will:

"(1) minimize the human, mechanical and other errors throughout all phases of production such as manufacturing, processing, packaging and labeling, and

"(2) assure the user or ultimate consumer that his package of the product has all the characteristics of identity, strength, quality, and purity which it is represented or purported to possess, including those which are required, claimed, or implied, taking into account each of the uses for the product which are intended, represented or customary."

This definition covers a broad concept of adequate quality control. The mere adoption of a plan will not satisfy this definition. To insure adequate control under this definition, a manufacturer must not only have a plan but also facilities and procedures, a qualified staff and the necessary know-how to carry out a program of quality control on a continuous basis. Close supervision and inspection at the point of manufacture is necessary if the claim of adequacy is to be thoroughly supported.

The Commission is the agency having primary responsibility to protect the public against false and misleading advertising so far as standard pharmaceuticals are concerned, and for this reason it must bear special responsibility in the area of quality control. Currently, this responsibility is greater than it has been in the past, because of the

expanded use of generic-named drugs and the concurrent use of claims of adequate quality control by the manufacturers of such drugs. The public is greatly concerned with the quality of pharmaceuticals, and government agencies charged with the protection of the public interest must necessarily reflect that concern. Accordingly, I am of the opinion that false claims of quality control can severely damage the reputation and standing of a member of the pharmaceutical industry who may make such claims.

For many years, the Commission has taken very little action in the field of false claims of quality control, but, in the past year, it has issued a complaint against a manufacturer of generic-named drugs. (*West Ward, Inc. et al.*, Dkt. No. 8141). This proceeding challenges the use of representations in advertising relating to quality control and alleges that such representations are false and misleading. It is expected that additional complaints may be forthcoming since investigations of this nature are now under way and if the evidence obtained during the course of these investigations provides the Commission with substantial and adequate reason to believe that deceptive claims of quality control have been made, formal proceedings will no doubt be instituted. In view of the foregoing, it would seem advisable that the industry, acting in the public interest and its own self-respect, should cooperate with the Commission in insuring that all claims of adequate quality control are truthful. Failure to take such action may invite further government controls and further action under present laws.

You will no doubt be vitally interested in the only qualification to the broad coverage of Section 15 of the Wheeler-Lea Act which states:

"No advertisement of a drug shall be deemed to be false if it is disseminated only to members of the medical profession, contains no false representation of material fact, and includes, or is accompanied in each instance by truthful disclosure of, the formula showing quantitatively each ingredient of such drug."

So far as I am aware, the Commission has never challenged a statement in advertising relating to the therapeutic qualities of any drug product where such advertising was directed solely to a physician, so that the full meaning of this qualification has never been resolved. When Section 15 was enacted in 1938, the probability of deception of the medical profession respecting the efficacious and widespread benefits, as well as the harmful effects of the drugs then in use, was slight. During the past few years, a large number of new drugs

have been introduced into the channels of trade. Such drugs are so powerful that they greatly effect basic bodily processes. These drugs have been widely advertised to physicians and the methods of presentation in such advertisements have caused many, including members of the Commission's staff, to conclude that, at present and for some few years past, even physicians are now being, and may have been, deceived by the advertisers of the so-called ethical drugs. It is apparent that the average busy physician does not have time to thoroughly explore all the beneficial effects of such drugs or in fact even those effects which may be harmful. It is doubtful that physicians may be able to examine the basic literature available on all of these new drugs. Accordingly, it is believed that advertising directed to physicians should receive very careful scrutiny by the Commission, particularly where such ads do not fully acquaint the physician with the harmful aspects of such drugs. Consequently, those of the Commission's staff most concerned with this problem have recently given thought to suggesting to the Commission additional legislation which would amend that portion of Section 15 relating to advertising directed solely to physicians. There has been in the public press a clear indication that the Commission will make a recommendation to Congress regarding this form of advertising in the near future. No such recommendation has been made as of this date.

As previously indicated, the broad authority and the varied activities of the Federal Trade Commission, in many instances, touch upon those of other federal agencies. This is especially true of the Food and Drug Administration, charged with responsibility for the labeling of foods, drugs, cosmetics and devices. While Section 12 of the Federal Trade Commission Act excludes labeling from the definition of false and misleading advertising, the jurisdiction of the Commission over false and misleading statements on labels as a violation of Section 5(10) has not been revoked.

In order to correlate more effectively the work of the Commission and the Food and Drug Administration and to prevent overlapping activities and duplication of effort, a working agreement between the agencies was devised, and has proven highly satisfactory.

It was agreed that the Federal Trade Commission would exercise sole jurisdiction over advertising and the Food and Drug Administration over labeling, in the absence of express agreement to the contrary. While such an agreement might appear to delineate clearly

and simply the respective areas of activity, continuing and careful liaison is necessary in instances where:

(1) The same, or similar, claims are found in both labeling and advertising;

(2) Written, printed or graphic material may be construed as either advertising or as accompanying labeling or both, depending upon the circumstances of distribution; and

(3) The article is a drug or device and appears to be misbranded solely because of inadequacy of directions for use appearing in the labeling for conditions for which the article is offered in advertising generally disseminated to the public.

Such liaison arrangements have also been established with a number of other government agencies, in order to prevent duplication or conflict of effort.

Today, we have made reference to only a small segment of the Commission's activities in the field of false and misleading advertising. It might be profitable to discuss at length other specific points but I believe that the principle of truth in advertising is abundantly clear. Advertising, particularly as it relates to foods, drugs, cosmetics and devices, must be truthful in its declaration as well as its negative aspects. Such advertising must avoid misleading implications as it must avoid any explicit falsehood. The truth must be capable of being understood by both the uninformed as well as those persons who are knowledgeable and sophisticated. In other words, advertising must be true in all respects and capable of being understood by all persons to whom it is directed.

The reputation of the advertising done is a trust of every advertiser and must be the cornerstone of every advertising agency. By discharging your obligations in this respect, you can set an example of your industry's concern for the public interest. If you fail in this respect, you must be prepared to accept additional government controls. We, in the bureau of investigation, are thoroughly convinced that consumers and honest competitors will not tolerate either positive or negative misrepresentations in advertising. Currently, the Commission is receiving some 500 complaint letters every month. Many of these come to my office and give a fairly clear indication of the public interest in the type of advertising representations made by advertisers throughout the United States. **[The End]**

# What Level of Drugs Can Be Used in Feeds?

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A FEW WEEKS AGO I received a telephone call from a state feed control official near Washington, D. C. This state official had one question which he wanted answered. He wanted to know if 400 grams of chlortetracycline could be used in a ton of poultry feed.

The state official said that he had recently received a request from a feed mixer to register this particular feed in his state. At first, the official said, he objected to the feed. However, the feed mixer was persistent in his demands. He insisted that there should be no objection to his feed since the antibiotic feed regulations of the Food and Drug Administration made no mention as to the maximum level of an antibiotic that could be used in a feed.

The feed mixer pointed out to the state official that the antibiotic feed regulations of the FDA were self-explanatory in regard to drug levels. The regulations state that a feed must contain, per ton of finished feed, the equivalent of not less than so many grams of antibiotic. This minimum level was necessary before a therapeutic claim could be made for the drug.

The feed mixer concluded from his analysis that there should be no objection to his proposed feed since it did contain the minimum level of drug required by the regulations.

## What Limits Drug Dosages?

What limits drug dosages in feeds? This question must be answered before we can determine whether or not a food with a high drug content is permissible.

The poultry feeder may contend that the economics of feeding a drug should determine the level of that drug in a feed. He may reason that a poultryman will tend to feed only the level of drug necessary to accomplish the desired effect and that this level will be fed only when it is economically feasible. Further, it can be said that the feeder could not afford to feed a higher level of drug nor could he afford to feed a level of drug that would not be effective—the cost would be too great.

However, under the Federal Food, Drug, and Cosmetic Act, the safety and efficiency of the drug are the prime factors for consideration. The drug must be safe not only to the animal receiving the drug but to the ultimate consumer of the products from the treated animal.

Under the Federal Food, Drug, and Cosmetic Act, there are three sections which may control the level of a drug in a feed: (1) Section 507; (2) Section 505; and (3) Section 409.

**Section 507.**—Section 507 pertains to certifiable antibiotics. This section covers those drugs containing, in whole or any part, penicillin, streptomycin, chlortetracycline, chloramphenicol or bacitracin, or any derivative thereof. Derivatives of these antibiotics are those such as dihydrostreptomycin, zinc bacitracin and tetracycline.

When any of these drugs are added to feeds, data must be available to show that the drug is safe and efficacious for all claims made.

The regulation for controlling the certifiable antibiotic drugs in feeds is Section 146.26 of the antibiotic regulations. This section of the regulations specifies the drugs that may be used in a feed. The drugs include nonantibiotic drugs which may be used in combination with the certifiable antibiotics, as well as the antibiotics themselves. Feeds containing one or more of these drugs can be used only as prescribed in these regulations.

**Section 505.**—Section 505 is the new drug section. Drugs other than the certifiable antibiotics may or may not be considered under this section of the law. How the drugs are handled depends upon whether they are considered "new drugs" or "not new drugs."

For a "new drug," the safety of the drug has not been full determined nor recognized through extensive use. These drugs must be handled under the new drug section. The "new drug" provisions require that a new drug application be submitted and allowed to become effective before the drug can be used.

The law limits the distribution of new drugs to the final dosage form as described in the application.

If a drug is considered a "not new drug," it is not subject to these provisions of the law. Drugs cease to be classified as new drugs when, in the opinion of qualified experts, sufficient experience has been gained in the use of the drugs to warrant their removal from new drug status. However, these "not new drugs" remain susceptible to other provisions of the law for adulteration or misbranding. Also, these "not new drugs" may again become "new drugs" under different conditions of use and representation.

**Section 409.**—Section 409 is the food additives section. This section covers any substance, the intended use of which results, or may reasonably be expected to result, in its becoming a component or otherwise affecting the characteristic of any food. Exempted from this section are those substances which are generally recognized among experts to be safe for their intended use, and those substances having "prior sanctions" as that term is used in the food additives amendment.

The food additives section makes no distinction between foods intended for man and those intended for animals. Any substance added to an animal's food would be considered under this section of the law.

To comply with Section 409, an additive must be shown to be effective for its intended use and the level of drug recommended must be only that which is reasonably necessary to accomplish the effect. The law provides that where a tolerance is necessary for a food additive, this tolerance shall not be fixed at a level higher than that reasonably required to accomplish the effect for which such additive is intended. Higher levels of the additive than necessary are not permitted.

## Disease Prevention and Treatment

The level of drugs that can be used in feeds depends upon the use that is to be made of the drug and the safety of the drug for such use. The drug must be safe not only to the chicken, turkey, pig or

cow receiving the drug, but also to the consumer of the edible products obtained from the treated animals. There must be no residues of the drug remaining in the meat, eggs or milk at levels that would be detrimental to human health.

**Antibiotic drugs.**—The level of certifiable antibiotic drugs that may be used in feeds are as listed in the antibiotic feed regulations, Section 146.26. Under part (b) of this section, each antibiotic and nonantibiotic drug that may be used in a feed is given. The claims that can be made for the drug are listed and the quantity of drug required for these claims is set forth.

For chlortetracycline in a poultry feed, the regulations permit the claims blue comb, chronic respiratory disease, infectious sinusitis and synovitis. In the treatment of these diseases, the feed must contain not less than 100 grams per ton of feed, chlortetracycline or of the combination chlortetracycline and oxytetracycline except for the claim synovitis when the feed must contain not less than 200 grams of antibiotic per ton of feed.

The regulations also provide that other drugs such as furazolidone and trithiadol may be used in combination with chlortetracycline. The dosages for these drugs and the claims that can be made are set forth in the regulations.

So far, from our discussion it appears that the formula of the feed mixer as submitted to the state feed control official complies with our regulations. The feed mixer is supplying the minimum level of chlortetracycline in his feed as required by the antibiotic regulations.

However, there is one point the feed mixer failed to take into account. This point is, the possibility of residues of drug ingredient remaining in the tissues of the treated animal. The quantity and combination of drugs as permitted by the different paragraphs under part (b) of the antibiotic feed regulations must be kept at a level in a feed which will prevent drug residues in edible products. For the most part, this requires that the regulations be followed to a "t."

Where we have a level of drug in a feed that is higher than the level listed or a combination of drugs that is different than those quoted in the antibiotic feed regulations, a question is raised as to the safety and efficacy of that drug. We must be sure in feeding drugs to animals that the drug is safe not only to the animal but to the consumer of the product from that animal.

Unless the Food and Drug Administration has previously approved higher levels of an antibiotic drug than as quoted in the regulations, the higher levels cannot be permitted without additional safety data. The higher level of drug without adequate data would be in conflict with the food additives amendment.

Under the food additives law we must have data to show that the higher level of drug in the feed would leave no drug residue in the animal tissue that would be unsafe for human consumption. These data must be submitted before an amendment to the food additives regulations permitting the use of the drug can be considered.

For a moment, let us go back to our poultry feed with 400 grams of chlortetracycline. This level we would not approve in the absence of supporting data that would permit issuance of a food additive regulation. Levels higher than 200 grams per ton of feed have not been approved for poultry.

For penicillin and bacitracin we would not approve levels significantly above the 100 grams per ton minimum stated in the regulations, and for streptomycin, 75 grams per ton.

When the antibiotic regulations were first drafted, it was thought that the cost of an antibiotic would limit the amount of the drug that would be added to a feed. At the time, we did not believe it necessary or even advisable to specify the maximum level of the antibiotic that could be used. For ease of handling, the antibiotic regulations were written to include the proviso "not less than."

The drafting of the regulations in this form was not intended to authorize the use of antibiotics far in excess of the amounts stated in the specific regulations but rather to permit reasonable overages consistent with good manufacturing operations and to provide assurance of effective levels for the desired purposes.

The feeding of antibiotics have now become more economical for the most part. Requests have been received by the Division of Antibiotics for antibiotics in feed as high as 1,000 grams per ton of finished feed. The cost of the drug isn't putting a brake on the amount to be added to the feed. As a result, we are having to take another look at our regulations.

We are exploring the possibility of amending the antibiotic regulations to provide for both a minimum and maximum level of an antibiotic that can be added to a feed.

**New drugs.**—The levels of "new drugs" which can be added to animal feeds are as authorized in the effective new drug application. The levels as permitted by the new drug application have been shown to be safe for their intended use.

The "new drug" itself may or may not be included in the antibiotic feed regulations. Whether an amendment is made to the antibiotic regulations to include the new drug will depend on the data available. We must have the same safety data on the combination of new drug and antibiotic as we had on the individual drugs.

The most recent two new drugs to be added to the antibiotic regulations are those of zoalene and amprolium. These drugs can safely be added to poultry feeds at levels of .0125 per cent and .025 per cent, respectively. Both drugs are used for the control of coccidiosis in chickens.

Usually, the level of a new drug which can be added to an antibiotic feed is the same as provided in the new drug application. However, the levels could be different if one drug, for one reason or another, affects the use of the other.

**Not new drugs.**—If the drug to be used in a feed is considered a "not new drug," it may be used in a feed at a dosage level which is considered safe for such use. Under these conditions of use the "not new drug" does not take a food additive regulation. The "not new drugs" are recognized as having been adequately shown under the conditions of their intended use to be safe.

When the "not new drug" is combined with another drug or is used at levels other than those generally recognized as safe, it may again become a "new drug." For these different conditions of use the drug would be handled as a "new drug."

The use of "not new drugs" in combination with the certifiable antibiotics are as outlined in the antibiotic feed regulations. The combinations and dosage levels permitted in a feed are listed in these regulations.

## Growth Promotion

A number of drugs are added to poultry and swine feeds for the promotion of growth and increasing feed efficiency. These drugs include both the nonantibiotic and antibiotic drugs.

**Nonantibiotic drugs.**—Part (a) of the antibiotic feed regulations lists five nonantibiotic drugs which may be added to the antibiotic

feeds as growth promotants. They are the arsenical compounds and the nitrofurans.

These compounds may be used in antibiotic feeds as specified by the antibiotic feed regulations. The regulations give the feed to which the drug may be added and the quantity of the drug that must be in the feed.

**Antibiotic drugs.**—The most widely used growth promotants are the antibiotics. They include penicillin, chlortetracycline, oxytetracycline and the bacitracins. Of these antibiotics, penicillin, chlortetracycline and bacitracin are certifiable. Oxytetracycline is not certifiable except when in combination with one of the other antibiotics.

The total number of antibiotics that may be used in any one feed for growth promotion depends upon the level of the antibiotics being used. So long as the total antibiotic content of all antibiotics in the feed does not exceed 50 grams per ton of finished feed, any number and any combination of the antibiotics may be used. It is possible to have penicillin, chlortetracycline, oxytetracycline and bacitracin all in the same feed.

The feeds to which low levels of antibiotics can be added are limited. The species of animal to which a growth promotion level of an antibiotic can be recommended are specific. Before a drug can be used as a growth promotant, data must be available to show that the drug will be effective for this purpose. Although we have not specified in the antibiotic regulations each species of animal to which the low level antibiotic can be fed, they are nonetheless established.

Penicillin, streptomycin, chlortetracycline, oxytetracycline and bacitracin may be added to chicken, turkey and swine feeds for growth promotion. Oxytetracycline and chlortetracycline may in addition be added to sheep and cattle feeds for this same purpose.

Only recently have we considered it necessary to set the minimum level of an antibiotic which must be used in the feed to promote growth. We are now in the process of establishing the minimum effective level for each antibiotic and for each species of animal.

Two antibiotic drugs and their levels have been set for chickens. The antibiotics are: procaine penicillin and streptomycin. For procaine penicillin, the minimum level considered effective is four grams per ton of feed (2.4 grams sodium penicillin master standard). For streptomycin, the minimum level is 30 grams per ton of feed.

If either one or both of these two antibiotics are used in a chicken feed, the feed must contain the minimum level as quoted for each antibiotic. You will find these levels stated in both the antibiotic and food additive regulations. From now on, as our regulations are amended to provide for the use of low level antibiotics in feeds, the minimum as well as the maximum level of the antibiotic necessary for growth promotion will be stated.

The addition of antibiotics to duck, pheasant, pigeon or game bird feeds is prohibited. The same is true for rabbits. The Food and Drug Administration does not have adequate data on the safety and efficacy of antibiotics in feeds for these animals.

There may be some question as to the wisdom of setting minimum levels of antibiotics for growth promotion. However, we in the Food and Drug Administration believe there is a real need for this action. Only recently we had the opportunity to review a poultry feed formula which contained only 64 milligrams of procaine penicillin per ton of finished feed. We can hardly consider this level adequate to promote growth; we can't even find it in the feed.

## Summary

What level of drugs can be used in feeds depends upon the use that is made of the drug and the safety of the drug for that use.

To treat diseases in farm animals, the dosage of the drug administered to the animal must be within safe and effective limits for the animal and within safe limits for the consumer. The minimum level of a certifiable antibiotic that can be used in a feed for the treatment of disease is the level specified in the antibiotic feed regulations. This is also the maximum level even though the regulations do not so specify except to the extent that a reasonable overage consistent to good manufacturing procedure is allowable.

New drugs can be used in feeds at the levels specified in the new drug application. These are levels that have been adequately shown to be safe to the animal and will leave no harmful residues in the edible tissues.

To promote growth, the level of a drug that must be in the feed is that level which can reasonably be assured to give a response. The minimum level of an antibiotic necessary in a feed depends upon the antibiotic and species of animal being fed. For chickens, four grams of procaine penicillin is required for each ton of finished feed (2.4

grams sodium penicillin G master standard). For streptomycin, the minimum level required is 30 grams per ton of feed. The minimum levels for other antibiotics and for other species of animals will be established as data justify.

If the level of a drug in a feed is higher or lower than the levels quoted in the antibiotic regulations or in the new drug application, a question is immediately raised as to the safety and efficacy of the drug. Not only should the drug be effective for its intended use but there must be no residues of drug ingredients in the meat, milk or eggs that will be detrimental to human health.

We do not believe that a drug should be added to a feed just for the sake of adding the drug. Neither can we condone the addition of a drug to a feed for the treatment of disease when such drug will be toxic to the consumer of the animal products.

Levels of a drug in a feed for which there is no valid purpose or which leaves toxic residues in edible products of the treated animal will not be tolerated. The protection of the public must be foremost in our use of veterinary drugs. **[The End]**

## GOVERNMENT WINS ROUND IN CANDY CASE APPEAL

The government has won what may be a key round in its appeal from a lower court judgment dismissing "slack fill" charges against a candy mint package making what the government considered excessive use of hollow dividers. The Third Circuit stated two grounds on which a court could hold for the claimant in such a case (and which could prove difficult to meet):

(1) The ordinary purchaser was not misled into expecting a larger quantity of the product than was actually in the package.

(2) Even if he were misled into expecting the larger quantity, the form and filling was justified in order to protect the contents, taking into consideration the alternative safety features available.

Here, the lower court had found, first, that there was no proof the ordinary purchaser expected to find any particular number of mints in the box. Not enough, said the court of appeals. The question is whether he expected to find *more* than were actually in the box. As to protective construction, the lower court had found that the package did serve protective purposes, and its form was neither adopted nor used to deceive. Again, said the court of appeals, this is not enough. The lower court "has to find that the container's efficacy outweighs its deceptive quality [and] . . . that the available alternative efficacious means are not less deceptive than those actually employed." Accordingly, it vacated and remanded the judgment in favor of the manufacturer for more specific findings and whatever judgment is ultimately called for.—*Delson Candy Company*, CCH FOOD DRUG COSMETIC LAW REPORTS ¶ 7642 (CA-3, 1961).

# FOR THE READING LIST

## Pure Food Centenary 1960

*Pure Food and Pure Food Legislation.* A. J. Amos. Butterworth, Inc., 7235 Wisconsin Avenue, Washington 14, D. C. 1960. 167 pages. $4.

This book contains the papers delivered at a recent conference held in London commemorating the centennial of the first general Pure Food Law. The problem in 1860 was one of quality and the chemists taken into the food industry as a safeguard against unintentional contraventions of the early food and drugs acts were later given the task of supervising factors of quality other than purity, such as, appearance, taste, texture, nutritive value and keeping properties. So foods not only became purer but they looked better, they tasted better and they kept better. The problem in 1960 is one of quantity. "We may have less time to solve our problem," said A. J. Amos, chairman of the Pure Food Centenary Executive Committee, "than the administrators and scientists of 1860 had to find a solution to theirs."

There are papers by: J. H. Hamence, president elect, Association of Public Analysts, past president, Society for Analytical Chemistry; E. G. Hughes, past president, Society for Analytical Chemistry, past chairman, Food Group of Society of Chemical Industry; J. G. Malloch, scientific adviser to the High Commissioner for Canada; N. C. Wright, Deputy Director-General, Food and Agriculture Organization of the United Nations, past chief scientific adviser (Food), Ministry of Agriculture, Fisheries and Food; A. C. Frazer, professor of medical biochemistry and pharmacology, University of Birmingham, president, British Food Manufacturing Industries Research Association; C. A. Morrell, Director, Food and Drugs Directorate, Department of National Health and Welfare, Canada; F. H. Reuter, associate professor of food technology, The University of New South Wales; G. P. Larrick, Commissionner of Food and Drugs, Department of Health, Education and Welfare of the United States.

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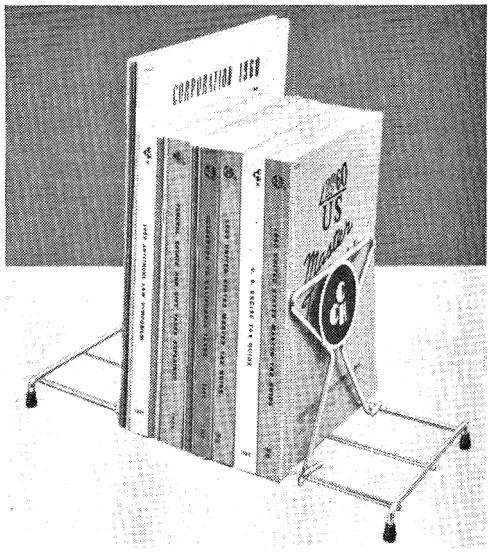


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