/ VOL. 20, NO. 8 AUGUST 1965

Food Drug Cosmetic Law JOURNAL

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

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

The FOOD DRUG COSMETIC LAW JOURNAL is published monthly by Commerce Clearing House, Inc. Subscription price: 1 year, $20; 3 years, $49; single copies, $2. Editorial and business offices, 4025 W. Peterson Ave., Chicago, Ill. 60646. Printed in United States of America.

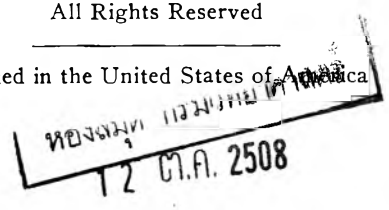
August, 1965
Volume 20 • Number 8

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

FOOD DRUG COSMETIC LAW JOURNAL

Table of Contents . . . . . August, 1965

VOLUME 20 NUMBER 8



FOOD DRUG COSMETIC LAW JOURNAL

Editorial Advisory Board

REPORTS

TO THE READER

Food Laws and Regulations in France.—This was the topic of a paper presented at the 78th Annual Meeting of the Association of Official Agricultural Chemists in Washington, D. C.

The author, *Henri Cheftel,* is president of the Scientific Commission of the International Committee Permanent de la Conserve in France. In this article, starting on page 436, he traces the development of French food laws, and stresses the need for standard methods of food product analysis. He also mentions the need for protection of traditional names and quality, and for harmonization of international food standards.

Criminal Liability for Deceiving the Food and Drug Administration.—*George Rosner,* in the article beginning on page 446, discusses developments in application of federal law to those who deceive the Food and Drug Administration. The incursion of United States Code Title 18, Section 1001, into areas generally regulated by the Food, Drug and Cosmetic Act is cited as a major development. This section deals with criminal liability for making material false statements to government agencies. Not only direct, but indirect deceptions have led to convictions under this law.

Much of the article is devoted to forecasts of probable incursions of Section 1001 into situations involving the monitorial and regulatory functions of the Food and Drug Administration.

Recent Developments in the Law Relating to the Retail Sale of Drugs.—*J. Richard Edmondson* and *William F. Weigel,* members of the New York Bar, are the co-authors of this article beginning on page 469. In it they deal with the controversy between organized pharmacy and general merchants about the right of the nondruggist retailer to sell nonprescription packaged medicines.

They maintain that the controversy results from the failure to define "proprietary" or "patent" medicines. These medicines are generally exempt from state pharmacy statutes restricting retail sale of drugs, medicines and poisons to licensed pharmacists. Inconsistent court interpretations of the proprietary exemptions have added to the confusion. The authors seem to feel that the basic problem is that courts have been concerned primarily with considerations of semantics. The courts should, the authors believe, recognize that the "proprietary" exemptions in the state pharmacy statutes were based upon considerations of public health, and should be construed in a manner that would accomplish this end. The question should not be the definition of the term "proprietary," but whether or not public safety is endangered by general sale of the product.

Vol. 20, No. 8 August, 1965

Food·Drug·Cosmetic Law
Journal

Establishment and Functioning of the Food Laws and Regulations in France

By HENRI CHEFTEL

The Following Article Was Presented at the 78th Annual Meeting of the Association of Official Agricultural Chemists in Washington, D. C., in October 1964. Mr. Cheftel Is President of the Scientific Commission of the International Committee Permanent de la Conserve in France.

Such is the prevailing dishonesty, that all one sells now is the name of the vineyard; and wines are adulterated right from the vat . . . The most wholesome wine is that to which nothing has been added before fermentation. As to wines treated with marble, plaster or lime, who is the man, however strong, who would not dread them?

THIS WAS WRITTEN ABOUT 50 A.D.; and while it is open to question whether the most expert agricultural chemist could have detected the hidden poison in Eve's apple and thereby averted the evils which have befallen mankind, the above sentence from Pliny, the ancient, clearly shows that the need of food regulations and inspection was felt already many centuries ago.

In Roman times, a certain amount of fraud or deception in trade appears to have been admitted: besides *dolus malus* which nullified the sale, a *dolus bonus* was recognized and accepted, probably even held as a proof of smartness. But was not Mercury the god of thieves as well as of merchants?

The necessity of protecting honest trade and of safeguarding the health of the consumer had led to various restrictive measures even

in ancient Rome; and by the end of the 18th century, in France, shortly before the French Revolution (1789), rules and controls enacted by the corporations prescribed to each individual active in a trade or craft what he could do and how. Severe penalties were foreseen, and a large number of inspectors were maintained to supervise every step of the manufacture. This system hampered trade and favored the building up of monopolies and eventually was not to the advantage of the consumer. The French Revolution abolished it, according to the principle whereby each citizen, provided he respects the law, shall be free in his actions under his own responsibility.

However, without specific regulations penalizing the adulteration or misbranding of foodstuffs, frauds and falsifications could now be prosecuted only under the provisions of the Penal Code; and these, except for two articles concerning beverages (wine was always given much consideration in France), were far too general to deal efficiently with the matter. Guile was soon on the increase again.

One may wonder why so many centuries had to elapse before the present compromise between complete freedom and excessive controls was adopted. The answer is simple: the precise definition of foodstuffs, and the enforcement of regulations by inspection at the moment of sale, are not possible unless appropriate analytical methods are available—and these had to wait for the development of the sciences. Considering that biochemistry and bacteriology were just born when the first food laws were passed, the latter may even be regarded as a proclamation, by the French and the British Parliaments, of their faith in the future of science.

Development of French Food Law

The first French law specifically concerning foodstuffs was passed on March 27, 1851, and soon was extended to beverages by another law on May 5, 1855. The first British Food and Drugs Act appeared in 1860.

The two French laws just mentioned, although devoted to foodstuffs, defined but general principles: they punished not only fraud but also attempted fraud; they concerned goods held for sale or offered for sale as well as goods actually sold; they fought adulteration and misrepresentation. They were, in fact, but a step to a more precise and elaborate legal instrument, the law of August 1, 1905, introduced in 1898 before Parliament and still in force. It may be recalled that in the United States of America the first Pure Food Law

was passed at about the same time (1906), another sign that similar conditions of development bring the same fruits.

The law of August 1, 1905, concerns the repression of frauds in the sale of goods, and of adulterations of foodstuffs, drugs and agricultural products. It defines principles, sets the frame inside which the law has to be applied, and gives power to appropriate authorities to issue the texts ("décrets" or decrees, countersigned by the Council of State; "arrêtés ministériels" or ministerial orders; and administrative circulars) necessary for putting the law into effect. A number of such texts, and also various laws, have implemented through the years the law of 1905, but without altering its character.

I have no intention of following step by step the development of this body of legislation, but will just try to note its most characteristic features as it now stands, and, in fact, as it stood already 50 years ago.*

One principle, not peculiar to French legislation, is that the intention to deceive has to be proved before a correctional penalty may be imposed; failing to prove the intention to deceive, the eventual penalty is a simple police fine.

The law gives a detailed classification of the various kinds of frauds: on the *nature* of the goods, for example, cotton instead of wool, or herring instead of sardines; on their *substantial qualities,* that is, those qualities which the buyer unequivocally prizes and which he has asked for, for example, a particular vintage of a wine, or a particular variety of a fruit; on their *composition,* be it defined by regulations or by usage; on their *contents in useful principles,* as it may be either prescribed by a standard, or stated on the label, or known by custom, for example, the percentage of acetic acid in vinegar; on their *species or origin,* notably the territorial names of wines or cheeses; on the *quantity;* on the *identity,* distinguishing for instance a particular batch of a product, or an individual animal.

It may be argued that this classification is perhaps too artificial, and that it is not always easy to distinguish between nature and species, or substantial qualities and useful principles. The main interest of the above classification lies however in the fact that it clearly declares all and each such kinds of fraud to be punishable, thus precluding possible ways of escaping the law.

* The reader wishing more details is referred to the books mentioned in the bibliography which follows this article.

Various texts give definitions of specific food products, or prescribe rules about labelling or advertising; they are not peculiar to the French law. Two points, on the contrary, deserve mention: the rules regarding food additives, and those referring to the procedure to be followed for the prosecution.

The fundamental principle regarding additives is, and has been since the start, that no additive be allowed unless it has been specifically authorized, for a well defined and limited use; the Higher Council for Public Hygiene and the National Academy of Medicine have to be consulted. Thus the positive list is an old custom with France, and this explains why the French legislation has been so wisely conservative with regard to the use of artificial coloring, chemical preservatives, and the like. The fact that the legislatures of other countries have, one after the other, come to adopt the same principle, is indeed a proof that it is sound.

Of course the list of accepted dyes was modified, new additives or packaging materials were admitted and some old ones rejected; but contrary to what took place in other countries, no "revolution" was necessary, since nothing had to be changed in the sound principles already embodied in the fundamental law.

Regarding the procedure, its various steps are set out in great detail. I have no intention of going through them all, but will just mention that when an official laboratory believes it has detected a falsification or an adulteration, and asks for judicial action, the examining magistrate formally asks the defendant whether he requests a "counter-analysis" or "counter-valuation" to be made. If yes, he is entitled to choose one expert, a second one being nominated by the magistrate. The two experts then jointly proceed to the analyses and experiments they think necessary, and give their conclusions.

This system, besides affording the defendant a guaranty against a possible error in the analyses or bias in the conclusions of the official laboratory, offers him also the opportunity of calling in to study the technical aspects of the case someone who is really conversant with the matter under discussion. This I consider almost as important as the legal guaranty; in our age of ever increasing specialization, the correct interpretation of experimental results requires usually a thorough knowledge of the particular art or science which is involved.

It may be appropriate at this point, even if it leads me somewhat away from my subject, to say a few words about the analytical methods to be used by the official laboratories.

A decree, taken in 1906 (and amended in 1919), stated that official methods of analysis should be established, and for this purpose provided the setting up of a permanent scientific advisory committee. How long this committee was at work is difficult to say, but it was not permanent since it was never active after World War I. Official methods of analysis were published by "arrêtés" from 1907 to 1914, and some, notably for wine and spirits, are still in force; most of them, however, had become so obsolete when normal activities were slowly resumed after the war, that the task of completely reshaping them and of keeping them up to date was never undertaken. On the other side, a number of organizations, national or international, came into being and took up the task of establishing standards, and analytical methods, usually for one particular trade or class of products. I shall mention but a few: Bureau International Permanent de Chimie Analytique (International Permanent Office for Analytical Chemistry), Fédération Internationale de Laiterie (International Dairy Federation), Commission Internationale d'Oenologie (International Committee for the Science of Wine Making), Comité International Permanent de la Conserve (International Permanent Canners' Committee); for France only, the Association Française de Normalisation (AFNOR-French Association for Standardization), the Société des Experts Chimistes de France (Society of French Expert Chemists), and a number of technical trade associations.

Moreover, in various instances the official texts giving the definition of food products described also the appropriate analytical methods; and the Food and Nutrition branch of the Centre National de la Recherche Scientifique (National Research Council) also undertook to collect and publish the methods of analysis for certain groups of food products.

Besides the lack of means after World War I, another difficulty arose from the fact that while the official laboratories have to use prescribed methods of analysis, the experts themselves—who act as aids of the Tribunals—are free to use whatever analytical method they think proper to help in discovering the truth. Some of them even declared that the obligation to use one particular method of analysis constituted an infringement upon their freedom, thereby forgetting

that in many cases, for example, total solids, a standard cannot be defined independently of the analytical procedure.

The situation is indeed confused, especially for an outsider who would not know where to look for methods which, if not official, are nevertheless accepted as standard in a particular trade.

We wish indeed we could have a book like the *Association of Official Agricultural Chemists (AOAC) Manual,* but as you well know a collection of standard methods of analysis loses its value quite rapidly unless it is kept up to date, and unfortunately in Europe we lack so far the ways and means, human, administrative and financial, for following your splendid example.

Analytical Procedures

As you know, the AOAC methods of analysis are already widely used in France and in other European countries. In various international associations, the *AOAC Manual* is already the starting point for the development of standard methods for the analysis of food products. In this respect I may be permitted to mention the steps which the Scientific Sub-Committee of the Comité International Permanent de la Conserve (International Permanent Canners' Committee) has adopted since 1951 for the choice and elaboration of analytical procedures:

1. Take the AOAC method as a starting point, and subject this to a critical examination, both theoretical and practical;

2. Complete this work by an examination of the information sent in by each delegation concerning the principal methods for any given substance employed in the various countries;

3. Put forward to the Committee: either the AOAC method as such, or a modified AOAC method, or a completely different method. Each "rapporteur" should take on himself the responsibility of proposing a method. It is stressed that each method should end by giving detailed instructions, following the style of the AOAC, of the proposed method;

4. With the help of various members of the Committee, compare the proposed method, carried out exactly as indicated, with the method in use at the laboratory of the person making the comparison;

5. Send to the "rapporteur" the results obtained and the comments arising from these comparative tests; and

6. If a choice has to be made between the AOAC method and another method deemed equivalent, preference shall be given to the AOAC method.

Could we not go a step further, and try to establish a cooperation with you gentlemen in the study, testing and evaluation of analytical methods?

I am sure that if one or the other of your committees asks for cooperation on a specific item under study, for instance through the associations of food analysts which exist in various European countries, they will get it. From your side, I think that you might well take more account of non-English publications, and perhaps extend somewhat the bibliographical references, which are the only possible source for the explanations one may need.

I suggest that we refrain, at the start, from setting up a too complicated administrative organization, and rather find the means for encouraging and implementing the personal contacts which already do exist.

Let us proceed informally, and so to say experimentally—precise rules may be evolved later.

Coming back to our main subject, two recent acts implementing the regulations are an administrative circular providing for the inspection of goods at the stage of being manufactured, and, by way of consequence, of the manufacturing operations proper; and a decree regulating the production and labeling of dietetic food products.

Factory inspection in itself is of course not new; besides the Workers Health and Welfare Inspection and the Veterinary Inspection, there existed also an Inspection Service for factories handling marine products, and semi-official Inspection Services sponsored by trade associations and agreed to by the authorities. It is, however, the first time, under the law of 1905, that the Ministry of Agriculture, through his "Service de la Répression des Fraudes," tackles directly the problem of surveying the manufacturing operations.

Regarding dietetic foods, they have been left so far in a sort of no man's land, where they flourished unhampered by regulations. This situation resulted from the fact that the legislation and inspection of pharmaceutical products had been handed over to the Ministry of Public Health, leaving dietetic foods as an object of dispute since their "amphoteric" character made it difficult to decide if they were foodstuffs or medicines.

I will, before finishing my talk, expound briefly on two points I have mentioned above: frauds on the nature, species or origin of the goods, and improper or deceptive labeling—offenses which are often linked together.

Protection of Traditional Names and Quality

As is well known, the French are very particular about gastrology and gastronomy. They are even accused of paying too much attention to good eating. Be that as it may, they have traditionally devoted much talk, but also great care, to the preparation and selection of their wines, their cheeses, to the breeding of animals—and they are willing to pay the price for a particular kind or quality of product, which indeed costs more to obtain.

French legislation has been careful to adequately protect traditional denominations and geographical names of goods, particularly when they unequivocally describe a well identified product. Such protection is afforded of course to foreign goods as well as to French ones: Port wine has to come from Porto, Parmesan cheese from Parma.

Is it surprising then that the French deeply resent the use of their centuries-long, traditional names for different, and cheaper, products? For the consumer such use is indeed a fraud, and for the manufacturer or producer a deliberately unfair trade practice. What indeed is surprising is that such practices are tolerated, nay officially endorsed, in a country like the United States where so much attention has been devoted to enforcing informative labeling, clear and complete statements about the composition of food products, detailed standards of identity and elaborate definitions of quality—all of which have served as examples elsewhere.

Would it be loyal to the consumer and to the producer to sell oranges from Morocco and advertise them as Californian? And why should not the same rule apply to Burgundy, Sauterne or Champagne —whose South African, Australian or, by the way, Californian imitations are far more different from the originals than a navel orange grown in California is from the same variety grown in North Africa?

Other well known examples are cheeses, at least those which have been manufactured for centuries in a particular region and are distinguished by its geographical name. The case of some so-called Roquefort cheeses, not necessarily American, is especially astonishing, since the genuine sort is 100% ewe's milk (notably more expensive than cow's milk and white in colour) whereas the imitation is made from cow's milk, artificially bleached—so as to resemble ewe's milk—by treatment with oxidizing chemicals (benzoyl peroxide) which destroy the vitamin A. The improper use of the name is com-

plemented by a falsification, and by the deliberate destruction of a valuable nutrient.

Stating that "petits pois" (that is, garden peas=*Pisum sativum,* as opposed to field peas=*Pisum arvense*) means "little peas" is just ignorance of the French language; but failing to distinguish sardines from sprats and herrings, or "foie gras" from plain goose liver paste, is indeed deliberate disregard of facts of two orders: first, that the nature, species and "substantial qualities" of the genuine product differ widely from those of the substitute product; second, that there is also as a rule a large difference in market value (for example, in 1963 in French ports, sardines, *Clupea pilchardus W.* cost about 1.50 frs.—$0.30—per kilogram; sprats, *Clupea sprattus,* about 0.50 frs. —$0.10; herrings, *Clupea harengus,* about 0.80 frs.—$0.16; "foie gras," that is, *fattened* liver of geese, costs 65 frs.—$13.00; goose liver 7 frs.— $1.40).

It may be suggested that it is not quite appropriate that I should indulge here in such criticisms; but I am not so much criticizing as giving examples—those I know of—of a situation which I think deserves careful study and corrective measures.

My concern is due to the fact that manufactured food products are looking today to ever expanding markets, and to consumers located—permanently or temporarily—in all parts of the world. If these consumers are to be reached, and goods exchanged as freely as possible, the labeling must be acceptable internationally, that is, at least respect the characteristics and the original names of the traditional products of each country.

Harmonization of European Food Standards

It may not be out of place to indicate that in the European Common Market (European Economic Community, EEC) a number of committees have been at work for some years already with the purpose of bringing into agreement the food legislations of the six countries. The functioning of the system is the following: the EEC Authorities in Brussels ask each particular section of the food industry of the six countries to work out joint proposals through their trade associations. Such proposals are used by the Service for harmonization of legislation as a basis to establish a draft regulation, which is then submitted to various committees: scientific, linguistic, economic and social, before reaching the EEC General Assembly. The draft, if approved, is then sent to the official experts delegated by

each government, who have to give their final agreement or to suggest amendments. The draft is also submitted to the General Union of Manufacturers of the EEC.

The procedure is unavoidably slow, since the problems have to be tackled one by one, and all interested parties are offered an opportunity to give, through their representative bodies, their opinions.

One point has, however, been agreed upon from the beginning: that is the respect of geographical names of products whenever the country concerned requests it.

Our fight against food adulteration and misbranding must continue in the interest of the consumer and of fair trade practices. I think it is our duty to insist that no labelling should infringe fundamental moral rules or induce confusion in the mind of the buyer.

Just to show that "deceptive labelling" was already a serious concern many years ago, even in matters other than foodstuffs, I conclude by citing the following order enacted in 1770 by the Parliament of Paris:

> Any female who lures into the bonds of marriage any male subject of his Majesty by means of rouge, powder, scent, lotion, false teeth, false hair, corsets, crinolines, bustles or high heeled shoes shall be prosecuted for witchcraft, and the marriage shall be declared null and void.

Who says our fight is finished? **[The End]**

Selected Bibliography

De Gaillard-Bancel, "Les anciennes corporations et la lutte contre la fraude," *Bloud,* Paris, 1913.

Monier, Chesney and Roux, "Traité théorique et pratique pour la répression des fraudes," *Larose & Tenin,* 2nd Ed., Paris, 1925.

Turpaud, "La vente des marchandises: fraudes et falsifications," *Paton,* Troyes, 1955.

Toubeau, "Fraudes et falsifications," *Berger-Levrault,* Paris, 1957.

Fourgoux and Cheftel, "La fabrication et la vente des produits alimentaires conservés — Statut juridique," *Ed. Revue Conserve,* Paris, 1956.

Fourgoux and Cheftel, "Statut juridique des produits alimentaires conservés," *Ed. Altil,* Paris, 1963.

Dehove, "La réglementation des produits alimentaires et non alimentaires—Répression des fraudes et controle de la qualité," *Commerce-Editions,* Paris, 1964.

Criminal Liability for Deceiving the Food and Drug Administration

By GEORGE ROSNER

Mr. Rosner Is an Attorney and a Chemist.

SECTION ONE: BACKGROUND SURVEY

1. Introduction

IN THE ROUGH AND TUMBLE DAYS of the early 1930's, the federal government was engaged in an all out struggle to destroy the Capone criminal enterprises.

One of the potent legal weapons used by the Department of Justice in its offensive against crime was United States Code Title 18, Section 1001—hereafter in this article designated simply as section 1001. This section dealt with criminal liability for making material false statements to government agencies.

A typically successful invocation of this section appears in the case of *Capone v. United States,* 51 F. 2d 609 (1931). Defendant Ralph Capone had written a letter to the Collector of Internal Revenue offering to compromise his income taxes for the years 1922 to 1925. In this letter Capone stated falsely:

> My liabilities are very much greater than my assets, and the only tangible assets I have is a half interest in two racing horses. . . .

The truth, as uncovered by Federal Bureau of Investigation agents, was that during the time in question Capone had close to two million dollars in hidden assets. Capone was removed from circulation by a long prison term for having violated section 1001 (in those days known as section 80).

Today, more than thirty years later, section 1001 is still invoked to discourage either fraudulent or otherwise intentionally made material misstatements directed to government agencies. But, as we shall see, the misstatements are of a far more complicated and sophisticated type, and the defendants are too often drawn from a strata of our society not usually associated with criminal misconduct —namely, research scientists and research physicians.

For example, in the recent case of *United States v. Wm. S. Merrell Company et al.* (United States District Court, District of Columbia, Criminal No. 1211-63 (1963)) two research scientists who were conducting preclinical bio-chemical tests on animals to determine the safety and efficacy of certain new drugs proposed for human use, received suspended sentences for their connection with the issuance of false reports of their findings, which had been submitted by their employer to the Food and Drug Administration (FDA) as part of a New Drug Application (NDA).

In a second recent case, *United States v. Dr. Bennett A. Robin* (United States District Court, District of Columbia, Criminal No. — (1964)) defendant physician had undertaken to run clinical tests on human subjects to determine the safety and efficacy of a new drug evolved by a drug manufacturing concern. Dr. Robin falsely reported in writing that he had conducted the necessary clinical tests, and that these tests showed the drugs to be efficacious. It turned out that the physician had conducted no clinical investigation of any nature, and that he had dreamed up the entire gamut of tests and test results. Here again, as in the *Merrell* case, defendant knew that his false reports were destined for the FDA as part of a NDA.

Both of these cases are historic because they represent the first incursions of section 1001 into an area of activity generally regulated by the Food, Drug and Cosmetic Act, and for this reason they will merit our further examination. Moreover, now that section 1001 has found a toehold in the food, drug and cosmetic area, it is most natural to expect that section 1001 will find expanded application in that area; this potential area of application will also be surveyed.

However, before going into the further details of the two "rigged research" cases, and before thereafter examining the potential applications of section 1001 in the food, drug and cosmetic area, some salient background material relating to section 1001 will be presented to demonstrate its scope and force, and to fortify views later presented in this article.

2. Aims of Section 1001

United States Code Annotated, Title 18, Section 1001 reads as follows:

Statements or Entries Generally

Whoever, in any matter within the jurisdiction of any department or agency of the United States knowingly and wilfully falsifies, conceals or covers up by any trick, scheme, or device a material fact, or makes any false, fictitious or fraudulent statements or representations, or makes or uses any false writing or document knowing the same to contain any false, fictitious or fraudulent statement or entry, shall be fined not more than $10,000 or imprisoned not more than five years, or both.

An aim of this statute is to nip in the bud any false statements which might cause a government agency to deviate from official decisions or actions it normally would take when it has the full and true facts before it. Communications by means of which agencies receive pertinent data must not be cluttered with agency-misleading statements. An equally important aim of the statute is to make certain that no one try to conceal pertinent data from the government by any "trick, scheme or device". Communications by means of which agencies receive data must not have missing therefrom any information which has a natural tendency to affect agency judgment.

3. False Statements

Because of the basic philosophy behind section 1001, it is not surprising to find numerous decisions to the effect that the success of a section 1001 prosecution for false statements is not dependent upon a showing that the government has suffered a pecuniary loss, or that the agency has already acted in some way in reliance upon a defendant's misstatement or omission. The government need not wait that long before striking back:

It seems well established in federal criminal jurisprudence that actual influence of the department or agency involved is not essential to a prosecution under section 1001. The true test is whether the false statement has a natural tendency to influence, or was capable of influencing, the decision of the department or agency in making a determination required to be made. (*United States v. Blake,* 206 F. Supp. 706 (1962).)

This "natural tendency" test has been fairly universally adopted by the federal courts as a basic test of the materiality of a false statement.

Not only is it unnecessary that the false statement actually influence government decision, it is also unnecessary that the false statement either be in writing or be under oath, or even that the misstatement be made in the course of following an administrative procedure outlined and required by some statute.

A rather remarkable case in these particulars is *Marzani v. United States,* 168 F. 2d, 133 (1948), affirmed 335 U. S. 895.

Marzani, a State Department employee, orally stated to his superior: "I am not and never was a member of the Communist Party". The statement was untrue, and he was convicted of violating section 1001. The remarkable features of this case were: (1) Marzani was under no compulsion to make *any* statement. At the time he made the statement, he was not required by law or regulation to make any statement. (2) Marzani had heard that his political connections were under investigation, so he asked to see his immediate superior; and at a highly informal meeting between Marzani and his superior, he made the misstatement voluntarily. (3) It was Marzani who initiated the informal meeting.

None of these circumstances had the slightest exculpatory effect on Marzani's guilt.

Incidentally, one of the points raised by defendant in the *Blake* case, above, was that defendant's misstatement was not made under oath. The court held this point legally inadequate, citing *Marzani.*

4. False Statements Plus Concealment

While the *Marzani* case concerned itself exclusively with intentional misstatements, some cases cover counts in the indictment involving both misstatements and concealment. Such a case is *Neely v. United States,* 300 F. 2d 67 (1962). The *Neely* case offers an excellent illustration of the type of concealment by trick, scheme or device that section 1001 seeks to discourage.

Neely tried to outwit an Internal Revenue Agent. He employed the trick, scheme or device of submitting to the Revenue Agent a copy of a certain written lease, from which copy Neely had intentionally omitted a vital clause which had appeared in the original lease. The omitted clause was one giving Neely an option to purchase the land described in the lease.

Neely knew that if the tax authorities became aware of the existence of the option clause in the original lease, they might call upon him to pay more taxes. (This consequence was not inevitable: it depended on the tax authorities' interpretation of the entire instrument.)

Neely therefore attempted to pass off the abbreviated copy of the lease as the complete lease.

For intentionally suppressing a vital segment of the document Neely was convicted of concealment under section 1001.

Not only was Neely convicted of concealment by the trick of using the truncated written lease in place of the complete written instrument, but he was also convicted under a separate count of

making a positive oral material misstatement to the Revenue Agent who was investigating Neely's taxes. Neely's indictment on this latter point read:

> He orally stated to the Internal Revenue Agent that there was no option to purchase involved in said Neely's lease, whereas in truth and fact Neely well knew the lease agreement contained an option to purchase.

Neely's conviction for his oral misstatement had behind it the authority of the *Marzani* case.

5. Concealment by Deeds Alone

The use of a truncated document as the device to conceal is only one of many possible methods of concealment. Acts of concealment involving neither written documents or oral communications between defendant and the affected agency, while uncommon, do occur. In *United States v. White et al.,* 69 F. Supp. 562 (1946), an indictment was upheld which stated that defendants:

> did knowingly and wilfully conceal and cover up by trick, scheme and device.... ... the whereabouts of fifty-one Mexican aliens illegally in the United States, by placing said Mexican aliens in a closed van, by locking the door of said van, by transporting said aliens . . . in the night time.

The defendants in the *White* case, by their deeds alone had hoped to impede the immigration authorities in the performance of the authorities' duties. Said the Court:

> Count 2 states an offense because it charges the defendants devised a trick . . . in the matter of the detection and apprehension of aliens illegally in the United States.

The illegal deeds consisted exclusively of the acts of placing the Mexicans in a closed van, locking the door and transporting the aliens to locations not generally covered by the immigration authorities. Neither oral nor written words, directed to the affected agency, were involved in this crime.

6. Indirect Deceptions

In both the *Marzani* and *Neely* cases, the defendants dealt directly with the general agencies whose decisions and activities the defendants tried to influence.

Sometimes the defendant remains in the background and uses some intermediary as the vehicle to mislead the government agency. The defendant assumes the role of an undisclosed prime-moving principal working through an agent. The agent or intermediary in turn may be either innocent or guilty, as the case may be, of trying to mislead the government agency.

And finally it should be pointed out that sometimes the criminal misstatement originates not with the principal, but with the inter-

mediary; but because the undisclosed principal is the prime mover, the principal is nevertheless held accountable for the misstatement. This is true even though the principal did not know the contents of the intermediary's misstatement to the government agency.

A neat application of this "criminal respondeat-superior" doctrine turned up in *Todorow v. United States,* 173 F. 2d 43 (1949). Defendant Todorow wanted to buy some surplus oil delivery trucks offered for sale by the War Assets Administration (WAA). Knowing that under the law war veterans could purchase these trucks at preferential terms, Todorow induced a veteran named Taylor to purchase the trucks under Taylor's name, with the understanding that Taylor would thereafter transfer the trucks to Todorow. In the purchase application form, which Taylor filled out, Taylor falsely stated that he, Taylor, needed the oil delivery trucks because he was going into the oil delivery business.

Even though Todorow, the undisclosed principal, had no knowledge beforehand of what misstatement Taylor was going to make in the purchase-application form, nevertheless Todorow knew that the intermediary Taylor was bound to make some misstatement to the WAA, and this was sufficient to impose a section 1001 liability on Todorow.

An interesting "innocent-intermediary" situation appears in *Boushea v. United States,* 173 F. 2d 131 (1949). Defendant Boushea owned a potato warehouse. Potato-farmer Linquist stored his potato crop at Boushea's warehouse; then Linquist borrowed money from the Commodity Credit Corporation, a federal agency, pledging the stored potatoes as collateral for the loan.

Shortly thereafter Boushea sold Linquist's potatoes and pocketed the proceeds, all without Linquist's knowledge or consent. The warehouseman told Linquist the potatoes had rotted in storage and had been dumped. He told Linquist to file a "dumping statement" with the federal agency, assuring the farmer that the agency on receiving the dumping statement would release the farmer from his loan obligation.

Innocently, and knowing no way to check Boushea's veracity, Linquist filed a statement with the agency to the effect his potatoes had rotted in storage and had been dumped.

Needless to say, Boushea was found guilty under section 1001. Linquist was held entirely blameless. The court specifically stated that Boushea was a "principal acting through an innocent agent."

Note that in both the *Boushea* and *Todorow* cases, the principals were guilty of "causing" the making and using of false statements.

This "causing" need not be the result of a positive pressure exerted by the defendant on the intermediate. It is sufficient if defendant issues a false writing with knowledge that the recipient intends to utilize the writing in some transaction with a federal agency. In *United States v. Mellon,* 96 F. 2d 462 (1939), defendant Mellon made false statements to a bank in order to get a loan. He knew the bank intended to insure the loan with a federal agency as the insurer and that the bank intended to turn over defendant's statements to the agency in the course of getting the loan insured. This guilty knowledge by the defendant of the use intended by the recipient sufficed to uphold a conviction. The defendant "adopted" the intermediary's intended use of the false data as his own intended use. Some cases in this general area of criminal responsibility express this concept by saying the intermediary is acting as "agent" for the defendant, and that therefore the defendant is "causing" the crime. An excellent discussion of this agency theory appears in *United States v. Selph,* 82 F. Supp. 56 (1949). Invoked also in this *Selph* case was 18 U. S. C., 2b which states:

> Whoever causes an act to be done which if directly performed by him would be an offense against the United States, is also a principal and punishable as such.

7. Statutory Interplay

Very often section 1001, a statute of general application, appears on its face applicable to a set of facts which is also covered by some other more specific criminal statute. Forthwith the courts must decide whether the second statute constitutes an implied repealer of section 1001. The answer depends upon a study of the express or implied congressional intents relating to the two statutes.

An implied repealer of section 1001 by a federal perjury statute, 18 U. S. C. 1621, was found by the court in *United States v. Allen,* 193 F. Supp. 954 (1961). Allen had made a false statement before a federal grand jury, and his indictment charged him with violating section 1001. The court dismissed the indictment, specifically holding that the indictment should have been brought under the perjury statute.

Very often the court will find no implied repealer, but on the contrary will find that both statutes peacefully coexist. Here, however, the prosecutor must elect which one of the two coexisting statutes he will invoke against the defendant. Courts refer to these

coexisting statutes, either of which may be applied against defendant, as identic statutes.

That one statute defines a felony, while a second covering the identical facts defines a misdemeanor, does not prevent the two statutes from being classified as identic, and does not prevent the government from selecting the felony statute as the one to impose upon the defendant. In *Ehrich v. United States,* 238 F. 2d 48 (1956), felony statute section 1001 was successfully applied over defendant's objection that he should have been prosecuted under a less stringent identic misdemeanor statute. Held the court:

> It is well settled law that where a single act violates more than one statute the government may elect to prosecute under either. A defendant cannot complain merely because charge against him is brought under the statute carrying the more serious penalties when the two statutes cover the same general acts.

The problem of whether one criminal statute impliedly repeals another, or whether the two can coexist so as to give the prosecutor an option to select one of them, arises only where the facts to be proven are identical under both statutes.

The moment we find that one or more of the facts which must be proven under one of the statutes need not be proven to support a conviction under the other statute, there is no longer a problem of the interplay or impact of one of the statutes on the other. The statutes are no longer identic, nor does one impliedly repeal the other. Each statute is now totally independent of the other. Here a defendant under separate counts in the same indictment may be tried at one trial, and if found guilty of violating both statutes, receive separate and consecutively running sentences for each statutory violation.

The two statutes are independent statutes, in the sense that one in no way impinges upon the other.

It is a legal truism that intentions are facts. (The state of a man's mind is as much a fact as the state of his digestion.) Therefore, if two statutes require proof of the same facts except that one requires proof of an intention not required by the other, the two statutes are not identic statutes, but are on the contrary independent statutes in the sense described above.

An elegant illustration of the role of different intentions in eliciting distinct and independent crimes is offered by the case of *United States v. Baumgarten,* 300 F. 2d 807 (1962).

Baumgarten placed nylon hosiery in a package, labelled the package "Books," and then mailed the package to Argentina. He mis-

labelled the contents of the package for two reasons. In the first place he knew that Argentina placed a duty on nylons, but none on books, and he wanted to avoid paying the Argentine duty. In the second place he knew that the United States Post Office charged a lower mailing rate for books than for nylons and he wanted to avoid paying the higher postage rate.

The intent to defraud Argentina subjected Baumgarten to a criminal statute which forbids using the mails to defraud (18 U. S. C. 1341).

The intent to defraud the United States Post Office subjected Baumgarten to section 1001 because he had made a written misstatement on his package with the intent of inducing the post office thereby to charge a lower mailing rate that it would otherwise have charged.

Baumgarten was convicted of violating both statutes.

Here is a case where a single written word led to a conviction for committing two distinct felonies! The objective facts proven under each of the statutes was identical. Only the subjective intents differed. This difference in intents sufficed to give rise to two distinct crimes under two distinct statutes.

8. Awareness of Government Involvement

Very often in criminal law a defense will be proffered that the defendant was not aware of the legal ramifications of his conduct.

Defendant will admit *arguendo* that his acts were illegal; but he will contend that since this illegal conduct was directed to and intended for a particular victim, the crime for which he should be punished should be confined to the crime as defined against his intended victim. However, he will argue, none of his acts should be extended to embrace some other defined crime in any case where defendant was both unaware of the fact that he was committing this second crime and was unaware of the involvement in this second crime of some other persons or agencies.

Substantive criminal law answers that defendant nevertheless is responsible for committing this second crime, as well as the original crime.

An explosive illustration is the well-known case of *United States v. Anderson*, 101 F. 2d 325 (1939). Defendants bombed interstate railroads. They were found guilty of criminal conspiracy to obstruct interstate commerce. But they were also found guilty of obstructing the passage of United States mail. Ruled the court:

> It is urged by appellants that there was no proof of conspiracy in the mail indictment. True, there was no proof of an express agreement to interfere with

the mail. However, the appellants will be presumed to have intended the natural consequences of their acts; when they conspired to stop all railroad transportation they were bound to know that as a natural consequence the mails would be greatly interferred with on those railroads carrying mail.

In the *Anderson* case the defendants were "bound to know" that the mails were involved. But even if defendants could not ascertain after reasonable inquiry that a government agency was involved, they would be guilty. Consider the facts in *Haugen v. United States,* 153 F. 2d 850 (1946).

In the *Haugen* case the Olympic Commissary Company had a secret contract with the War Department to feed certain DuPont employees engaged in top-secret atomic bomb projects. Under the secret contract all food as well as all monies collected from the sale of the food was government property. Defendant Haugen embarked upon a plan to defraud Olympic of the food and money. He did not know and could not know of the War Department's involvement. He printed up false "meal tickets" and passed them off as the genuine meal tickets used and sold by Olympic in its commissary operation.

In spite of the fact that Haugen did not know and could not know of the War Department's involvement, Haugen was convicted of defrauding the War Department. Haugen admitted *arguendo* that the false printing (the false meal tickets) was intended to defraud Olympic but:

> Haugen claims that the element of the crime of defrauding the government is not proved because he is not shown to have known that the meal tickets and the money collected from the sale were government property. As well could it be claimed of a thief stealing government property from a general warehouse that he did not know it was government property. There is no merit to this contention. A man is presumed to do what he actually does. The judgment sentencing appellant is affirmed.

Haugen's argument that he did not know that his false tickets were in fact directed to a matter within the cognizance of the War Department failed. His criminal conduct, deliberately aimed at one person (Olympic) necessarily victimized someone else (the War Department) and this generated a crime against the latter.

Finally, coming down to a case specifically involving section 1001, the case of *Anna Lee Walker v. United States,* 192 F. 2d 47 (1953), seems in point. Defendant obtained a narcotic prescription from her physician. Upon being asked by the physician where she resided, she gave him a false address, which he wrote on the prescription. Defendant then filed this false-address prescription with a druggist. This filed prescription under the Harrison Narcotic Act was a record under the official surveillance of the Treasury Depart-

ment. The filed prescription was then a matter within the jurisdiction of a federal agency. Despite total absence of proof that the defendant knew that the prescription data was officially cognizable by a federal agency the moment it was filed with the druggist, or that defendant intended to deceive or mislead the agency by means of the false statement (the false address), defendant's guilt under section 1001, on the charge of filing the false prescription, was sustained.

The rule fairly deducible from these cases is that where the defendant, by his own acts, propels a false statement into an area of federal agency jurisdiction or official surveillance, he will suffer the criminal consequences of his act of propulsion even though he was not aware of the federal agency's official involvement in the area, and even though he did not intend to deceive the agency. That defendant's acts were initially directed to and intended solely for some victim other than the federal agency is legally immaterial.

9. Supervening Causation

The rule proclaiming defendant's guilt even though he is in fact unaware of government agency involvement applies only when some special duty-relationship exists between the recipient of defendant's false statement and the government agency. In the *Walker* case, for instance, the Harrison Narcotics Act imposed on the druggist receiving narcotic prescriptions the statutory duty to keep the prescriptions and to exhibit them to the Treasury Department for the latter's inspection and surveillance. Thus, the filing of a false prescription with the druggist was tantamount to filing it with the Treasury Department.

But if no special duty, either contractual or statutory, compels the recipient of a false statement to transmit or expose the statement to a federal agency, then the courts take the position that the act of the recipient in transmitting or exposing the false statement to a federal agency is the voluntary, independent, adventitious act of the recipient. And consequently, if it further appears that the defendant did not intend the false statement to fall into the hands of a federal agency, and was unaware of the recipient's intention to transmit defendant's statement to the agency, defendant cannot be held for a section 1001 violation. For it is now the adventitiously exercised free-will-act of the recipient, rather than the *sine qua non* act of the defendant that propels the false statement into the ambit of agency jurisdiction. The supervening causation by the recipient is the key to defendant's non-liability.

In *Terry v. United States,* 131 F. 2d 40 (1942), defendant was party to a transaction in which a loan was granted on the basis of false statements appearing in a realty-completion certificate. Thereafter, the lender innocently, but of his own free will, presented the certificate to the Federal Housing Administration (FHA) in order to get the loan insured by that agency. The insurance was issued. Later the FHA had to pay the lender because of default of the debtor. Defendant was prosecuted under section 1001 (then section 80). Said the court, in dismissing the indictment:

> It is clear that the Housing Administration had no cognizance of the (original) loan transaction on which the indictment rests. . . . Whether the Administration would or would not obtain such cognizance depended entirely upon the *free will* of other parties over whom defendant had no control.

While in the *Terry* case there is a serious question as to whether defendant was or was not aware of the intent of the recipient of the false-statement-containing certificate to transmit it to the federal agency, the ruling is correct if one assumes defendant's lack of awareness of the recipient's intended use of the certificate, and further assumes recipient had an untrammeled choice as to whether he would or would not thereafter insure the loan.

Of course, once it can be shown that defendant knew at the time he made a false writing that the writing would thereupon be used by the recipient in some matter within the jurisdiction of a federal agency, the defendant is a prime-mover and violates section 1001. The result is the same as if the defendant deliberately "used" the recipient as a transmitting agent to get the false writing to a federal agency. The discussion of "indirect violations," above, makes this clear.

SECTION TWO: RIGGED RESEARCH

1. Introduction

Now that we have scanned some general background material indicating the scope and force of section 1001, we are in a better position to appraise the *Robin* and *Merrell* cases considered earlier in a brief fashion.

The *Robin* case is the first on record in which a physician was prosecuted for causing the submission of false data to the FDA. Attention will now be directed to this historic case.

2. Rigged Research: Clinical Data

Under section 505 of the Food, Drug and Cosmetic Act[1] a pharmaceutical firm desiring to put a new drug on the market must first obtain the approval of the FDA. This approval is conditioned upon convincing proof presented to the FDA that the proposed drug is both safe and efficacious. The proof is presented through the medium of an application, submitted to the FDA, called a New Drug Application (NDA).

21 Code of Federal Regulations 130.4, sets forth the requirements of an NDA and demands that any and all applications must contain:

> Full reports of investigations that have been made to show whether or not the drug is safe for use and effective in use.

The regulatory language just quoted is lifted bodily from section 505(b) of the Food, Drug and Cosmetic Act, which reads:[2]

> Any person may file with the Secretary an application with respect to any (new) drug. . . . Such person shall submit as part of the application full reports of investigations which have been made to show whether or not such drug is safe for use and whether such drug is effective in use.

Returning for the moment to Regulation 130.4, this regulation also states that an application may be refused unless it contains "full reports and contains all the following . . . Reports of all clinical tests sponsored by the applicant. . . ."

Prior to 1960, White Laboratories Inc., a New Jersey drug concern, engaged defendant, Dr. Robin, on a consultant basis to conduct clinical tests on human patients with a new drug, "Entoquel with Neomycin Syrup," with the understanding that the clinical data to be collated by Dr. Robin would be incorporated in an NDA thereafter to be submitted by White Laboratories.

Doctor Robin conducted no tests whatsoever; instead he concocted a wholly false report involving fictitious patients who received imaginary doses of Entoquel which effected imaginary cures. This false clinical report was submitted to White Laboratories Inc. who thereupon innocently made the false report a part of its NDA, which in due course was submitted to the FDA.

When the truth was unearthed, Dr. Robin was indicted under section 1001. The first count of the indictment reads as follows:

Count I.

The Grand Jury Charges:

On or about September 20, 1960, within the District of Columbia, the defendant, Bennett A. Robin, M.D., unlawfully, wilfully and knowingly used and

[1] FOOD DRUG COSMETIC LAW REPORTS ¶ 71,051.

[2] FOOD DRUG COSMETIC LAW REPORTS ¶ 71,053.

caused to be used in a matter within the jurisdiction of a department and agency of the United States, a false writing and document knowing the same to contain false, fictitious and fraudulent material, statements and entries, in that the defendant, then engaged in the practice of medicine at 317 University Boulevard East, Silver Spring, Maryland, knowingly and wilfully caused White Laboratories Inc. of Kenilworth, New Jersey, a body corporate, to file, on or about September 20, 1960, with the Food and Drug Administration of the Department of Health, Education and Welfare, an agency and department of the United States in Washington, D. C. as part of a New Drug Application, designated as NDA 12-621, for Entoquel with Neomycin Syrup, a new drug then subject to Section 505 of the Federal Food, Drug and Cosmetic Act (21 U.S.C. 355), and which was then and there a matter within the jurisdiction of the said Food and Drug Administration, certain clinical test reports, to wit, individual patient case studies, in which defendant falsely, fictitiously and fraudulently stated and represented, and caused to be falsely, fictitiously and fraudulently stated and represented, that clinical tests of the said Entoquel with Neomycin Syrup theretofore had been made by him, whereas, in truth and fact, as the defendant then and there well new, he had not made such clinical tests. (18 U.S.C. 1001.)

Dr. Robin was also indicted on four other counts, involving four other drug firms, — all of the same tenor as Count I. He pleaded *nolo contendere* to all five counts and was sentenced accordingly.

Observe that we have here a case in which the defendant did not directly file the false statements himself, but acted through an innocent intermediary, White Laboratories Inc. Nevertheless, defendant, just as in the *Boushea* case, above, was held guilty of violating section 1001.

If Dr. Robin had been engaged to undertake research by White, but White had not informed Dr. Robin that the research data was to be transmitted to a federal agency, Dr. Robin might have defended on the ground of his lack of awareness of White's intent to involve a government agency, coupled with White's free choice to transmit or not transmit the data to the agency, as White saw fit. The supervening causation defense mentioned in discussing the *Terry* case, above, would have held up; for then Dr. Robin could not have been charged with having "used and caused to be used . . . a false writing" in an agency matter.

However, defendant here was in effect found guilty of wilfully "causing" White Laboratories to file the false clinical test reports with the FDA. Hence the issue of causation did not arise.

But what is interesting is the nature of the causation in the Robin case.

Dr. Robin "caused" White Laboratories to file his false report not by exerting any pressure on White Laboratories, but simply by handing over to White Laboratories his false reports at a time when he

knew White Laboratories intended to transmit these reports to the FDA as part of its forthcoming NDA.

And, as we saw in our discussion of indirect deception, this knowledge of the recipient's intended use of defendant's false statements sufficed to invoke section 1001 against the defendant, for then Dr. Robin could be said to have adopted White Laboratories' intention to transmit the data to the agency; or White Laboratories could be said to have acted as Dr. Robin's "agent" in the matter.

3. Rigged Research: Preclinical Data

Whereas the *Robin* case was concerned with clinical tests on human beings, the *Merrell* case (to which we now turn) dealt with false statements in the area of preclinical investigations on laboratory animals.

Regulation 130.4, as we have seen, demands of all NDA's that they contain "full reports of investigations that have been made to show whether or not the drug is safe for use and effective in use".

The regulation later states that such an application may be refused unless it contains full reports of adequate tests and presents:

> Detailed reports of the preclinical investigations including studies made on laboratory animals.

In the *Merrell* case, preclinical animal investigations were undertaken by certain of the individual co-defendants employed as research scientists by the defendant, Wm. S. Merrell Company (hereinafter referred to as Merrell). Merrell ran an extensive battery of tests on various laboratory animals to determine the safety and efficacy of the new drug Mer/29.

Trouble arose, however, when in an NDA for Mer/29 filed by Merrell, the results of certain of the tests were materially distorted. Further trouble arose when Endocrine Laboratories of Madison, a consulting laboratory under contract with Merrell, submitted their research findings with respect to Mer/29 to Merrell; and Merrell, because the Endocrine report was adverse, deliberately omitted to include the Endocrine findings as part of a subsequent amendment to their NDA.

These troubles took the form of two counts in an indictment under section 1001. (The indictment contained twelve counts but we shall limit ourselves to the two.)

The first count gave specific examples of the distortions of the findings of Merrell's own bio-chemists. Merrell, for instance, reported in the NDA that a certain dosage of Mer/29 killed only 50% of

the rats receiving the dose—whereas in truth all the rats died; Merrell reported no blood abnormalities—whereas there were in fact serious blood abnormalities; livers of monkeys receiving dosages were reported in the NDA as normal—whereas in truth necrosis of the liver had been observed by defendant.

Merrell pleaded *nolo contendere* to this count, but was fined $10,000.

The first count also included two individual co-defendants, biochemists in the employ of Merrell. These two also pleaded *nolo contendere,* but received suspended sentences. The degree of involvement of these two individual defendants is not clear but appeared to be minimal in view of the light sentence.

The second count is particularly interesting because it deals with concealment and covering up by trick and scheme of material facts in a matter within the jurisdiction of the administration, by omitting reports of a toxicity investigation conducted by Endocrine Laboratories pursuant to a contract to determine the effect of Mer/29 on fertility and gestation. Endocrine Laboratories had submitted to the corporate defendants a toxicity investigation report setting forth that certain adverse effects of Mer/29 had been noted, such as reduced conception rate among rats receiving doses of the drug, reduced sizes of litters and an increased death rate in the young rats. This report was completely suppressed by the corporate defendant in an amendment to its NDA.

The liability for suppression of the Endocrine report is clear.

Every New Drug applicant uses the application form prescribed in Regulation 130.4. The applicant expressly states in this form that:

> The undersigned submits this application with respect to a new drug pursuant to section 505(b) of the Federal Food, Drug, and Cosmetic Act. Attached hereto are the following:
>
> 1. Full reports of investigations that have been made to show whether or not the drug is safe for use and effective in use.

Consequently, the applicant expressly represents that what he is submitting is a *full* report of all investigations he has made or sponsored. If he submits a partial report, and cuts out data which might have a natural tendency to influence agency decision, then, as we have seen in the *Neely* case, above, this truncation is a material concealment violative of section 1001.

In addition to the total omission of the Endocrine Laboratories report, the second count specified copious excisions of material data from findings by the corporate defendant's own scientific personnel.

The criminal liability of a drug firm like Merrell for deliberately suppressing adverse data derived from investigations it has sponsored, either through the use of its own employees or through the use of consultants on a contract basis, is clear enough.

What is not quite as clear is the criminal responsibility that attaches to the deliberate suppression from an NDA of adverse data of which the firm is aware, which data appears in the scientific literature, or is derived from other reputable independent sources.

It is true that Regulation 130.4 states that:

> . . . the unexplained omissions of any pertinent reports of investigations or clinical experience received or otherwise obtained by the applicant from published literature or other source that would bias an evaluation of the safety of the drug or its effectiveness in use constitutes grounds for the refusal, or withdrawal of approval, of an application.

But these penalties are trivial compared with the criminal penalties imposed by section 1001.

The writer believes that the deliberate omissions of such pertinent reports, made with the intent of hiding from the agency the lack of the safety or efficacy of the drug, coupled with the presentation of biased data showing alleged safety or alleged efficacy, is a section 1001 concealment by "trick, scheme or device." An NDA, in this view, contains the implied representation that the data presented therein, barring some accidental omission, constitutes a full and complete picture of the safety and efficacy of the new drug as far as the applicant knows at the date of filing.

One last pronouncement regarding general behavior connected with NDA's should be made.

After an NDA is filed, an applicant will generally hold one or more post-filing conferences with the FDA. These conferences may or may not lead to supplementation of the original application. Often these supplements are in the form of a letter. It is well to remember that section 1001 applies not only to these letters but also to any and all communications, whether written or oral, and whether formal or informal, which may have a tendency to influence agency decision in regard to the new drug under consideration. We have already seen both in the *Marzani* and *Neely* cases, above, that oral statements to government agencies, even though made under the most informal circumstances, can come under the scrutiny of section 1001. It follows that communications of any nature to the FDA in regard to the NDA must be circumspect and encompass the total truth known to the applicant at the time. Anything less is criminally dangerous.

SECTION THREE: FORECASTS

1. Introduction

Section 1001, having successfully penetrated into the food, drug and cosmetic law domain, will undoubtedly proliferate in that area. Section 1001 has had a past general history of ever expanding application, and there is no reason to expect a change in this trend in the fertile new field in which the statute now has a firm foothold.

An attempt to forecast imminent potential applications of section 1001 in the food, drug and cosmetic area should start with the observation that the FDA performs two main functions—the regulatory function and the monitorial function.

The regulatory function is concerned mainly with the promulgation of regulations as well as approval of certain applications and the issuance of certain permits. We have already encountered one facet of the regulatory function in the consideration of the NDA's involved in the *Robin* and *Merrell* cases.

The monitorial function is implemented mainly by the FDA's staff of inspectors, who, in general, police the interstate shipments of products manufactured by food, drug and cosmetic firms. The inspectors gather samples of products suspected of being misbranded or adultered, make factory sanitation inspections, and perform allied duties.

Let us first direct attention to the possible incursion of section 1001 into situations involving the regulatory activities of the FDA; later we will consider section 1001 in relation to the monitorial functions of the FDA.

2. Section 1001 and Regulatory Functions

The regulatory functions are mainly directed to the issuance of specifications of conditions precedent to permissible interstate commerce in food, drugs or cosmetics.

In most cases the exercise of the regulatory function by the FDA results in the issuance of a regulation. This regulation is the end-product of an FDA procedure generally initiated by a person or firm interested in the promulgation of the regulation in question.

This interested person or firm will initiate this procedure by filing a petition with the agency. The requirements of the petition are set forth in the Food, Drug and Cosmetic Act as well as in the supporting Code of Federal Regulations. After a series of administrative steps, if all goes well, the petition will be granted and the regulation duly promulgated.

This procedure via petition is employed in many areas covered by the Food, Drug and Cosmetic Act but a typical procedure, namely, a Petition for a Food Additive Regulation will suffice for our purposes.

Consider a food manufacturing firm that wishes to market a new ingredient. This ingredient is safe for human consumption only if used in limited quantities and only if used in particular foodstuffs. Because the ingredient is not safe for general use, but safe only if sold under strict legal safeguards, the food concern correctly decides that the ingredient is a "food additive" within the meaning of the Food, Drug and Cosmetic Act, and can be marketed only after the FDA has issued a food additive regulation strictly defining both the quantities and areas of permissible use.

Accordingly the firm files a food additive petition. Under section 409(b) of the Food, Drug and Cosmetic Act:[3]

(1) Any person may . . . file . . . a petition proposing the issuance of a regulation prescribing the conditions under which such additive may be safely used.

(2) Such petition shall . . . contain—

(A) the name and all pertinent information concerning such Food . . .

(B) . . .

(C) all relevant data bearing on the physical or other technical effect such additive is intended to produce . . .

(D) . . .

(E) full reports of investigations made with respect to the safety for use of such additive, including full information as to the methods and controls used in conducting such investigations.

It should be obvious that the food additive petition procedure in the food field is the analogue of the NDA in the drug field. And insofar as section 1001 is concerned, what has been said about the relation between section 1001 and NDA's in the discussion of the *Robin* and *Merrell* cases, above, applies equally to the relation between section 1001 and food additive petitions. Indeed, the *Robin* and *Merrell* rulings, and the discussions thereunder, apply to *all* situations in which a food, drug, or cosmetic firm seeks to invoke the regulatory functions of the FDA either by formal or informal communications.

Deliberate distortions or suppressions of "reports of investigations made with respect to the safety for use of such additive" (see (E) above) violate section 1001 when they relate to material data obtained through investigations sponsored by the food concern.

[3] Food Drug Cosmetic Law Reports ¶ 55,103.

And, in this writer's view, the deliberate omission by a petitioner of material data gleaned by the petitioner from the technical literature or other reputable source, when the omission is motivated by the petitioner's belief that the presentation of the data might lead to the FDA's rejection of the food additive petition, amounts to a violation of section 1001. The situation is no different than the deliberate omission of material data from an NDA under the same circumstances.

For, in the last analysis, a petitioner has no right to test the truth or falsity of the data appearing in the literature by suppressing the data, then putting the additive on the market (after succeeding in getting the regulation promulgated) and using the consuming public as the guinea pig to determine whether the additive is safe or dangerous. This observation applies with equal force to NDA's.

The Food, Drug and Cosmetic Act pushes hard to protect the health of the consuming public, and the courts will invoke section 1001 as a collateral statute to buttress this objective.

3. Section 1001 and the Monitorial Functions

The monitorial function is most commonly exercised when an FDA inspector visits a food, drug or cosmetic plant for official inspection purposes. These visits may present opportunities for violation of section 1001. A few hypothetical situations will make this clear.

1. An inspector visits a drug manufacturing concern. He asks the firm to produce for his inspection its present formula for a prescription drug product that the firm is producing and which it has shipped in interstate commerce earlier the same day. He specifically asks for a complete list of the ingredients used, and the weight of each ingredient. He also asks for a sample of the label the firm places on packages containing the drug product, explaining that he wishes to compare the ingredients listed in the formula with the ingredients listed on the label to make sure that there is an exact correspondence.

It so happens that the firm had, some months before, changed its formula radically, but had not bothered to change the labels, so that there is now a wide variance between the ingredients listed in the present formula for the drug, and the ingredients appearing on the label.

To cover up this discrepancy, the firm hands over to the inspector the previous obsolete formula, and orally states that it is the formula it is now using in manufacturing.

Under the doctrine of the *Neely* case, above, the firm would be guilty of violating section 1001 under two counts, one based on con-

cealment by the trick, scheme, or device of proffering the false formula, and the other based on the oral misrepresentation.

Note that under the law a drug firm is compelled to expose its prescription-drug formulas to an inspector. This is not true in the case of a food processing concern. A food processing firm cannot be forced to show its formulas—but, of course, it can do so voluntarily.

If a food processing firm, in the same situation as the drug firm above mentioned, voluntarily handed over to the inspector an obsolete food formula passing it off as the formula it was presently using, it would be guilty under section 1001 to the same extent as the drug firm just considered. For as we have already seen in the *Marzani* case, above, a voluntary false statement is also subject to section 1001 attack.

2. An inspector visits a food processing plant and announces that he wishes to examine all its equipment to make sure that the equipment is kept clean and to make sure that the manufacturing is performed under sanitary conditions. The top floor of this plant contains food handling equipment used daily to make one of the firm's products. This equipment is filthy and is never properly cleaned. The plant manager takes the inspector on a tour of the plant, but intentionally steers the inspector away from the top floor. He tells the inspector that the top floor is devoted exclusively to storing old company records and therefore there is no point in examining the top floor. He also states that the inspector has already seen all the machinery and equipment the firm uses. Section 1001 has been violated.

3. A food processor of prepared cake mixes wants to eliminate adding expensive powdered egg yolk to its "yellow cake mix" which it packs in one pound packages for the retail grocery trade. However, the processor wants the consumer-housewife to be attracted to his product, so he prints on his packages, in large letters, "Contains not less than 3% powdered egg yolks." In truth, the mix contains no egg yolk whatsoever. The processor is intentionally deceiving the consumers, as well as the processor's customers.

But this processor goes further. He does not want the FDA chemists to discover the total absence of yolk from any samples of its product that food inspectors might obtain and turn over to the chemist for analysis.

The processor knows that FDA chemists calculate the percentage of egg yolk present in a cake mix by determining the percentage of cholesterol in the mix, and then deriving the percent yolk present on the basis of the cholesterol found. So the firm makes and packs

yellow cake mix containing no yolk; but the processor adds just enough cholesterol to the mix so that an analysis of the mix will give cholesterol yields which, when extrapolated, will indicate that there is at least 3% yolk in the mix.

In due course, the processor ships this product in interstate commerce.

Here we have a covering up of the complete absence of yolk by the trick, scheme, or device of substituting cholesterol in the place of egg yolk. This act of substitution is deliberately calculated to mislead and hinder the FDA's chemical staff in the performance of its function and duty to discover misbranding and adulteration. The case is curiously akin to the *White* case, above, where the act of the defendant was deliberately calculated to hinder the federal immigration authorities in the performance of their function and duty to discover aliens illegally entering the country.

In addition to concealment, the processing firm can also be found guilty under section 1001, in a second count, for having made the positive false statement "contains not less than 3% egg yolk," inasmuch as this false statement, although primarily directed to consumers, might reasonably be found (by a jury) to be also directed to the FDA's chemists with the intent of deceiving them into believing that the cholesterol they might find on analysis came from egg yolk, and has not been added to the mix in the form of pure cholesterol.

There is yet another fascinating facet to this hypothetical case.

That the misbranding of the product is a misbranding in violation of the Food, Drug and Cosmetic Act is beyond argument. And the deliberate intent to deceive purchasers and consumers is admitted for the purposes of this case, as is the interstate shipment of the goods.

Now, Section 303 (b) of the Food, Drug and Cosmetic Act states that:[4]

> . . . in case of a violation . . . with intent to defraud or mislead, the penalty shall be imprisonment for not more than three years . . . .

The deliberate misbranding, the intent to deceive consumers and purchasers, and the interstate shipment clearly puts the processor in the grip of this criminal provision of the Food, Drug and Cosmetic Act.

We are saying, then, that not only is the processor guilty of violating section 1001, but that he is also simultaneously guilty of violating section 303(b) of the Food, Drug and Cosmetic Act.

---

[4] Food Drug Cosmetic Law Reports ¶ 2213.

The intent to deceive the FDA places the defendant within the purview of section 1001. And the intent to deceive consumers places defendant within the purview of section 303(b).

This case is a parallel to the *Baumgarten* case, above, in that the objective facts to be proven under each statute are identical. Only the subjective intents differ. This difference in intents suffices to give rise to two distinct crimes under two distinct statutes.

Implied in this conclusion is the further conclusion that section 303(b) does not impliedly repeal section 1001. Nor are the two statutes identic in the sense that they both cover precisely identical facts and that the prosecutor must therefore select but one of the two criminal statutes under which to proceed. The two statutes are totally independent. And as a consequence, consecutive sentences may be imposed if the defendant is found guilty of violating both section 1001 and section 303(b).

5. The final hypothetical case varies somewhat from the previous one to illustrate one more point.

Suppose our food processor, instead of having added cholesterol to his mix, has added a relatively easily identifiable yellow color (chemically speaking). His one and only intent in doing so, however, is to mislead consumers and purchasers into believing the mix contains egg yolk. He has no subjective intent to deceive the FDA or its inspectors or chemists. His packages still have printed on them the legend "Contains not less than 3% egg yolk."

In a section 1001 prosecution brought against him for making a false writing—namely, the false legend on his packages—the processor now contends that when he made the interstate shipments of his mix and at all times prior thereto he was not thinking at all about the FDA, and had no intention to deceive or mislead the FDA.

The contention fails. For the defendant has by his own act of placing the false-statement-containing packages in interstate commerce, propelled the false statement into an area of federal agency jurisdiction, and the defendant must suffer the criminal consequences thereof, even though he was not aware of a federal agency's official involvement. This point was discussed above when we considered the general problem of defendant's awareness of government involvement.

SECTION FOUR: GUIDELINE

1. Conclusion

The following guideline should prove useful in dealings with the FDA: Honesty is the best policy. **[The End]**

Recent Developments in the Law Relating to the Retail Sale of Drugs

By J. RICHARD EDMONDSON and WILLIAM F. WEIGEL

Messrs. Edmondson and Weigel Are Members of the New York Bar.

THE SUPREME COURT OF NEW JERSEY, in a recent case,[1] reversed a lower court judgment which had imposed a statutory penalty upon a nonpharmacist retailer for the unlawful sale of a medicinal preparation (citrate of magnesia). The lower court had held that, since its formula was generally known, citrate of magnesia did not come within the pharmacy statute exemption for "patent or proprietary medicines" and, thus, could be sold only by a registered pharmacist. In reversing, the court acknowledged that it was unable to define precisely the quoted term, "patent or proprietary medicine," but was not persuaded that the statute was intended to regulate the sale of the particular commodity. In a separate opinion[2] Justice Francis concurred in the result, but stated, "in doing so I cannot escape a sense of unfinished business." He then proceeded to set forth his understanding of the statutory term "patent or proprietary" medicine,[3] formulating a definition designed to carry out the legislative intent and concluded that citrate of magnesia was clearly within its purview.

Justice Francis was attempting to do what so many courts and legislatures have evidently been unwilling or unable to do—put an

[1] *Board of Pharmacy of the State of New Jersey v. Anderson,* 40 N. J. 40, 190 A. 2d 664 (1963).

[2] See citation in footnote 1 at p. 42.

[3] "Any nonprescription medicine or drug which is prepackaged, fully prepared by the manufacturer or producer for use by the consumer, and is accompanied by adequate directions for use." See citation in footnote 1 at p. 43.

end to the so-called "restrictive sales" controversy between organized pharmacy and general merchants about the right of the nondruggist retailer to sell nonprescription packaged medicines. The question has been the subject of much litigation, discussion and emotion, but still remains unresolved. It would appear that a termination of this unfinished business is long overdue.

State pharmacy statutes uniformly restrict the retail sale of drugs, medicines and poisons to licensed pharmacists.[4] Invariably, however, there is some exemption for packaged, nonprescription preparations designed for use in self-medication. In most instances the exemption is stated in terms of "proprietary" medicines, or "patent" medicines or a combination of the two.[5] The controversy has resulted from an attempt to define the statutory terms and, thus, determine which products may be sold by general merchants and supermarkets.

Inconsistency in Court Decisions

Unfortunately, the courts have not been at all consistent in their interpretations of the proprietary exemptions in the various state pharmacy acts and have arrived at conflicting results or have decided individual cases without terminating the underlying controversy. It would appear that the courts have all too often concerned themselves with matters of semantics rather than legislative rationale. Statutes regulating the sale of medicinal preparations are based upon considerations of protection of the public health and should be construed in a way that will accomplish that end. It matters not a whit whether a particular medicinal preparation can satisfy an arbitrary definition of "proprietary," provided that the public health will not be jeopardized by permitting its sale by general merchants or unregistered personnel within the drugstore. Nevertheless, the courts in deciding these cases seem unwilling to go behind the statutory language and attempt to determine the legislative intent.

In recent years the druggists have become alarmed at the attrition of much of their nonprescription business to the supermarket with its modern merchandising methods. In order to stem this tide the pharmacy boards, invariably composed of retail druggists,[6] have

[4] "State Regulation of Drugs: Who May Sell 'Patent and Proprietary' Medicines," 63 *Yale Law Journal* 550 (February 1954).

[5] See, for example, 11 Minn. Stat. Ann. A 151.26(19); N. J. Rev. Stat. 45:14-29; Code of Va. (Amended), Tit. 54, ch. 15, § 399 (17) (1950).

[6] See, for example, § 6802 Educ. Law, Tit. 8, Cons. Laws of N. Y.

tried a variety of methods to create a monopoly for the drugstore in over-the-counter medicinal preparations. One approach has been to place a very narrow construction upon the meaning of the term "proprietary" medicine in the various exemptions. In a number of earlier decisions the courts, looking to the dictionary for the meaning of the term, have backed the boards and construed it to include only secret remedies or those in which someone had an exclusive or "proprietary" right.[7] Attempting to perpetuate this interpretation, some boards now argue that the requirement of the 1938 Federal Food, Drug and Cosmetic Act that drug labels disclose all active ingredients,[8] has, in effect, destroyed the "proprietary" character of all drug preparations. This has been referred to as the "technical" interpretation of the term "proprietary."[9] It finds no justification in the underlying public health purpose of the pharmacy statutes, and is a strictly semantic approach to the problem. Nevertheless, it has been accepted by some courts.[10]

An alternative approach, adopted by a greater number of courts, has been to apply the so-called "common usage" definition of "proprietary," consistent with its generally accepted meaning in the drug trade. This would encompass all prepackaged, nonprescription preparations which are advertised and sold directly to the public under a trademark.[11] Although also a semantic approach and not necessarily related to the public health, it would appear to be more consistent with the purposes the "proprietary" exemptions were supposed to achieve. It is also more likely to preserve the constitutionality of a pharmacy statute which necessitates such an exemption to avoid being construed as an unjustified grant or privilege to one class of merchants to the detriment of another.[12]

---

[7] *State v. Jewett Market Co.*, 209 Iowa 567, 228 N.W. 288 (1929); *State v. Zotalis*, 172 Minn. 132, 214 N.W. 766 (1927); *White v. State Board of Pharmacy*, 138 N. Y. S. 2d 448, 285 App. Div. 486 (1955).

[8] 21 U. S. C. 352(e), FOOD DRUG COSMETIC LAW REPORTS, ¶ 70,143.

[9] Cited at footnote 4, pp. 551-552.

[10] Cited at footnote 7. Also, *State v. Wakeen*, 263 Wisc. 401, 57 N.W. (2d) 364 (1953). The adoption of the technical definition in *State v. Jewett Market Co.* (cited at footnote 7) was later superseded by legislation (Code of Iowa, ch. 155, § 3.7).

[11] *People v. Heron*, 34 Cal. App. (2d) 755, 90 Pac. (2d) 154 (1939); *Wrigley's Stores v. Michigan Board of Pharmacy*, 336 Mich. 583, 59 N.W. 2d 8 (1953); *Board of Pharmacy of the State of New Jersey v. Adelman*, Bergen Cty. Dist. Ct., March 18, 1957 (unreported).

[12] *State v. Childs*, 32 Ariz. 222, 257 Pac. 366 (1927); *Noel v. The People*, 167 Ill. 587, 58 N.E. 616 (1900); *State v. Donaldson*, 41 Minn. 74, 42 N.W. 781 (1889); *State v. Wood*, 51 S. D. 485, 215 N.W. 487 (1927).

Faced with a choice between the "technical" and "common usage" approaches, the courts have decided the status of proprietary medicines in many jurisdictions on the basis of definitions without reference to the inherent nature of the drug involved. This has led to conflict, confusion and some unrealistic results.

Many of the cases have involved the sale of aspirin tablets—the most widely used of all drugs and one which is generally considered to be safe for self-medication. Since there are a substantial number of manufacturers of aspirin tablets, it has been argued that no one may have an exclusive or "proprietary" right in aspirin. Accordingly, whereas some courts have held aspirin to be an exempt "proprietary,"[13] others have held that it does not so qualify.[14] Some have limited the exemption to particular brands of aspirin.[15] And, although there has been considerable controversy about the sale of plain aspirin, aspirin compounds have been generally exempted.[16] Interestingly, at least one court, in the District of Columbia, exempted the sale of "Bayer" aspirin tablets for the simple reason that competitive headache remedies, such as "Anacin," "Alka-Seltzer" and "Bufferin," were being freely sold in supermarkets and grocery stores in the District.[17]

The most important of the "Aspirin" cases was probably the *Loblaw* case[18] decided by the New York Court of Appeals in 1962. This involved the sale of "Bayer" aspirin and was the first time the Court of Appeals had occasion to consider the "proprietary" question. The Appellate Division [19] decided that upon the expiration of the patent on aspirin and the subsequent loss of the "Aspirin" trademark, the product ceased to be a "proprietary" medicine. The Court of Appeals did not think these were valid public health considerations. Nevertheless, it too analyzed the conflicting definitions and concluded that the manufacturer did have a proprietary interest in its own product and that "Bayer" aspirin came within either definition. In doing so,

[13] *Loblaw Inc. v. Board of Pharmacy,* 11 N. Y. 2d 102, 181 N.E. 2d 621 (1962); *Board of Pharmacy of the State of New Jersey v. American Stores Company.* Camden Cty. Dist. Ct. October 19, 1955 (unreported).

[14] *State v. Zotalis,* cited at footnote 7; *State v. Wakeen,* cited at footnote 10; *State v. Combs,* 169 Ore. 566, 130 P. 2d 947 (1942).

[15] *Loblaw Inc. v. New York State Board of Pharmacy,* cited at footnote 13.

[16] *Board of Pharmacy of the State of New Jersey v. Adelman,* cited at footnote 11; *Wrigley Stores v. Michigan Board of Pharmacy,* 336 Mich. 583, 59 N.W. 2d 8 (1953).

[17] *District of Columbia v. Safeway Stores, Inc.,* D. C. Munic. Ct., 1958 (unreported).

[18] *Loblaw Inc. v. New York State Board of Pharmacy,* cited at footnote 13.

[19] *Loblaw Inc. v. New York State Board of Pharmacy,* 12 A.D. 2d 180, 210 N. Y. S. 2d 709 (1961).

it placed considerable importance upon the economic aspects of the controversy.[20]

Confusion a Result of Semantic Approach

The confusion which is apparent in the aspirin cases is clearly the result of the semantic approach, since, as stated, aspirin is generally considered to be one of the safest of all over-the-counter drug preparations, but also the product most frequently restricted. This approach has also created inconsistent results on numerous other occasions. On the one hand, the sale of such a familiar preparation as milk of magnesia has been restricted in a number of states on the basis that it wasn't a "proprietary" solely because it is listed in various compendia.[21] In an unreported Ohio case,[22] however, a narcotic-containing cough preparation, "Cheracol," was permitted to be freely sold even though the court had some doubts about its safety, because it fitted the definition of a "proprietary." It, thus, appears that the courts have all too often looked to the dictionary rather than the dispensatory for the protection of the public health. As a result, the sale of some of the safest remedies has been restricted, whereas more potent preparations are sold without interference.

The better-reasoned cases have either ignored the conflicting definitions or applied them in such a way as to achieve a common sense result. These courts have looked to the underlying reasons for including proprietary exemptions in the pharmacy statutes.[23] They have considered the inherent nature of the drugs involved, their safety and the effect of unrestricted sale upon the public health.[24] They have found no correlation between harm from proprietary medicines and the place of sale.[25] They have been unwilling to grant one

[20] "The public health will not be used as a pretext to aid one group in the community in the competitive race against another or to confer a monopoly in the sale of products." (See footnote 13, *Loblaw Inc.* p. 107).

[21] See, for example, *Minnesota v. F. W. Woolworth Co.*, 184 Minn. 51, 237 N.W. 817 (1931).

[22] *State v. Elliot,* Columbus Munic. Ct., 1961 (unreported).

[23] *State v. Hanchette,* 88 Kan. 864, 129 Pac. 1184 (1913); *Kentucky Board of Pharmacy v. Cassidy,* 115 Ky. 690, 74 S.W. 730 (1903); *State v. Donaldson,* see footnote 12 ("One man can do it just as well as another, if he can read the label on the package and make change with the purchaser.")

[24] *Board of Pharmacy v. Adelman,* see footnote 11; *The Proprietary Association v. Board of Pharmacy of the State of New Jersey,* 27 N. J. Super 204, 99 A. 2d 52 (1953), rev'd on other grounds, 16 N. J. 62, 106 A. 2d 272 (1954); *Lehn & Fink Products Corporation v. Griffin,* D. C., Polk Cty. Iowa, 1960 (unreported).

[25] *Board of Pharmacy v. Adelman,* see footnote 11 ("It appears quite conclusive that there is no causal relationship between the ingestion of excessive amounts, or the improper use of the products under examination and the manner in which they are purchased or the place where the purchase is made.")

class of merchants a monopoly in the sale of packaged medicines because they might not fit some antiquated and unrealistic definition of the statutory terms.[26] They have refused to draw an artificial distinction between pharmacopoeial items and combination products.[27] It is significant to note they have uniformly exempted the sale of virtually all advertised preparations which, under federal law, may be sold over-the-counter.

Perhaps the most striking example of the confusion attendant upon the restrictive sales controversy was occasioned by the Supreme Court of Minnesota which applied both approaches in the same case. In *State v. Red Owl Stores, Inc.*[28] the Minnesota Board of Pharmacy in 1954 filed a complaint wherein it sought to enjoin the sale by a supermarket chain of 18 well-known packaged medicines,[29] which the board contended were not "proprietary." The first time the case reached the Minnesota Supreme Court,[30] it was held, in a widely criticized opinion,[31] that an injunction would lie, even though it was a criminal statute, if proper findings were made. The case was remanded to determine if there was any danger to the public health from the sale of these remedies by the supermarket. The trial court, after a protracted trial, found that "no harm has ever resulted to the health of anyone from sales of these trade-named products through these (nonpharmacist) outlets," and denied the injunction. In an effort to terminate the endless litigation, the court added, by way of *dicta,* that in its opinion, each of the items involved was an exempt "proprietary medicine." Again, the case found its way to the Minnesota Supreme Court, which in 1962 concurred with the lower court that the controversy was primarily economic in nature and affirmed the refusal to grant injunctive relief.[32]

---

[26] *Noel v. The People,* see footnote 12 ("The public health is not protected by limiting these sales to registered pharmacists, who make no examination of what they sell."); *State v. Stephens,* 102 Mont. 414, 59 P.2d 54 (1936).

[27] *State v. Geest,* 118 Neb. 562, 225 N.W. 709 ("It is apparent that it does not tend to promote public safety or welfare. . . ." p. 567); *Board of Pharmacy of the State of New Jersey v. American Stores Company,* see footnote 13; *District of Columbia Board of Pharmacy v. Safety Stores, Inc.,* cited at footnote 17.

[28] 262 Minn. 31, 115 N.W. 2d 643 (1962).

[29] Bromo-Seltzer, Anacin, Aspergum, Thrifty Spot Aspirin Compound Tablets, Alka-Seltzer, Bufferin, 4-Way Cold Tablets, Bromo Quinine, Pepto-Bismol, Pinex, Vick's Cough Syrup, Vick's Va-Tro-Nol, Murine, Castoria, Ex Lax, Feen-a-mint, Sal Hepatica and Lysol.

[30] *State v. Red Owl Stores, Inc.,* 253 Minn. 236, 92 N.W. 2d 103 (1958).

[31] See 76 *Harvard L. Rev.* 1488(1963); 8 *Buffalo L. Rev.* 298 (1959); 28 *Fordham L. Rev.* 161 (1959).

[32] "We think the record as a whole supports the conclusion of the trial court that the state and the association have

(Footnote continued on next page.)

Although the board's right to an injunction was clearly the only issue in the case, the court thought it necessary to plunge into the "proprietary" issue. Having found that the proprietary exemption did, in effect, afford adequate protection to the public, the court could have given real meaning to the exemption. Nevertheless, it saw fit to involve itself in meaningless semantics and concluded that the products in question, under a technical interpretation, were not "proprietary;" [33] and added that "there are today few, if any, proprietary medicines within the meaning of the Pharmacy Act."

We, thus, have the anomalous situation of the court, finding that public health considerations did not require injunctive relief, and, at the same time, by way of an advisory opinion, declaring that the defendants had violated a criminal statute for the sole reason that modern methods of quantitative analysis had unlocked the mysteries previously attributed to such remedies.

Interestingly, the Minnesota Court specifically stated that it did not agree with the *Loblaw* decision which had been decided a few days earlier.[34] Thus, whereas, *Loblaw* has tended to clarify the New York picture to a considerable degree, *Red Owl* has left Minnesota in a more chaotic situation than when the controversy arose ten years ago.[35]

It has been suggested that the "restrictive sales" controversy was, in effect, decided by the 1952 Durham-Humphrey Amendment to the Federal Food, Drug and Cosmetic Act.[36] The provisions of that amendment clearly define which drugs can be labeled for safe use in self-medification and need no professional supervision and which cannot be so labeled and must be limited to sale on prescrip-

(Footnote 32 continued.)
failed to establish that there is any greater danger to the public when these drugs are sold at self-service counters in supermarkets than when sold by a clerk in a drugstore. The public receives no greater protection in one case than in the other. Moreover, the record supports the trial court's conclusion that there is no causal relationship between injuries sustained by the excessive use of these drugs and the place where they are purchased." (See footnote 28 at p. 43.)

[33] "It would appear from the record that it is now doubtful if anyone can claim exclusive right of ownership to the properties which constitute the beneficial ingredients of the drugs under consideration. There is no longer a secret or mystery as to the properties which impart to them their medicinal value." (See footnote 28 at p. 48.)

[34] See footnote 13, *Loblaw Inc.* at pp. 55-56.

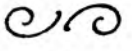
[35] As evidenced by the fact that the court found it necessary to grant an appeal on the question of which was actually the prevailing party for the purpose of taxing costs. 262 Minn. 31, 56, 115 N.W. 2d 659 (1962).

[36] Weigel, "State Legislation Restricting the Sale of Drugs," 13 FOOD DRUG COSMETIC LAW JOURNAL 48 (1958).

tion.[37] It would appear that, since federal law has determined that labeling shall be the criterion of safety, any further restriction would constitute an artificial restraint of trade. The Durham-Humphrey Amendment has proved to be a relatively effective law and has removed much of the uncertainty about drug labeling. It was designed to be flexible and has been able to adjust to changes and improvements, so that its validity has been applicable to the newer and more potent drugs.

The Food and Drug Administration (FDA) has traditionally kept aloof of the economic controversy as to where nonprescription drugs should be sold at retail.[38] It has concentrated its efforts on making sure that such products are adequately labeled so that they may be safely used, irrespective of the place of sale. This has proved to be a simple and effective approach which has afforded the maximum protection to the public health. The states could profit by this example.

It is generally agreed that an end should be put to this unfinished business—that the restrictive sales controversy has plagued the drug industry too long. Unfortunately, it will probably continue so long as courts indulge themselves in esoteric considerations of semantics.[39] If and when they recognize that the "proprietary" exemptions in the state pharmacy statutes are based upon considerations of public health and not mental gymnastics, they may well conclude that no real controversey exists. **[The End]**



[37] 21 U. S. C. 353(b), FOOD DRUG COSMETIC LAW REPORTS, ¶ 70,193—70,197.

[38] Compare, Justice Department attitude in opposing H.R. 10597, 86th Cong. 2nd Sess. (1960). ("preventing supermarkets and related stores from selling such products (proprietary medicines) would substantially lessen competition and unduly inconvenience the consumer by limiting market access.")

[39] See L. Hand, J., in *Cabell v. Markham*, 148 F.2d 737, 739 (C.A. 2, 1945): "But it is one of the surest indexes of a mature and developed jurisprudence not to make a fortress out of the dictionary; but to remember that statutes always have some purpose or object to accomplish, whose sympathetic and imaginative discovery is the surest guide to their meaning."

Now Law . . . Order Yours Today!

Timely CCH Helps on the Dramatic New

"MEDICARE and SOCIAL SECURITY LAW of 1965"

1. MEDICARE AND SOCIAL SECURITY EXPLAINED. Gives CCH explanation of Social Security Law as amended, with detailed explanation of medicare, new benefits, rules, and other information. Handy tables and practical examples supplement the easy-to-understand text. *All explanation—no law text!* Topical index, table of contents, 176 pages, 6" x 9", heavy paper covers. Price, $2.50 a copy. *Now ready!*

2. WHEN YOU'RE 65 OR THEREABOUTS—Medicare - Social Security-Income Taxes. For the older set and everyone concerned with their problems, this nontechnical handbook tells how big new Medicare and Social Security law works. Easy-to-understand explanations tell who is qualified and what should be done to gain maximum benefits. Covers raise in Social Security benefits, hospital-nursing home care and low cost medical insurance for those 65 and older—plus helpful explanations of how current income tax rules apply to *everyone* 65 or over. Topical index, table of contents, 64 pages, 6" x 9", heavy paper covers. Price, $1 a copy. *Now ready!*

3. MEDICARE AND SOCIAL SECURITY LAW. Contains full official text of new medicare, OASDI, and public welfare provisions of Social Security law and related statutes as amended in 1965. Also includes Federal Insurance Contributions Act, Self-Employment Contributions Act and pertinent administrative and procedural provisions of Internal Revenue Code. *Law text only—no explanation!* Topical index, table of contents, about 500 pages, 6" x 9", heavy paper covers. Price, $6 a copy. *Ready in early September.*

4. MEDICARE AND SOCIAL SECURITY BENEFITS. Tremendously popular as a good-will builder, this handy pocket-size booklet answers such questions as "What do I get?" "What do I have to do to get it?" "Am I covered?" and the like. Written in laymen's language, it's made to order for customers and friends. You can order 250 copies or more, with your imprint at no extra charge, at special large quantity prices. Table of contents, 48 pages, 2⅝" x 4", heavy paper covers. Price, 8 for $2 (minimum order). *Now ready!*

USE HANDY ORDER CARD ATTACHED! ⟶

CCH PRODUCTS COMPANY

A DIVISION OF

COMMERCE CLEARING HOUSE, INC.

FOOD DRUG COSMETIC
LAW JOURNAL

PUBLISHED BY
COMMERCE CLEARING HOUSE, INC.
PUBLISHERS of TOPICAL LAW REPORTS
4025 W. PETERSON AVE., CHICAGO, ILL. 60646
RETURN REQUESTED

SECOND CLASS POSTAGE PAID
AT CHICAGO, ILLINOIS AND
AT ADDITIONAL MAILING OFFICES

A COMMERCE CLEARING HOUSE PUBLICATION